2020 Draft Report Delaware Health Resources Board

150th General Assembly, 2nd session



Respectfully submitted to the Joint Legislative Oversight and Sunset Committee March 2020

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FACT SHEET

March 3, 2020 **ILOSC Review of HRB**



Health Resources Board ("HRB") Duties

- **>** Reviewing CPR applications.
- \rightarrow Developing and maintaining a Health Resources Management Plan ("HRMP").
 - Last updated in September 2017.
 - Assesses the supply of health care resources.
 - Outlines process for reviewing CPR applications.
- Identifying and gathering types of data and information needed to carry out responsibilities.
- Address specific health care issues requested by the Governor and General Assembly.

Certificate of Public Review ("CPR") Process

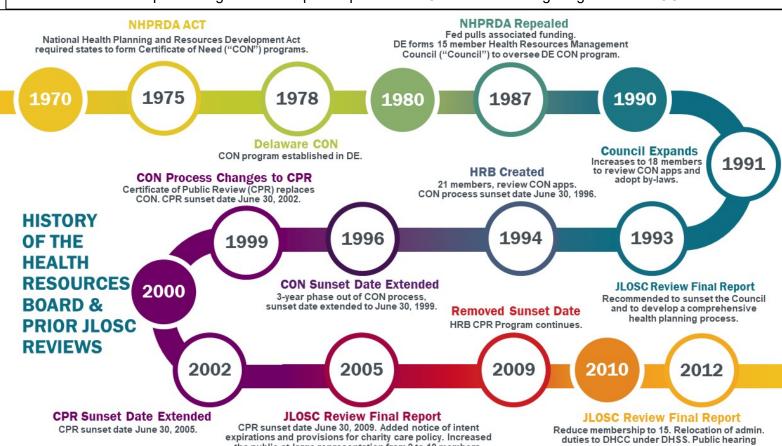
- → CPR required for the following 4 activities: *
 - Construction or development of a health care facility.
 - Capital expenditure more than \$5.8M.
 - Change in bed capacity by more than 10 beds or 10% of total licensed bed capacity in 2-year period.
 - Acquisition of major medical equipment.
- → Applicant files "Notice of Intent."
 - Once application is complete review begins.
 - Filing fees due 30 days after review notification.
- → Overview presentation at HRB meeting.
 - Review Committee selected for review.
- → Board reviews Review Committee's recommendation and makes final decision based on 7 items of statutorily mandated CPR criteria.

*See HRMP for full details.

required when modifying the HRMP.

Opportunities for Improvement

- → Evaluate Certificate of Public Review process and determine if it supports Delaware's current health care delivery system and interest in health care innovation and transformation.
- → Evaluate the activities subject to review and the current 7 items of statutorily mandated CPR criteria.
- → Review the Board's size and composition, consider adding clarity to the statutory definition of quorum.
- → Review and update filing costs for capital expenditures. Consider allocating filing fees to DHCC.



expirations and provisions for charity care policy. Increased the public-at-large representation from 9 to 10 members.

INTRODUCTION

About JLOSC and the Review Process

The Joint Legislative Oversight and Sunset Committee ("JLOSC" or "Committee") is a bipartisan body comprised of five members of the Senate appointed by the President Pro Tempore and five members of the House of Representatives appointed by the Speaker of the House. JLOSC completes periodic reviews of agencies, commissions, and boards. The review's purpose is to first determine the public need for the entity and if need exists, to determine whether the entity is effectively performing to meet the need. JLOSC reviews aim to provide strength and support to entities that are providing a State recognized need. JLOSC performs its duties with support provided by the Division of Research's dedicated and nonpartisan staff in the form of two JLOSC analysts, a legislative attorney, a legislative fellow, and an administrative assistant.

A note about this Draft Report

The information provided in this report is taken from the Joint Legislative Oversight and Sunset Committee Performance Review Questionnaire, as it was completed by the agency under review. When appropriate, the analyst who prepared this report made minor changes to grammar and the organization of information provided in the questionnaire, but no changes were made to the substance of what the agency reported. Any points of consideration which arose in analyzing the questionnaire and compiling this report are addressed in the section titled, "Additional Comment from the Committee Analyst." It is the intent of the analyst to make any substantive changes which may be required, as the result of findings made through the review processes, in the final version of this report.

The statutes governing and applying to the agency under review are included as appendices to this draft report. They are included only as a reference for JLOSC members and may not be included in the final report.

EXECUTIVE SUMMARY

During the 1960s and 1970s the federal government saw a need for comprehensive health planning. This led to the creation of the National Health Planning and Resources Development Act of 1975, which required all 50 states to convene oversight agencies and Certificate of Need ("CON") programs to provide a review of proposed new health facilities and services and major capital expenditures.

Delaware established its CON program in 1978 and, by 1987, the federal government repealed the National Health Planning and Resources Development Act and all its associated funding. This prompted Delaware to create a 15-member Health Resources Management Council ("Council") to oversee the CON program. Since its creation, JLOSC reviews have resulted in numerous changes. The CON process evolved into the Certificate of Public Review ("CPR") program and the Council changed to the Health Resources Board.

This 2020 review marks the fourth review conducted by JLOSC of the state's CON process and its associated Board. Prior to this review, the program received 5 different sunset dates with the final sunset date removal occurring in 2009. The dollar amount threshold that triggers the CPR process increased numerous times and the activities of review have seen some decrease over the years. Common themes from all 4 reviews include size of board membership, conflicts of interest, and the structure and overall need for the program.

JLOSC PERFORMANCE REVIEW QUESTIONNAIRE

AGENCY HISTORY

The Health Resources Board ("HRB") originates from the National Health Planning and Resources Development Act ("NHPRDA") of 1975. The NHPRDA required all 50 states to convene oversight agencies and Certificate of Need ("CON") programs to provide a review of proposed new health facilities and services and major capital expenditures.

The NHPRDA was based on the economic assumption that excess health care capacity directly results in health care price inflation. States established CON programs to restrain health care costs and allow for coordinated planning of new services and construction based on a genuine community need. CON programs also emphasized the importance of distributing health care services to disadvantaged populations or geographic areas that may be ignored by new and existing facilities.

The federal government repealed NHPRDA in 1987 and dissolved all associated federal funding. Most recent data suggest 35 states and the District of Columbia have retained their CON programs, 12 state have discontinued their CON programs, and 3 states have variations. Florida most recently repealed portions of their CON program in 2019 and 8 other states (Georgia, Maryland, Ohio, Rhode Island, Tennessee, Vermont, Virginia, and Washington) enacted legislation to modify CON regulations.

Delaware codified its CON program in 1978, placing CON oversight within the Department of Health and Social Services' ("DHSS") Bureau of Health Planning and Resources Development.² The General Assembly established HRB in 1994; it further modified the state-level CON program and replaced it with the Certificate of Public Review ("CPR") program in 1999.³

The HRB CPR program, like other states' CON programs, originated to regulate the number of beds in hospitals and nursing homes and to prevent excessive purchasing of expensive medical equipment. Since 1999, HRB has considered CPR applications within the context of Delaware's dynamic health care delivery system. In 2012, administrative support for HRB moved under the DHSS, Office of the Secretary, Delaware Health Care Commission ("DHCC").

PURPOSE

The HRB CPR program helps protect the statewide health care infrastructure necessary to meet the expected and projected health care needs of all Delawareans. Like other state CON programs, the HRB CPR process works to improve geographic and economic

¹ See Appendix A.

² HB 956 of the 129th General Assembly (1978).

³ HB 33 of the 137th General Assembly (1994) and SB 74 of the 140th General Assembly (1999).

access to care for residents in the state. As available, data is provided to guide this public process.

Delaware's CPR process also provides a public comment forum where all interested parties, including citizens, can express their views pertaining to Delaware's health care delivery system. Additionally, any individual may submit a public hearing request in writing during the CPR process.⁴ Most recently, a public hearing was requested and held on June 5, 2019, on MeadowWood's CPR application for a 20-bed expansion.

Without the HRB CPR process, several implications would result:

- No formal oversight, review, and evaluation of new health care facilities expanded health services, and new or novel major medical equipment.
- No forum for public scrutiny and comment.
- Health care spending and costs could increase.
- Conversely, health care competition could increase and thereby reduce spending and costs.
- Potential overutilization of health care resources (facilities, services, equipment, etc.).
- Another state agency or entity may need to provide oversight, as was previously handled by the Bureau of Health Planning and Resource Management (currently located within the Division of Public Health).

In 2019, HRB reviewed 2 CPR applications that both requested to construct free standing emergency departments within 10 miles of each other, on the same road, in Sussex County. The Bayhealth and Beebe health systems argued that emergency medical services were needed in the area. After holding a formal review process and public hearing, HRB denied Beebe's application; Bayhealth withdrew their application before the vote. HRB denied Beebe's application for the following reasons:

- Comments made at the public hearing stated that emergency services are currently available within the proposed service areas.
- The proposal does not align with Delaware's initiative to lower the costs of health care.
- Less costly alternatives are available than additional freestanding emergency services.
- The proposed emergency department would have a negative impact to the existing health care system.

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⁴ 16 Del. C. § 9303.

These applications are an example where there could have been a situation of over utilization of health care services, increased health care costs, and a potential negative impact to the existing health care system.

MISSION, GOALS, OBJECTIVES, & AUTHORITY

HRB's purpose is 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.⁵ The enabling legislation accurately reflects the mission of the HRB.

HRB's duties and responsibilities include:⁶

- Develop a Health Resources Management Plan ("HRMP"), to assess the need for and supply of health care resources, particularly facilities and medical technologies.
 - HRB maintains a HRMP, last updated in September 2017, which includes a statement of principles to guide the allocation of resources and rules and regulations which are formulated for use in reviewing CPR applications.⁸
- 2. Review filed CPR applications and make decisions.9
 - Decisions must 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 HRB's responsibilities.
 - Identify the types of data not available so that efforts can assure that legitimate data needs are met in the future.
- 4. Address specific health care issues that the Governor or the General Assembly request.
- 5. Adopt by-laws as necessary for conducting HRB's affairs. 10
 - HRB members must comply with the State Ethics Code and the Freedom of Information Act ("FOIA").
- 6. Coordinate activities with DHCC, DHSS, and other groups as appropriate.

⁵ 16 Del. C. § 9303.

^{6 16} Del. C. § 9303.

⁷ See Appendix D.

⁸ See Appendix E.

⁹ 16 Del. C § 9304.

¹⁰ See Appendix F.

HRB adheres to the HRMP for measuring the goals and objectives of the CPR program. The HRMP is a document that establishes the guiding principles for health care resources in the state and the rules and regulations for reviewing CPR applications.¹¹

HRB cooperates with DHCC and other state health policy activities. 12 HRB also works with DHSS's Division of Health Care Quality regarding licensing and certifications.

COMPOSITION & STAFFING

Membership:

According to statute, HRB consists of 15 members. ¹³ As of February 2020, HRB has 3 vacancies, including the vice chair. The Governor appoints the vice chair from among HRB members. The other 2 vacancies are for a representative involved in purchasing health care coverage for employers with more than 200 employees ¹⁴ and a representative of a provider group other than a hospital, nursing home, or physician. ¹⁵ The Governor's office has been advised of these vacancies.

Meeting Frequency¹⁶

HRB's by-laws require regular meetings be held on a bi-monthly basis and held at least 4 regular meetings per year. The Board can hold a special meeting at any time by request of the chair or at the written request of at least 8 members. HRB can create committees or task forces to assist in conducting HRB business.

Meeting Order, Quorum, and Voting: 18

HRB conducts meetings under Roberts' Rules of Order. HRB's statute defines quorum as consisting "of at least 50% of the membership." which, when all HRB positions are filled, is 8 members. ¹⁹ HRB has interpreted the statute to allow them to enact by-laws that require 8 members to achieve quorum regardless of vacancy. The by-laws further define a voting quorum as a majority of members who are present at the meeting and able to vote. Members who must abstain from a vote do not affect quorum. ²⁰

Member Removal:

The Governor may at any time, after notice and hearing, remove a member for gross inefficiency, neglect of duty, malfeasance, misfeasance, or nonfeasance in office. A member is in neglect of duty if absent from 3 consecutive meetings without good cause or attend less than 50% of meetings in a calendar year. A member has not been removed since HRB has been under DHCC.

¹¹ See Appendix C.

^{12 16} Del. C. § 9303.

¹³ See Appendix G for current Board member roster.

¹⁴ Vacant as of October 18, 2012.

¹⁵ Vacant as of October 31, 2019.

¹⁶ Analyst Note: This section added by Analyst from by-laws as indicated.

¹⁷ See Appendix H for Board member meeting attendance as provided by DHCC.

¹⁸ Analyst Note: This section added by Analyst from by-laws as indicated.

¹⁹ 16 *Del. C*. § 9303.

²⁰ See Appendix F.

Member Compensation:

Members serve without compensation but may seek reimbursement 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.

Member Training and Handling Conflicts of Interest:

HRB does not offer special training opportunities. HRB's assigned Deputy Attorney General ("DAG") has reviewed the provisions of the Public Integrity Act with members to ensure that they are complying with the provisions in the law. Some members of the HRB have had individual consultations with the Public Integrity Commission ("PIC") for clarification regarding conflicts of interest.

HRB avoid conflicts of interest by complying with the State Ethics Code. Additionally, HRB by-laws regarding conflicts of interest.²¹ HRB does not permit members to participate in the review or disposition of any matter in which they have a conflict of interest and require members to declare their conflict at the earliest time possible. HRB by-laws indicate that a member has a conflict when:

- Any action or inaction would result in a financial benefit or detriment to member or a close relative (parents, spouse, children, or siblings) to a greater extent than the benefit or detriment would accrue to others who are members of the same class or group of persons.
- The member or close relative has a financial interest in a private enterprise (whether profit or not for profit) and the enterprise or interest would be affected by HRB action or inaction on a matter to a lesser or greater extent than like enterprises or other interests in the same enterprise. A member has a "financial interest" in a private enterprise if:
 - The member has a legal or equitable ownership interest in the enterprise of more than 10%, or 1% or more in the case of a corporation whose stock is regularly traded on an established securities market.
 - The member is associated with the enterprise and received from the enterprise during the last calendar year or might reasonably be expected to receive from the enterprise during the current or the next calendar year income in excess of \$5,000 for services as an employee, officer, director, trustee, or independent contractor.
 - The member is a creditor of a private enterprise in an amount equal to 10% or more of the debt of that enterprise, or 1% or more in the case of a corporation whose securities are regularly traded on an established securities market.

²¹ See Appendix F.

DHCC Staff for HRB:

DHCC staff perform administrative duties for HRB as follows:

- Manager of Statistics and Research (merit position) 90% devoted to HRB:
 - 10% Reviews CPR applications for technical completeness.
 - 10% Collects information from applicants needed to assure applications are complete prior to the review by HRB.
 - 10% Sends out meeting correspondence to HRB, staff, and the public, includes applicants.
 - 10% Coordinate and provide staff support to HRB meetings, public hearings, and review committee meetings.
 - 10% Post meeting materials to the HRB website and State of Delaware Public Meeting Calendar.
 - 10% Send public notices to newspapers for CPR review announcements.
 - 10% Composes agenda and meeting minutes. Conducts research and analysis for use by HRB in evaluating applications.
 - 10% Prepares review committee reports for HRB.
 - 10% Provide staff expertise on the CPR process and assist to ensure efficiency and accuracy of the CPR program.
- Executive Director (appointed position) 10% devoted to HRB:
 - 5% Provides the leadership to ensure the efficiency and accuracy of administering the CPR program and to enforce HRB is operating in accordance to statutory guidelines.
 - 5% Attends HRB meetings and review committee meetings.
- DAG (non-merit position) 10% devoted to HRB:²²
 - 5% Provides legal guidance and counsel to HRB during HRB meetings, public hearings, and review committee meetings.
 - 5% Prepares written orders of HRB decisions for CPR applications.

DHCC sufficiently staffs HRB, as described above.²³ In times of increased CPR applications, the workload is significant for the Manger of Statistics and Research, who works as HRB's program manager. In times of appeals, the workload for the DAG increases dramatically.

DHCC recruits administrative staff for HRB through the State hiring process. Currently, DHCC employs no temporary or contractual staff. There is no formal orientation session for new hires other than traditional State new employee onboarding. Staff receive HRB guidelines and procedures documents.

²² In times of litigation the Board's DAG devotes an additional 25% of time to the HRB.

²³ See Appendix I.

No training opportunities are available to staff regarding HRB. Staff has access to resources such as policies, statutes, and information readily available on the HRB website.

Certificate of Public Review ("CPR") Process²⁴ CPR Process Guiding Principles:²⁵

The following general principles are intended to assist potential CPR applicants in understanding HRB's expectations and assist HRB in conducting CPR reviews, particularly in matters where specific guidelines are lacking.

The essential challenge that HRB faces is striking an appropriate balance in its consideration of access, cost, and quality of care issues. Evidence that an applicant has seriously embraced this challenge should permeate every CPR application. The problem of medical indigency is extremely complex. DHCC continues to provide leadership in this area. It is expected for CPR applicants to contribute to the care of the medically indigent.

Historically, health care delivery has too often been episodic and disjointed. Projects which support a managed, coordinated approach to serving the health care needs of the population are to be encouraged.

Given Delaware's small size and proximity to major metropolitan referral centers, particularly in Philadelphia and Baltimore, every health care service need not be available within its borders. Potential CPR applicants are expected to consider the availability of out-of-state resources.

The cost-based reimbursement system has historically provided little incentive for financial restraint; over-utilization has been encouraged, and revenue centers (not cost centers) were emphasized. Projects which reflect or promote incentives for over-utilization, including self-referral, are discouraged.

HRB has embraced DHCC's adopted a strategy of strengthening market forces as a central theme in health care reform. Projects resulting from or anticipated to enhance meaningful markets are encouraged. In the past, "competition" has often been based on amenities for physicians, as in the medical arms race, and patients, such as swanky waiting rooms. In meaningful markets, there must be a sensitivity to elements of both cost and quality.

Prevention activities such as early detection and the promotion of healthy lifestyles are essential to any effective health care system. The Choose Health, Delaware State Health Care Innovation Plan identifies several opportunities to improve the health status of Delawareans. The potential for a project to bring about progress in these areas will be viewed as a very positive attribute.

²⁴ Analyst Note: Analyst added this section, where indicated, from the HRB website and materials supplied by DHCC. Information inadvertently not requested in the JLOSC Performance Review Questionnaire.

²⁵ Analyst Note: Analyst added this section, information obtained from HRB website.

Requirement for a CPR:²⁶

In Delaware, a CPR is required for 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, not including a medical office building, more than \$5,800,000, which is considered a capital expenditure.
 - Expenditures more than \$5,800,000 may be exempt from review if they are necessary to maintain the physical structure of a facility and are not directly related to patient care.
- 3. A change in bed capacity of a health care facility which increases the total number of beds, distributes beds among various categories, or relocates beds from 1 physical site to another, by more than 10 beds or is more than 10% of total licensed bed capacity, whichever is less, over a 2-year period.
- 4. The acquisition of major medical equipment for use by students, employees of a school or university, or by inmates and employees of a prison, excluding the replacement of major medical equipment or major medical equipment acquired by a business or industrial establishment for a dispensary or first aid station.

CPR Procedures:27

- 1. Applicant files Notice of Intent from the CPR Application Kit.²⁸
- 2. Applicant files application. When application is determined to be complete, applicant notified of the beginning of the review (Public Notice, etc.).
- At the first HRB meeting after an application is determined complete, there is an overview presentation by the applicant and an opportunity for questions. A Review Committee is selected.
- 4. Review Committee conducts public hearing, if requested.
- 5. Review Committee meets and deliberates as necessary to formulate a recommendation to HRB.
- Review Committee submits report to HRB, who makes the final decision. From the date of notification referred to in step 2 above, maximum review period is 90 days, with exceptions for requested public hearing or if mutually acceptable to HRB and applicant.

²⁶ Analyst Note: Analyst added this section, information obtained from HRB website.

²⁷ Analyst Note: Analyst added this section, information obtained from HRB website. See *Additional Comment from the Committee Analyst* for additional information.

²⁸ See Appendix E.

CPR Criteria:29

HRB's purpose is to assure that continued 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.³⁰ Through HRB's the efforts, the State focuses on balancing concerns for cost, access, and quality in the best interest of Delawareans.

In conducting reviews under the HRMP, HRB must consider 7 statutorily mandated criteria:

- 1. Relationship of the proposal to the HRMP.
- 2. The need of the population for the proposed project.
- 3. The availability of less costly 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 on the proposal on the costs of and charges for health care.
- 7. The anticipated effect of the proposal on the quality of health care.

Major Medical Equipment:31

A CPR is required prior to the acquisition of "major medical equipment," irrespective of whether the acquisition is made by a "health care facility." "Major medical equipment" means 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:

- 1. Entails a capital expenditure as defined in the statute and which exceeds \$5,800,000 or more which HRB has designated following an annual adjustment for inflation.
- 2. Represents medical technology which is not yet available in Delaware.
- 3. Represents medical technology which HRB has designated as being subject to review.
 - HRB designates the following medical technologies as subject to review because they are major medical equipment:
 - Cardiac Catheterization.
 - Megavoltage Radiation Therapy.
 - Extracorporeal Shock Wave Lithotripsy.
 - Positron Emission Tomography ("PET").

²⁹ Analyst Note: Analyst added this section, information obtained from HRB website.

^{30 16} Del. C. § 9301.

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³¹ Analyst Note: Analyst added this section, information obtained from HRB website.

CPR Applications Received 2017-2019:32

Since 2017, HRB has reviewed 17 CPR applications, with 15 receiving approval notices. The DHSS Division of Health Care Quality administers the licensing process for all CPR approvals.

	# of CPR applications received	# of CPR applications approved	# of CPRs issued	# of CPR applications rejected	# of CPR applications withdrawn
Calendar Year 2017	5	5	5	0	0
Calendar Year 2018	8	8	8	0	0
Calendar Year 2019	4	2	2	1	1

CPR Application Fees:³³

An application filing fee must accompany CPR applications.³⁴ Application fees are as follows:

Capital Expenditures	Application 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

Filing fees are due 30 days after the date of notification signaling the start of a review and may be extended up to 10 additional days at DHCC's discretion. Failure to pay the filing fee results in the application being withdrawn.

DHCC has not conducted a financial analysis to determine if the current CPR application fees sufficiently cover the cost of the administration activities, data collection, and analysis. CPR application fees are deposited into the General Fund and are not directly allocated to the DHCC or HRB. Changes to application fees require legislative approval.³⁵

³² Analyst Note: Information received from DHCC with completed JLSOC Performance Review Questionnaire.

³³ Analyst Note: Information received from DHCC with completed JLSOC Performance Review Questionnaire.

³⁴ 16 *Del. C*. § 9305.

³⁵ Analyst Note: These application fees have not changed since first implemented in July 1987.

COMPLAINT AND DISCIPLINARY PROCESS

No complaints have been filed with the Attorney General's Office regarding HRB. HRB has not conducted complaint investigations and therefore has not issued any disciplinary actions. HRB does have the ability to revoke a CPR and impose sanctions.

RECONSIDERATION, APPEAL, SANCTIONS, REVOCATION

An organization or individual may file an appeal regarding HRB's decision on a CPR application or request a reconsideration of an HRB decision.³⁶

Administrative reconsideration, HRB procedure:

Any person may, for good cause, request in writing a public hearing for purposes of reconsideration of an HRB decision. A request for a hearing must be received within 10 days of the decision. HRB may not impose fees for the hearing and must hold a hearing within 45 days of the request. HRB must deem a request for a public hearing appropriate if the request shows good cause by exhibiting the following:

- 1. Presents newly discovered, significant, relevant information not previously available to or considered by HRB; and
- 2. Demonstrates significant changes in factors or circumstances that HRB relied upon in reaching its decision; or
- 3. Demonstrates that HRB has materially failed to follow its adopted procedures in reaching its decision.

Applicant appeal:

HRB's decision following review of an application, an administrative reconsideration, or the denial of a request for extension of a CPR may be appealed within 30 days to the Superior Court. The appeal must be on the record. HRB's assigned DAG handles all appeals.

Sanctions:

Any person undertaking an activity subject to review, without first being issued a CPR 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.

In addition, 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 without first being issued a CPR.

A person who willfully undertakes an activity subject to review and who has not received a CPR 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 has authority over criminal violations under this subsection.

³⁶ 16 *Del. C.* § 9305.

Revocation:

A CPR may be revoked by the Board in the case of misrepresentation in the CPR application, failure to comply with conditions established by the Board, failure to undertake the activity for which the CPR was granted in a timely manner or loss of license or other authority to operate.

Prior to revoking a CPR, 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. The Board will not revoke a CPR without first providing the holder of the certificate an opportunity for a hearing. The Board's decision to revoke a CPR may be appealed.

ADMINISTRATIVE PROCEDURES ACT COMPLIANCE

HRB is authorized to promulgate rules and regulations under the Administrative Procedures Act ("APA").³⁷ Revisions to the HRMP must comply with the APA. HRB's DAG has reviewed the current rules and regulations for compliance with HRB's governing statute.³⁸ No revisions are planned.

FREEDOM OF INFORMATION ACT COMPLIANCE

All FOIA requests are processed in accordance with Delaware's FOIA statute. HRB staff sends a written response within 15 business days. HRB has never received a FOIA violation complaint.

HRB posts its meeting agendas and minutes on the Statewide Public Meeting Calendar and the public can obtain a draft copy of the meeting minutes 7 business days after each meeting. Within the past 3 calendar years, the HRB has conducted 1 executive session, on September 27, 2018 related to receiving advice regarding legal strategy from its DAG. Minutes of the executive session are available to the public.

JOINT LEGISLATIVE OVERSIGHT AND SUNSET COMMITTEE REVIEW

JLOSC last reviewed HRB in 2012, which resulted in 12 recommendations. HRB reports they have complied with all but 2 recommendations.³⁹ JLOSC also conducted reviews in 1993 and 2005. The "Additional Comment from the Committee Analyst" section of this Draft Report provides more detailed information on all prior JLOSC reviews.

PUBLIC INFORMATION

HRB website is available to the public and provides guidelines, rules, regulations, and policies for HRB and the CPR program. Monthly reports on HRB's activities are posted on the HRB website. The Statewide Public Meeting calendar is updated on a consistent basis, at least once a month, to provide meeting information, minutes, and agendas.

³⁷ 16 Del. C. § 9303.

³⁸ See Appendix C.

³⁹ Information received with the JLOSC Performance Review Questionnaire and included in this Draft Report with the full list of recommendations in the last section, Additional Comment from the Committee Analyst.

(Groups affected by agency action	Interest Groups (Groups affected by agency actions or represent others served by or affected by agency action			
Group or Association Name/Contact Person	Address	Phone Number Fax Number Internet Address		
Delaware Health Care Association	1280 S. Governors Avenue Dover, DE 19904	(302) 674-2853		
Delaware Health Care Facilities Association	726 Loveville Road, Suite 3000 Hockessin, Delaware 19707-1536	(302) 674-2853		
Delaware Health Systems and Hospitals	Christiana P.O. Box 1668 Wilmington, DE 19899 Beebe 424 Savannah Rd. Lewes, DE 19958 Bayhealth 640 S. State Street Dover DE 19901 Nanticoke 800 Middleford Rd. Seaford, DE 19973 Saint Francis Hospital 701 N. Clayton St. Wilmington, DE 19805	Christiana (302) 733-1000 Beebe (302) 645-3300 Bayhealth (302) 674-4700 Nanticoke (302) 629-6611 Saint Francis Hospital (302) 421-4100 Nemours (302) 651-4000		
	Nemours Alfred I. Dupont 1600 Rockland Road Wilmington, DE 19803			

National Organizations or other State Entities (that serve as an information clearinghouse or regularly interact with the agency)			
Group or Association Name/Contact Person	Address	Phone Number Fax Number Internet Address	
The Department of Health and Social Services, Division of Health Care Quality, Office of Health Facilities Licensing and Certification	261 Chapman Road, Newark, DE 19702	(302) 292-3930	

ENACTED LEGISLATION IMPACTING THE AGENCY

129th **General Assembly, June 1978, HB 956 with HA 2 & 3** – Established a system of health planning and review; defined the CON process and its period of effectiveness under the DHSS Bureau of Planning and Resources Management. Established CON review measures for health services subject to CON review, procedures and criteria for CON review, sanctions, immunity, and revocation.

134th **General Assembly, July 1987, SB 132** – Established the 15-member Council in the cessation of federal support and attendance requirements. Council created a new structure for health planning which involved the review of CON activities and established CON procedures for review, review considerations, and provisions to implement sanctions and CON revocations.

136th General Assembly, May 1991, HB 162 with HA 1 – Increased Council membership to 18 members to review filed CON applications and adopt by-laws.

137th General Assembly, June 1994, HB 33 with HA 1, 3, 5, 7 & 8 – Established the 21-member HRB to replace Council, develop a Health Resources Management Plan, review CON applications, and gather and analyze data to carry out responsibilities. The Bureau of Health Planning and Resources Management under DHSS provides administrative duties; the Bureau Director serves as HRB secretary. Additionally, DHCC tasked with completing a review of effectiveness of the CON process. Included a sunset date of June 30, 1996, for the CON process.

138th **General Assembly, July 1996, HB 640** – Provided for the 3-year phase out of the CON process and added a sunset date of June 30, 1999.

140th **General Assembly, June 1999, SB 74** – Changed all "CON" references to "CPR" and delayed the sunset date until June 30, 2002. Eliminated several categories of providers from the process of review, members of the HRB were permitted to serve for more than two consecutive terms, reviews were required for all acquisitions of nonprofit health care facilities, and failure to comply provisions to the language regarding revocation were added.

141st **General Assembly, May 2002, SB 305** – Extended the CPR program's sunset date to June 30, 2005.

143rd **General Assembly, July 2005, SB 181** – Implemented JLOSC recommendations and extended the CPR program's sunset provision to June 30, 2009. Added provisions for a charity care policy for free standing facilities, notice of intent expirations, continual care communities, and other non-traditional long-term care facilities to the scope of activities subject to HRB's review. Increased the capital expenditure threshold that triggers HRB review from \$5 million to \$5.8 million. Authorized HRB to adjust this figure annually based on an annual inflation index determined by the US Dept. of Labor's Bureau of Labor Statistics. Modified HRB membership, including removal of the member

designated by the Delaware Health Care Coalition and the addition of an additional publicat-large member, increasing the public-at-large representation from 9 to 10 members.

144th **General Assembly, July 2007, SB 87** – Corrected technical errors from the 2005 bill that inadvertently omitted wording to enable the enforcement of charity care requirements. Corrected references to the dollar amount that triggers the review of capital expenditures and the 15-day timeline for the review of applications.

145th **General Assembly, July 2009, SB 181** – At JLOSC's request, removed the CPR program's sunset provision.

146th **General Assembly, August 2012, HB 326** – Result of JLOSC recommendations, including reducing the number of members from 21 to 15; relocating administrative duties to the Office of the Secretary, DHSS under the DHCC; and requiring HRB to conduct a public hearing when modifying the HRMP. Additional requirements included requiring HRB establish rules and regulations for reviewing CPR applications and adding member removal provisions for gross inefficiency, neglect of duty, malfeasance, misfeasance or nonfeasance in office.

147th **General Assembly, June 2013, HB 89 with HA 1** – Added a definition for freestanding inpatient rehabilitation hospitals and waived CPR requirement. Eliminated the need for an additional CPR for a 34-bed facility in Middletown which previously received a CON and included a December 31, 2016, sunset provision for this exemption.

148th **General Assembly, June 2016, SB 226** – Resulted from the work of the Behavioral and Mental Health Task Force which indicated a greater need for psychiatric services statewide. Eliminated additional CPR for a 90-bed psychiatric hospital in Georgetown, which previously received a CPR by the Board. Included a December 31, 2020, sunset provision for this exception.

PENDING & PROPOSED LEGISLATION

150th **General Assembly, May 2019, SB 108** – Technical corrections and implementing 3 major changes to HRB, including reducing the number of members from 15 to 11, to aid in achieving quorum and filling vacancies, updating language to provide for 3-year terms, and authorizing members to elect a vice chair rather than requiring Governor appoint the vice chair. As of the printing of this report, SB 108 was voted out of the Senate Sunset Committee in June 2019 and has been placed on the Ready List for consideration.

FISCAL INFORMATION

Revenue generates through the collection of CPR application fees. As outlined in the CPR process, application fees are collected based on the capital expenditure amounts of the proposals. Application fees are deposited into the State's General Fund and are not directly allocated to HRB. HRB is unable to budget or project how many applications will be filed, or the capital expenditure amounts, therefore budgeted revenue is not applicable for fiscal year 2019 in the chart below. Additionally, HRB does not receive federal funds.

Actual Revenue:

Fiscal Year	Source(s)	Amount
FY19 (budgeted)	General Fund	Not applicable
		TOTAL
FY18 (actual)	General Fund	\$3,100.00
		TOTAL
FY17 (actual)	General Fund	\$46,200
		TOTAL

Actual Expenditures:

Fiscal Year	Source of Funds	Amount	
FY19 (budgeted)			
	General Funds	\$44,700	
	Federal Funds	\$0.00	
	TOTAL:	\$44,700	
FY18 (actual)			
	General Funds	\$19,118.06	
	Federal Funds	\$0.00	
	TOTAL:	\$19,118.06	
FY17 (actual)			
	General Funds	\$9,148	
	Federal Funds	\$0.00	
	TOTAL:	\$9,148	

Breakdown of FY19 budgeted expenses:

Line Item	Source(s)	Amount of Expenditures
Transcription Services	General Fund	\$1,214.97
Public Notices	General Fund	\$1,262.46
Meeting facility costs	General Fund	\$7,267.05
Consultant HRB statistical analysis	General Fund	\$9,975.00
	TOTAL:	\$19,719.48

ACCOMPLISHMENTS

- 1. HRB revised the HRMP effective September 11, 2017.40
- 2. HRB revised their by-laws effective October 13, 2016.41
- 3. HRB has reviewed and rendered a decision on 16 CPR applications since 2017.
- 4. HRB has adopted a more efficient nursing home bed need methodology to calculate bed projections.⁴²

⁴¹ See Appendix F.

⁴⁰ See Appendix D.

⁴² Additional information about this methodology found in Appendix D, HRMP page 32, Section X

5. JLOSC last reviewed HRB in 2012 and approved 12 recommendations; 10 recommendations are verified as being in compliance. Two are in non-compliance as indicated in the below "Additional Comment from the Committee Analyst" section of this draft report.

CHALLENGES

- Recusals: The Governor appoints all 15 HRB members. When rendering a decision on a CPR application, HRB by-laws require a quorum of 8 voting members. If a member recuses themselves from voting, that member does not count towards a quorum.⁴³
 - Many members need to recuse themselves during the CPR process due to conflicts of interest. As a result, HRB often does not have enough voting members available to render a decision.
 - CPR applications that need to be brought to a vote are sometimes not heard in a timely manner and statutory deadlines can be missed because of recusals.
 - Recusals and their effect on quorum can cause an inconvenience and negative impact for applicant and result with HRB not meeting statutory deadlines.
- 2. **Vacancies:** In October 2019, HRB had 3 vacancies. In February 2020, 1 vacancy was filled so that only 2 vacancies remain. Vacancies are counted for quorum, making it a challenge for HRB to meet quorum.
- 3. **Vice Chair:** HRB needs a vice chair to assist in situations when the chair is not able to attend a meeting or needs to recuse. Current statute requires the Governor to appoint a vice chair from among the members, but a vice chair has not been appointed since the last vice chair resigned in 2015.
- 4. **Appeals:** An HRB decision can be appealed to Superior Court. Anyone, applicant or non-applicant, can appeal. The appeal process is lengthy and a significant burden to the HRB's DAG.
- 5. **General Assembly:** The General Assembly can pass legislation to circumvent an HRB CPR application decision and this undermines the CPR process.

OPPORTUNITIES FOR IMPROVEMENT

1. Evaluate the purpose and need of the CPR process, activities subject to review, and the 7 review criteria items in place.

⁴³ Analyst Note: By-laws in Appendix F define a meeting quorum as 8 members and a voting quorum as a majority of members who are present at the meeting and able to vote. "The disqualification of a member from voting or a member abstaining from voting shall not affect the quorum. All matters, except as provided for in Article VI of these bylaws, shall be decided by a majority of the members present and voting. Members who abstain from voting on a particular matter are considered "present and voting" for purposes of determining a majority." It was stated in HRB November 14, 2019 meeting minutes that, "recusals are not counted as a quorum because it is best practice for the Board member to leave the meeting if recusing from a Board matter. It was noted that the recusal process adheres to the Public Integrity Commission's procedures."

- Consider whether the CPR process in Delaware supports the current health care delivery system and interest in health care innovation and transformation.
- 2. Fill HRB vacancies.
- 3. Evaluate the size and composition of the HRB to determine if 15 members is an appropriate number and the correct representatives are part of the Board.
 - The representative involved in purchasing health care coverage for employers with more than 200 employees has been vacant since 2012.
- 4. Provide clarity for the statutory definition of a quorum.⁴⁴ Currently the statute reads "A quorum shall consist of at least 50% of the membership. This can be interpreted to mean 50% of the current filled positions or 50% of the composition of the Board.
- 5. Review and update the filing costs for capital expenditures.⁴⁵ Application filing fees are deposited into the General Fund; HRB would like a percentage of the filing fees allocated to the DHCC for operational costs and additional staff support.

⁴⁴ 16 *Del. C.*§ 9303.

⁴⁵ 16 *Del. C.*§ 9305.

ADDITIONAL COMMENT FROM THE COMMITTEE ANALYST

JLOSC REVIEW HISTORY

JLOSC reviewed HRB and its predecessor in 1993, 2005, and 2012.

Summary from the 1993 JLOSC Final Report of the Council:46

JLOSC reviewed Council 7 years after its creation and, in JLOSC's final report, highlighted problem areas such as conflict of interests, review committee dysfunction, FOIA compliance, and insufficient staff support from the Bureau of Health Planning and Resource Management. JLOSC concluded that Council spent most of its time reviewing CON applications and were performing a superficial review of the statutory data they were mandated to collect.

JLOSC recognized that there was a need for a comprehensive health planning process and recommended terminating Council and a reconfiguration of the CON program to better support the State's comprehensive health planning process.

1993 JLOSC Recommendations

Recommendation #1: The Health Resources Management Council be abolished (sunset), and that the Governor and General Assembly be advised of the need to develop a comprehensive health planning process. The various commissions, councils, and boards can be brought under one umbrella agency dealing with health care planning. The Joint Sunset Committee agreed that the Certificate of Need review, the development of a comprehensive health policy, the centralization of health planning, and the issue of a regionally based health care planning process will need to be part of a comprehensive health planning process.

Recommendation #2: The Governor and General Assembly develop a program of regulations to centralize health care planning resources under a smaller umbrella of oversight, so as to make better use of resources and to centralize the health care decision-making process. This Recommendation will be in the form of a Resolution to the General Assembly.

Recommendation #3: The Deputy Attorney General assigned to the Health Resources Management Council attend all Council meetings.

Recommendation #4: The Health Resources Management Council be included under those agencies covered by the Administrative Procedures Act (Chapter 101, 29 Del. D.).

⁴⁶ See Appendix J.

Recommendation #5: Members of the Health Resources Management Council, by statutory change, be brought under the State Ethics Code Chapter 58, 29 Del. C.).

Recommendation #6: The members necessary for a quorum of the Health Resources Management Council be raised to 1 O (ten).

Recommendation #7: All meetings of the Health Resources Management Council, including subcommittee and review committee meetings, be posted and open to the public.

Recommendation #8: Minutes be prepared for all meetings of the Health Resources Management Council, and that such Minutes be available to the public before decisions are reached by the Council as a whole.

Recommendation #9: The statute governing the Health Resources Management Council be amended by striking relevant sections of Chapter 93, 16 Del. C., regarding the Appeal panel.

Recommendation #10: The Health Resources Management Council set aside a specific period of time for public comment at Council meetings.

Recommendation #11: A quorum of subcommittee members of the Health Resources Management Council be present for Review Committee meetings, including those at which public comment is taken.

Recommendation #12: Minutes be prepared for all meetings of the Health Resources Management Council, and that such Minutes be available to the public before decisions are reached by the Council as a whole.

Summary from the 2005 JLOSC Final Report: 47

After the 1993 review of Council, several changes occurred, most importantly the Council's termination, creation of HRB in 1994, and the CPR process replacing the CON process in 1999. The various changes of HRB and the CPR process received 4 different sunset dates during this period which brought on the 2005 JLOSC review.

JLOSC concluded in their final report that several areas should be addressed, including HRB's charity care policy; providing the public access to meeting minutes and agendas; providing CPR applications and procedures electronically through the creation and maintenance of a website; and fully complying with the statutory requirement to coordinate health planning activities with the DHCC, DHSS, and other health care organizations.

The 2005 final report also cited other reports and research, such as the 1996 Health Care Commission report, that concluded the State's CON processes were not effective in reducing health care costs.

2005 JLOSC Recommendations

The Joint Sunset Committee recommends continuance of the Delaware Health Resources Board, but only upon its meeting certain conditions or making certain modifications as identified below.

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⁴⁷ See Appendix K.

A. The Joint Sunset Committee recommends the following statutory changes:

Recommendation #1: Delete the sunset provision.

Recommendation #2: Insert a provision sunsetting the Delaware Health Resources Board on June 30, 2009.

Recommendation #3: Create legislation allowing the Delaware Health Resources Board to establish and enforce a charity care policy for free standing facilities.

Recommendation #4: Delete the statutory provision to include "1 representative designated by the Delaware Health Care Coalition."

Recommendation #5: Add one additional representative of the public-at large to the Board. This addition will increase the Board's public membership from 9 to 10 members.

Recommendation #6: Include non-traditional long-term care facilities in the scope of activities subject to CPR review. For purposes of definition, non-traditional long-term care facilities shall include continual care communities and other facilities identified by Department of Health and Social Services or the Delaware Health Care Commission.

Recommendation #7: Increase the 2005 capital expenditure threshold that triggers a CPR review from \$5 million to \$5.8 million, based on an annual inflation index determined by the US Dept. of Labor's Bureau of Labor Statistics.

Recommendation #8: Add a 180-day expiration date on the Notice of Intent.

B. The Joint Sunset Committee recommends that the Delaware Health Resources Board take the following action:

Recommendation #9: The Delaware Health Resources Board must comply with the statutory requirement to coordinate health planning activities with the Health Care Commission, the DHSS, and other health care organizations. (16 *Del. C.* §9303(d)(6))

Recommendation #10: The Delaware Health Resources Board shall revise the CPR application so that it directly addresses each of the statutory review criteria. (16 *Del. C.* §§9304, 9306)

C. The Joint Sunset Committee recommends the following action by the Division of Public Health:

Recommendation #11: The Division of Public Health shall create and maintain a CPR website with contact information, meeting minutes, agendas, the CPR application and CPR procedures. (16 *Del. C.* §9303(e))

Summary from the 2012 JLOSC Final Report:⁴⁸

In 2012, JLOSC conducted a third review of HRB and the CON process, which had evolved into the CPR process. Prior to this review, the program received 5 different sunset dates with the final sunset date removal occurring in 2009. The dollar threshold that triggers the CPR process increased numerous times and the activities of review saw decrease over the years.

In the 2012 final report, JLOSC highlighted the need to update CPR program documents, such as the HRMP and CPR application kit, and identified issues in filling HRB vacancies, handling conflicts of interest, lack of program staff assistance, and application filing fees.

Discussion regarding the need of the CPR program continued with this review. Then-Governor Markell and DHSS supported continuing the CPR process as a component of Delaware's comprehensive health planning system. Thirty-six states used a CON program like Delaware's CPR program, a number unchanged from research presented in the 2005 JLOSC Final Report. In addition, the pros and cons for the CON and CPR programs are still largely unchanged as of the 2020 review.⁴⁹

In the 2012 final report, JLOSC concluded that HRB would benefit from a reduction in membership, relocating administrative duties from the Bureau of Health Planning and Resource Management to DHCC, and requiring modifications of the HRMP to comply with the public hearing process.

2012 JLOSC Recommendations

The Joint Sunset Committee recommends the Delaware Health Resources Board be continued, provided HRB is meeting certain conditions or making certain modifications as identified below.

Recommendation #1: For administrative and budgetary purposes only, the Delaware Health Resources Board shall be relocated to the Office of the Secretary, Department of Health and Social Services. The Delaware Health Resources Board shall function in cooperation with the Delaware Health Care Commission, as well as other state health policy activities.

Recommendation #2: Amend 16 *Del. C.* § 9303 (c) as follows: The Delaware Health Care Commission and the Office of the Secretary, DHSS will be responsible for the administration and staffing for the Health Resources Board.

Recommendation #3: The total composition of the Delaware Health Resources Board shall be reduced from 21 members to 15 members. The membership shall be representative of all counties in the State.⁵⁰

Recommendation #4: Amend 16 *Del. C.* § 9303 (d) (1) to require that when revising the Health Resources Management Plan, the Board shall conduct a public hearing and shall

⁴⁸ See Appendix L.

⁴⁹ See Appendix A for current list of pros and cons from NCSL.

⁵⁰ See page 4 of Appendix L for additional information.

establish rules and regulations published in accordance with the procedures specified in the Administrative Procedures Act for reviewing Certificate of Public Review applications.

Recommendation #5: Amend 16 *Del. C.* § 9303 (d) (1) to reflect that the Health Resources Management Plan should be reviewed and approved by the Delaware Health Care Commission prior to submission to the Secretary of DHSS for final written approval.

Recommendation #6: Amend 16 *Del. C.* § 9304 (1) to clarify that only for-profit acquisitions of a nonprofit health care facility are subject to the Certificate of Public Review process. Not-for-profit acquisitions of another nonprofit health care facility would not require a review.⁵¹

Recommendation #7: Amend 16 *Del. C.* § 9303 to include a section as follows: 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.

Recommendation #8: The Delaware Health Resources Board, with assistance provided by DHSS and the Delaware Health Care Commission, shall conduct a comprehensive review of 16 Del. C. c. 93 and the Certificate of Public Review program. The focus of this government efficiency review should be aimed at streamlining operations, increasing efficiency, simplifying the application process and updating the categories for review. This review shall include, but is not limited to, the following: activities subject to a review; criteria considered during a review; procedures to review; timelines/deadlines for a review; feasibility of quarterly Board meetings; documents used by the Board; application fees and fee structure; strengthening the charity care requirements; consider publishing the list of equipment triggering a review through the regulatory process; consider adding assisted living communities to CPR process; consider IT capabilities and an increased online presence. The Delaware Health Resources Board shall report the key findings identified and make recommendations to the Joint Sunset Committee by January 1, 2013.⁵²

⁵¹ Non-compliance note from JLOSC Performance Review Questionnaire: 16 *Del. C.* § 9304 (1) currently states: "The construction, development or other establishment of a health care facility or the acquisition of a nonprofit health care facility is subject to the CPR process". This is not in compliance with recommendation 6 and would require a statutory amendment.

⁵² Non-compliance note from JLOSC Performance Review Questionnaire: According to the Board's bylaws, regular meetings of the Board will be held every two months. However, the Board may need to meet more frequently to conduct business. The HRMP has a charity care policy to include the intent, define services, eligibility and charity care guidelines, a formal charity care plan, annual reporting requirements and an enforcement clause, During the HRMP revision process, the Board discussed reviewing legislative changes during Phase 2 of the HRMP revision process.

Recommendation #9: The Delaware Health Resources Board shall review, and revise as needed, the conflict of interest definition enumerated in the by-laws. The Board shall develop guidelines for members to use when identifying and evaluating potential conflicts of interest. Additionally, the Board shall provide its members with the opportunity to participate in a Public Integrity Commission training session no less than once per year.

Recommendation #10: The Delaware Health Resources Board, with assistance provided by the Delaware Health Care Commission, shall undertake a comprehensive review of the Health Resources Management Plan and shall update the Plan to ensure that it supports the development of health services that are cost effective, consistent with meeting consumer needs and choice, and that the standards for a Certificate of Public Review are appropriate. Public hearings and forums should be held to solicit comment from all interested stakeholders and the public at large.

Recommendation #11: The Delaware Health Resources Board shall review and revise the current by-laws governing the Board to ensure consistency with Chapter 93, Title 16; by-laws shall be updated accordingly.

Recommendation #12: The Delaware Health Resources Board shall develop a toolkit for the CPR process. The toolkit should include, but not be limited to, the Board by-laws, the revised CPR applications, an overview of the CPR process outlining what applicants can expect at each step in the process, the options available for applications to be reconsidered if denied, as well as a general timeline detailing the average time needed to complete each step in the process for applications to be approved or denied by the Board. Upon completion of the toolkit, the Board shall make these documents available to the public on the Board's website.

FURTHER CONSIDERATION AND RESEARCH

CPR Procedures and Review Committees:

After attending meetings and reviewing the HRB website a further point of consideration and research could be in streamlining the CPR process and clearly defining the CPR procedures in the HRMP and CPR application kit.

Under the third step of the CPR process outlined on the HRB website,⁵³ an applicant provides an overview presentation to HRB and has an opportunity for questions. After the presentation, HRB assigns the application as a staff review or appoints a Review Committee. During the drafting of this report, DHCC provided clarification and explained that the website's information is incorrect and that after the applicant's presentation the selection of the Review Committee occurs. HRB does not decide between a staff review or a Review Committee selection, there is no choice, a Review Committee selection occurs. The staff assist the Review Committee in their duties, which include compiling a report for HRB review. DHCC indicates that the website will be modified to resolve the discrepancy. After receiving this clarification, the materials in the draft report were modified to match the process as explained by DHCC. There was additional confusion in

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⁵³ See Appendix M.

this area because the CPR procedures as described on the website do not have a similar description in HRB documents such as the CPR application kit or the HRMP.

During the review process, the analyst observed two regular HRB meetings and a meeting held by a Review Committee. During a Review Committee meeting, the analyst observed the Review Committee expressing the need for additional information, but the Review Committee and applicant did not discuss the issue at the meeting. Instead, a DHCC staff member contacted the applicant after the meeting with the Review Committee's questions. It is unclear if this is necessary for the process and if meetings could be more productive if the discussions occurred during the meeting.

Purpose and Need of the CPR Process:

Recommendation 8 of the 2012 JLOSC review required HRB to conduct a comprehensive review of Chapter 16, Title 93, and the CPR program, with assistance provided by DHSS and DHCC.

It is unclear if HRB conducted the comprehensive review or if a report containing the findings is available. Information in the JLOSC Performance Review Questionnaire indicate that the HRMP revision process occurred as prescribed by Recommendation 10.

Additionally, the healthcare industry has changed since the conclusion of the 2012 JLOSC review. Current trends encourage a shift from the traditional fee-for-service (cost-based reimbursement) to value-based reimbursement models, utilizing options such as Accountable Care Organizations and Patient-Centered Medical Homes. These changing trends should be considered when analyzing the CPR process.

Filing Fee Structure:

The filing fee structure in use today is the same fee used since its implementation in 1987. Additionally, the filing fees have always deposited into the State's General Fund.

The 2012 JLOSC Final Report cited research showing that revenue from Delaware's CPR application filing significantly lags in comparison to other states. Since the fee evaluation, HRB reviewed a couple proposals to revise the filing fees; the last proposal was reviewed in 2010; HRB took no action although it agreed that the fee amount and structure should be revised to cover the cost of operations, including staff positions and contractual needs.

Since the 2012 JLOSC review, HRB has moved under DHCC. Information received in connection to this 2020 review indicates that DHCC has not conducted a financial analysis to determine if the current CPR application fees are enough to cover the cost of the administration activities, data collection, and analysis. Legislative involvement and approval are necessary to revise the fees.⁵⁴

Health Resources Management Plan ("HRMP"):

The HRMP was last updated in September 2017.⁵⁵ The HRMP provides CPR program and charity care policy guidance and explains the State's policy and vision for health care quality and cost reduction. The JLOSC 2012 review recommendations implemented a requirement that HRB conduct a public hearing and publish "rules and regulations" in the

⁵⁴ 16 *Del. C.* § 9305.

⁵⁵ See Appendix D.

State's Register of Regulations in accordance with the Administrative Procedures Act for all revisions of the HRMP.

In reviewing the current Administrative Code, the text of the HRMP is not codified; instead, a link is provided to the HRMP document on HRB's website.⁵⁶ This does not follow the intent of JLOSC's recommendation, and is a questionable practice because it could allow HRB to modify the HRMP without following the formal APA process or requiring a public hearing on proposed modification. Additionally, any changes to the document's website location will result in a broken link and inaccessible information. ⁵⁷

⁵⁶ See Appendix C.

⁵⁷ DHCC Comment: "This is factually incorrect. There are statutory requirements for how the HRMP needs to be developed and revised. The statute does not require that it be codified in the Administrative Code. The board did follow the Administrative Procedures Act and all statutory requirements when revising the HRMP in 2017 including conducting a public meeting, obtaining approval of the Health Care Commission and the approval of the Secretary of the Department of Health and Social Services."

Appendix A: NCSL CON - Certificate of Need State Laws



CON-Certificate of Need State Laws

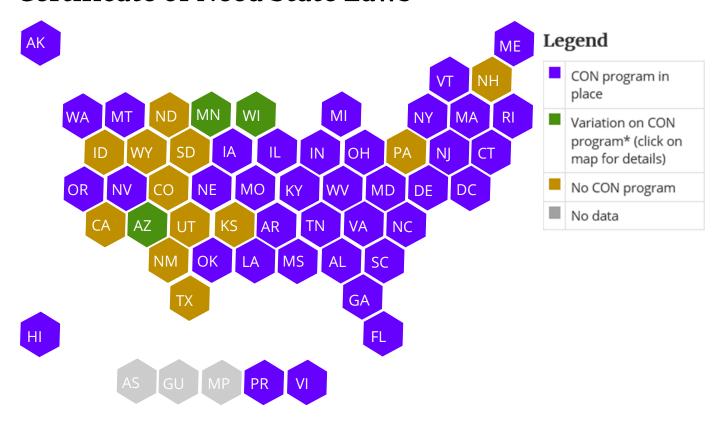
12/1/2019

Certificate of Need (CON) laws are state regulatory mechanisms for establishing or expanding health care facilities and services in a given area. In a state with a CON program, a state health planning agency must approve major capital expenditures for certain health care facilities. CON programs aim to control health care costs by restricting duplicative services and determining whether new capital expenditures meet a community need.

Interactive Map of State CON Laws

Currently, 36 states and Washington, D.C. operate a CON program with wide variation state-to-state. The following 50-state map lists the health care facilities and capital expenditures covered under the CON law for each state.

Certificate of Need State Laws



*Visit NCSL.org for an interactive map and detailed information about CON programs.

Intent and Structure of CON

The basic assumption underlying CON regulation is that excess health care facility capacity results in health care price inflation. Price inflation can occur when a hospital cannot fill its beds and fixed costs must be met through higher charges for the beds that are used. Larger institutions generally have larger costs, so hospitals and other health facilities may raise prices in order to pay for new, underused medical services or empty beds. CON programs require a health care facility to seek a health planning agency's approval based on a set of

criteria and community need. Once a health facility has applied for state approval, the health planning agency may approve, deny or set certain limitations on a health care project.

While the effectiveness of CON programs continues to be a heavily debated topic, many states consider CON programs as one way to control health care costs and increase access to care. Below is a list of both arguments in favor and against CON laws.

Arguments In Favor and Against CON Laws

Proponents of CON Laws Argue:

- Health care cannot be considered as a "typical" economic product. Most health services (like lab tests) are ordered by physicians, not patients. Patients do not shop around as they do for other goods and services.
- CON programs limit health care spending.
- CON programs help distribute care to disadvantaged populations or geographic areas that new and existing medical centers may not serve.
 Removal of CON will favor for-profit hospitals which may be less willing to provide indigent care.
- Removal of CON will lead to a proliferation of "low-volume" facilities, which some view as providing lower quality care.
- CON requirements do not block change, they mainly provide for an evaluation, and often include public or stakeholder input.

Opponents of CON Laws Argue:

- By restricting new construction, CON programs may reduce price competition between facilities and keep prices high.
- Some changes in the Medicare payment system (such as paying hospitals according to Diagnostic Related Groups – "DRGs") may make external regulatory controls unnecessary by sensitizing health care organizations to market pressures.
- CON programs vary state to state, with inconsistent metrics and management.
- CON programs allow for political influence in deciding whether facilities will be built, which can invite manipulation and abuse.
- Some evidence suggests that lack of competition encourages construction and additional spending.
- Identifying the "best interests" of a community isn't always clear; decisions ostensibly made for the greater good could have unintended consequences in the long-term, particularly in an unsteady economy or, for example, in a rapidlygentrifying community.

History

New York was the first state to enact a CON law in 1964; 26 states enacted CON laws throughout the following decade. Early CON programs typically regulated capital expenditures greater than \$100,000, facilities expanding their bed capacity and facilities establishing or expanding health care services.

In 1972, several states adopted Section 1122 waivers, which provided federal funding to states regulating new health care services receiving Medicare and Medicaid dollars. Congress then passed the National Health Planning and Resources Development Act of 1974 bolstering federal funding for state and local health planning regulations. The federal law required states to adopt CON laws similar to the federal model resulting in all states, except Louisiana, maintaining some form of a CON program by 1982. This meant states had broad regulatory oversight of several facilities—including hospitals, nursing and intermediate care facilities and ambulatory surgery centers—as well as the expansion or development of a facility's service capacity.

The federal mandate was repealed in 1987, along with the associated federal funding. Subsequently, several states repealed or modified their CON laws.

State Legislative Actions

In the past several years, many states have introduced or enacted legislation to change their CON program. Changes range from fully repealing an existing CON program to creating a new CON program. The following are state examples of legislative actions impacting CON programs:

- 35 states currently maintain some form of CON program. Puerto Rico, the US Virgin Islands and the District of Columbia also have CON programs. States retaining CON laws often regulate outpatient facilities and long-term care. This is largely due to an increase in free-standing, physician-owned facilities.
 - Indiana enacted legislation in 2018 establishing a certificate of need program, which the state initially repealed in 1999.
- Nine states—Florida, Georgia, Maryland, Ohio, Rhode Island, Tennessee, Vermont,
 Virginia and Washington—enacted legislation in 2019 to modify CON regulations for certain health facilities and services.
- Three states—Arizona, Minnesota and Wisconsin—do not officially operate a CON program, but they maintain several approval processes that function similarly to CON.
- 12 states fully repealed their CON laws. New Hampshire was the most recent repeal, effective 2016.

Moratoria

As part of a CON program, some states may place certain health care facilities and facility beds on moratorium. This means a state planning agency will grant no CONs for certain facility capital expenditures. Moratorium regulations most often affect nursing facilities and other long-term care facilities.

Several states—including Arkansas, Florida, Georgia, Hawaii, Illinois and Virginia—have restrictions on the development or expansion of certain health care facilities and beds through a needs and utilization assessment process. While not an outright moratorium, a state planning agency may determine there is no need for additional health care facility beds or services in a particular county or district.

Certificate of Need (CON) Moratoria				
STATE	MORATORIA?	FACILITIES COVERED UNDER MORATORIA		
Alabama	No			
Alaska	No			
Arizona	No			
Arkansas	Yes	Psychiatric residential facilities, intermediate care facilities for the intellecually disabled and residential care facilities.		
California	No			
Colorado	No			
Connecticut	Yes	Nursing home beds.		
Delaware	No			
Florida	No			
Georgia	No			
Hawaii	No			
Idaho	No			

STATE	MORATORIA?	FACILITIES COVERED UNDER MORATORIA
Illinois	No	
Indiana	No	
lowa	No	
Kansas	No	
Kentucky	No	
Louisiana	Yes	Intermediate care facilities for the developmentally delayed, nursing facilities, long-term care facilities and long-term care beds.
Maine	No	
Maryland	Yes	Acquisitions authorizing a general hospice to provide home-based hospice services on a statewide basis.
Massachusetts	Yes	Long-term care beds.
Michigan	No	
Minnesota	Yes	Hospitals and hospital beds, nursing home beds, intermediate care facilities for persons with developmental disabilities and radiation therapy facilities in certain locations.
Mississippi	Yes	Skilled nursing facilities; intermediate care facilities; intermediate care facilities for the mentally retarded; home health agencies; the conversion of hospitals beds to intermediate nursing home care; and Medicaid-certified child/adolescent psychiatric or chemical dependency beds.
Missouri	No	
Montana	No	
Nebraska	Yes	Long-term care beds and rehabilitation beds.
Nevada	No	

STATE	MORATORIA?	FACILITIES COVERED UNDER MORATORIA
New Hampshire	No	
New Jersey	No	
New Mexico	No	
New York	Yes	Licensed home care service agencies.
North Carolina	No	
North Dakota	No	
Ohio	Yes	Long-term care beds.
Oklahoma	No	
Oregon	No	
Pennsylvania	No	
Rhode Island	Yes	Nursing-facility licensed beds and increases to licensed capacity for existing nursing-facility licenses.
South Carolina	No	
South Dakota	No	
Tennessee	No	
Texas	No	
Utah	No	
Vermont	Yes	Home health agencies.
Virginia	No	
Washington	No	
West Virginia	Yes	Opioid treatment programs, skilled nursing facilities, intermediate care beds, skilled nursing beds, intermediate care facilitiey beds for individuals with an intellectual disability.

STATE	MORATORIA?	FACILITIES COVERED UNDER MORATORIA
Wisconsin	Yes	Hospital beds, psychiatric/chemical dependency beds and nursing home beds.
Wyoming	No	
District of Columbia	No	
Puerto Rico	No data	
US Virgin Islands	No data	

Additional Resources

NCSL Resources

State Legislation Relating to Transparency and Disclosure of Health and Hospital Charges
 updated 2014.

Federal Resources

- The Federal Trade Commission (FTC) website
 - FTC Statement to the Alaska Senate Committee on Health and Social Services on CON laws and SB 1 - March 2019
 - FTC and Department of Justice's (DOJ) Antitrust Division joint statement on proposed Alaska CON-repeal legislation - April 2017
 - FTC and DOJ's Antitrust Division joint statement on proposed South Carolina CONrepeal legislation - January 2016
 - FTC report Certificarte of Need Laws: A Prescription for Higher Costs December 2015
- The Department of Health and Human Services' report Reforming America's Healthcare
 System Through Choice and Competition November 2018

Other Resources

- The American Health Planning Association (AHPA) website
- State CON websites
- CON articles and essays

Part VIII Hospitals and Other Health Facilities

Chapter 93

Health Planning and Resources Management

§ 9301 Purpose.

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.

(61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, § 1; 72 Del. Laws, c. 64, § 2.)

§ 9302 Definitions.

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;

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- 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.
- (61 Del. Laws, c. 393, § 1; 65 Del. Laws, c. 69, § 2; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 1, 2; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, § 2; 72 Del. Laws, c. 64, §§ 1, 3-5; 75 Del. Laws, c. 192, §§ 1, 2; 79 Del. Laws, c. 50, § 1.)

§ 9303 Delaware Health Resources Board.

- (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. 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.
- (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 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.

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(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.

(66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 3, 4; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, §§ 1, 6, 7; 75 Del. Laws, c. 192, §§ 3, 4; 78 Del. Laws, c. 394, § 1.)

§ 9304 Activities subject to review [Effective until Dec. 31, 2020] [Effective until Dec. 31, 2020].

- (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.
 - (61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 5, 6; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, §§ 3-5; 72 Del. Laws, c. 64, §§ 1, 8-11; 75 Del. Laws, c. 192, §§ 5, 6; 76 Del. Laws, c. 87, § 1; 79 Del. Laws, c. 50, §§ 2, 3; 80 Del. Laws, c. 250, § 1.)

§ 9304 Activities subject to review [Effective Dec. 31, 2020] [Effective Dec. 31, 2020].

- (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].
- (61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 5, 6; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, §§ 3-5; 72 Del. Laws, c. 64, §§ 1, 8-11; 75 Del. Laws, c. 192, §§ 5, 6; 76 Del. Laws, c. 87, § 1; 79 Del. Laws, c. 50, §§ 2, 3; 80 Del. Laws, c. 250, § 1; 80 Del. Laws, c. 250, § 2.)

§ 9305 Procedures for review.

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.

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- (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:

Capital Expenditures	Filing 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

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.

(61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, § 7; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1; 75 Del. Laws, c. 192, § § 7, 8; 76 Del. Laws, c. 87, § 2.)

§ 9306 Review considerations.

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.
- (61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1.)

§ 9307 Period of effectiveness of Certificate of Public Review.

- (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.

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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.

(61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1.)

§ 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.
- (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.
 - (61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1.)

§ 9309 Surrender, revocation and transfer of Certificate of Public Review.

- (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.
 - (61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, §§ 1, 12.)

§ 9310 Immunity.

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.

(61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 186, § 1.)

§ 9311 Charity care.

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.

(75 Del. Laws, c. 192, § 10; 76 Del. Laws, c. 87, § 3; 77 Del. Laws, c. 132, § 2.)

§ 9312 Charity care [Transferred].

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

TITLE 16 HEALTH AND SAFETY DELAWARE ADMINISTRATIVE CODE

1

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

Delaware Health Care Commission

Delaware Health Resources Management Plan

This document is provided in PDF due to the size and formatting of the document.

Delaware Health Resources Management Plan http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Delaware%20Health%20Care%20Commission/HRMP.pdf

21 DE Reg. 222 (09/01/17)



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DELAWARE HEALTH RESOURCES BOARD

Certificate of Public Review

Health Resources Management Plan

[Adopted/Effective: September 11, 2017]



NANCY H. FAN, MD, CHAIR LAURA HOWARD EXECUTIVE DIRECTOR

STATE OF DELAWARE DELAWARE HEALTH CARE COMMISSION MARGARET O'NEILL BUILDING

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July 17, 2017

On Behalf of the State of Delaware Health Care Commission and the Delaware Health Resources Board (HRB), we are pleased to present the 2017 Health Resources Management Plan (HRMP) as approved by the Cabinet Secretary of the Department of Health and Social Services on July 13, 2017.

Pursuant to 16 *Del. C.* § 9303, the duties and responsibilities of the HRB include the development of a Health Resources Management Plan (HRMP) which shall include a statement of principles to guide health resource allocation within Delaware. The purpose of the HRMP is to establish the core set of common review considerations for use in reviewing Certificate of Public Review (CPR) applications submitted on behalf of applicants proposing health care-related projects falling under the jurisdiction of the HRB.

In 2012, the Joint Sunset Committee issued twelve (12) recommendations for HRB improvement to include the revision of the HRMP. This revised edition of the HRMP promotes the alignment of Delaware's existing health planning framework with statewide policy aimed at promoting health system improvement. In this manner, Delaware's health system infrastructure will align with the State's vision that all Delawareans receive accessible, effective, well-coordinated care throughout the health care system in a way that supports the "Triple Aim Plus One" framework – improved health care quality, health outcomes, patient experience and enhanced provider satisfaction.

As Delaware aspires to be a national leader on each dimension of the Triple Aim Plus One, the HRMP along with other health system transformational initiatives across the state, demonstrates the commitment of the State's leadership to achieve this aspiration.

Sincerely,

Nancy H. Fan, MD

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Chair

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EXECUTIVE SUMMARY

The Delaware Health Resources Board (HRB) Certificate of Public Review (CPR) program, like other national Certificate of Need (CON) programs, originated to regulate the number of beds in hospitals and nursing homes and prevent excessive purchasing of expensive medical equipment. Since relocation into the Department Health and Social Services, Office of the Secretary, the Delaware Health Care Commission (DHCC) has provided the administration and staffing for the HRB.

Delaware's CPR process, in tandem with community-based planning efforts, helps to protect the statewide health care infrastructure necessary to meet the expected and projected health care needs of all Delawareans. The CPR process works to improve geographic and economic access to care for residents in the state. And, subsequent to its procedural code, Delaware's CPR process provides a forum where all interested parties, including citizens, are able to express their views pertaining to Delaware's health care delivery system.

Pursuant to 16 *Del. C.* § 9303, the duties and responsibilities of the HRB include the development of a Health Resources Management Plan (HRMP) which shall include a statement of principles to guide health resource allocation within Delaware. Thus, the purpose of this HRMP is to establish the core set of common review considerations for use in reviewing CPR applications submitted on behalf of applicants proposing health care-related projects falling under the oversight jurisdiction of the HRB.

Since its adoption in 1995, the HRMP has been evaluated and adjusted to maintain pace with statewide health initiatives. This fully-updated edition of the HRMP promotes the alignment of Delaware's existing health planning framework with statewide policy aimed at promoting health system improvement. In this manner, Delaware's health system infrastructure will align with the state's vision that all Delawareans receive accessible, effective, well-coordinated care throughout the health care system in a way that supports the "Triple Aim Plus One" framework ((a) improved health outcomes; (b) improved health care quality and patient experience; (c) lower growth in per capita health care costs; and (d) enhanced provider satisfaction).

I. Introduction

A. Purpose

The purpose of this document, hereafter referred to as the Delaware Health Resources Management Plan (HRMP), is to establish the guiding principles for health care resource allocation within the state, as well as the rules and regulations for use in reviewing Certificate of Public Review applications pursuant to 16 *Del. C.* 93.

As stated in 16 *Del. C.* § 9301, "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."

B. Authority

16 Del. C. §9303 establishes a Governor-appointed 15-member Delaware Health Resources Board (HRB) 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.

Also pursuant to 16 *Del. C.* §9303, the duties and responsibilities of the HRB include the development of an HRMP which shall assess the supply of health care resources, particularly facilities and medical technologies, and the need for such resources. The HRMP shall include a statement of principles to guide the allocation of resources, as well as rules and regulations for use in reviewing CPR applications.

C. Certificate of Public Review (CPR) Program History

In 1975, the Federal government officially established state-level health resource oversight via the National Health Planning and Resources Development Act (NHPRDA). The NHPRDA required all 50 states to convene oversight agencies and Certificate of Need (CON) programs to provide a review of proposed new health facilities and services and major capital expenditures.

The NHPRDA was largely based on the primary underlying economic assumption that excess health care capacity directly results in health care price inflation. CON programs were established in an effort to restrain health care costs and allow for coordinated planning of new services and construction based on a genuine need in the community. CON program review activities also emphasized the importance of distributing health care services to disadvantaged populations or geographic areas that may be ignored by new and existing facilities.

When the NHPRDA was officially repealed in 1987, a majority of states retained their CON programs. In Delaware, the state-level CON program was replaced with the Certificate of Public Review (CPR) in June 1999. Since 1999, the HRB has considered CPR proposals within the context of Delaware's dynamic health care delivery system.

Delaware's CPR process, in tandem with community-based planning efforts, helps to protect the statewide health care infrastructure necessary to meet the expected and projected health care needs of all Delawareans. The CPR process works to improve geographic and economic access to care for residents in the state. And, subsequent to its procedural code, Delaware's CPR process provides a forum where all interested parties, including citizens, are able to express their views pertaining to Delaware's health care delivery system.

D. HRMP Alignment with Delaware's State Health Care Innovation Plan

Delaware aspires to be a national leader on each dimension of the "Triple Aim Plus One": better health outcomes, improved health care quality and patient experience, lower growth in per capita health care costs, and enhanced provider satisfaction.

In 2013, the Delaware Health Care Commission (DHCC) convened stakeholders across the state – including consumers, providers, payers, community organizations, academic institutions and state agencies – to work together to build a strategy to achieve these goals. That work culminated in Delaware's State Health Care Innovation Plan, a statewide road map for achieving shared broad aspirations for improved health, health care quality and experience, and affordability for all Delawareans.

At a macro level, Delaware's State Health Care Innovation Plan is built upon several fundamental health care themes including prioritizing health care innovation and efficiency, respecting the voice of consumers, reaching public health milestones, utilizing best practice methods whenever possible, and achieving measurable quality and fiscal results. Additional areas of focus include strengthening community health services, creating linkages across the care continuum, and addressing Delaware's health care capacity shortages.

In 2014, Delaware was awarded a four-year, \$35 million State Innovation Model (SIM) Testing Grant from the Center for Medicare and Medicaid Innovation to support implementation of the State Health Care Innovation Plan. Through the SIM initiative, Delaware is building upon a strong local foundation for innovation to achieve a system-level transformative healthcare plan that can serve as a scalable model for the nation.

As noted in the original edition of Delaware's HRMP, the HRB is best served by a HRMP that embodies flexibility. Since its adoption in 1995, the HRMP has been evaluated and adjusted to maintain pace with statewide health initiatives. Present-day reform activities are paving the way for a higher quality, more efficient health care system in Delaware. The HRMP has evolved, accordingly, so that Delaware's CPR process may respond to changes in our health care system.

This current HRMP promotes the alignment of Delaware's existing health planning framework with statewide efforts aimed at promoting health system improvement. In this manner, Delaware's health system infrastructure will align with the state's vision that all Delawareans receive accessible, effective, well-coordinated care throughout the health care system in a way that supports the Triple Aim.

II. Activities Subject to CPR Review

In Delaware, a CPR **is required** for the following activities:

- 1. The (a) construction, development or other establishment of a new health care facility, or the (b) acquisition of a nonprofit healthcare facility as defined in 16 *Del.C.* §9302).
- 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 16 *Del.C.*§ 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 one 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 in16 *Del.C.* § 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. [Effective until Dec. 31, 2016]. Notwithstanding any other provision in this chapter to the contrary, any person who held, as of June 1, 2013, a certificate of public review issued by the Delaware Health Resources Board authorizing the construction of a 34-bed freestanding acute inpatient rehabilitation hospital in Middletown, Delaware, regardless of such certificate's date of expiration or whether the certificate has otherwise been challenged on appeal, shall not be required to obtain any additional certificate of public review pursuant to this chapter prior to the construction, development, or other establishment of freestanding

acute inpatient rehabilitation hospital. Any acute inpatient rehabilitation hospital constructed, developed, or established pursuant to this section 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.

In Delaware, a CPR is **NOT required** for the following activities:

- 1. The establishment of or amendments to health care facilities owned and operated by the federal government.
- 2. The establishment of offices by a licensed private practitioner, whether for individual or group practice, including, but not limited to physical therapist, dentist, physician assistant, podiatrist, chiropractor, an independently practicing nurse or nurse practitioner, optometrist, pharmacist, or psychologist.
- 3. The establishment of or amendments to dispensary or first aid stations located within a business or industrial establishment maintained solely for the use of employees, provided that the facility does not contain inpatient beds.
- 4. The establishment of or amendments 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.

Any person, facility, or institution that is unsure whether a CPR is required pursuant to this HRMP should send a letter to the HRB that describes the project and requests that the HRB make a determination was to whether a CPR is required.

III. CPR Application Procedure

Pursuant to 16 *Del. C.* § 9305, CPR reviews are conducted in accordance with a standardized review schedule. All necessary CPR application forms are available online via the Delaware HRB website. Note that the general public shall be provided access to all CPR applications reviewed by the HRB and to all other written materials pertinent to any review of a CPR application.

Please refer to 16 *Del. C.* § 9305 of the aforementioned title for additional review schedule details, including an abbreviated CPR review schedule in the case of a project required to remedy an emergency situation which threatens the safety of patients or the ability of a health facility to remain in operation.

Step 1: Notice of Intent. At least 30 days, but not more than 180 days, prior to submitting a CPR application for review, the applicant shall submit to the HRB a notice of intent. If no subsequent CPR application for review is submitted to the HRB within 180 days following the date on which the notice of intent is submitted, the notice is rendered invalid.

Step 2: CPR Application Submission. The applicant submits its completed application packet directly to Delaware Health Care Commission (DHCC) staff responsible for assisting the HRB. Application forms are available online via the HRB website and vary according to the nature of the proposed CPR application.

Step 3: Determination of Application Completeness. Upon receipt of a CPR application, DHCC staff responsible for assisting the HRB shall have a maximum of 15 business days to notify the applicant as to whether the CPR application is considered complete and thus accepted for HRB review. A CPR application is considered complete only if all of the following conditions are satisfied: (a) depending on the nature of the proposed project, the correct application form has been completed; (b) the application includes all required information and signatures; (c) the application is accompanied by all supporting evidence and documents referenced in the body of the application.

If the CPR application is determined to be complete, written notification will be provided to the applicant on behalf of the HRB. If incomplete, the applicant will be notified in writing on behalf of the HRB as to what additional steps are necessary before the application will be considered complete. Following receipt of any additional information, DHCC staff members assigned to the HRB will again have 15 business days to assess application completeness.

Step 4: Applicant Filing Fees. Within 5 business days of providing the applicant with written notification of an application being deemed complete, the HRB will notify the applicant of any filing fee due. Please refer to 16 *Del. C.* § 9305 for the current CPR application fee schedule.

Filing fees shall be due 30 calendar days after the date of notification of the beginning of CPR review (described in Step 5, below). The filing fee due date may be extended up to 10 additional calendar days at the discretion of the HRB. Applications for which filing fees have not been paid

within this time frame shall be considered to be withdrawn from CPR review. All filing fees shall be deposited into the General Fund.

Step 5: Notification of Impending CPR Application Review. Within 5 business days of providing written notification of CPR application being deemed complete, the HRB shall provide written notification of the beginning of a CPR review. This 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 on which the notice appears in the newspaper serves as the date of notification to the general public.

This notification will identify the applicant, indicate the nature of the CPR application, specify the period during which a public hearing may be requested, and indicate the manner in which notice will be provided of the time and place of any hearing so requested.

Within 10 days of the notification described in this subsection, a public hearing in the course of review may be requested by any person; written request for a public hearing must be made directly to the HRB and submitted to DHCC staff assigned to assist the HRB. Upon receipt of written request for a public hearing, the HRB shall provide notification of the time and place for such a hearing in a newspaper of general circulation. A public hearing shall not be held less than 14 days after the notice appears in the newspaper. Fees are not imposed for public hearings; an opportunity must be provided for any person to present testimony.

Step 6: CPR Application Review. HRB review of a CPR application shall take no longer than 90 days from the date of notification of the beginning of review (Step 4, above). If a public hearing is requested (per Step 5, above), the maximum review period will be extended to 120 days from the date of notification.

Within 30 days from the date of notification of the beginning of review (60 days if a public hearing is requested), the HRB may extend the maximum review period up to 180 days from the date of notification. 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 HRP and the applicant.

Step 7: Notification of HRB Decision. Upon completion of a CPR review, the HRB 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 may be conditional, but the conditions must be related to the specific proposed project in question.

Step 8: Completion of Required Registrations. Upon successfully obtaining a CPR, the applicant will comply with all appropriate state and federal licensure requirements and any operational procedures required including, but not limited to, the Centers for Medicare and Medicaid Services, the Delaware Division of Long Term Care Residents Protection, Delaware Office of Health Facilities and Licensing, Delaware Department of Health and Social Services, and the Delaware Division of Professional Regulation.

Step 9: Administrative Reconsideration (only if necessary). Any person may, for a good cause shown, request in writing a public hearing for the purposes of reconsideration of an HRB decision rendered per Step 7 (above). A request for administrative reconsideration must be received by the HRB within 10 days of the decision rendered per Step 7.

A request for a public hearing shall be deemed by the HRB to have shown good cause if it:

- a. Presents newly discovered, significant, relevant information not previously available or considered by the HRB; and
- b. Demonstrates that there have been significant changes in factors or circumstances relied upon by the HRB in reaching its decision; or
- c. Demonstrates that the HRB has materially failed to follow its adopted procedures in reaching its decision.

The hearing to determine whether the request shows good cause shall take place within 45 days of the hearing request. Notice of the 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 HRB 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. If good cause for reconsideration is found, the Board will schedule a meeting to reconsider the application. If the Board reconsiders the application, the Board shall issue a further written decision on the merits of the application.

Step 10: Applicant Appeal (only if necessary). Within 30 days, an appeal may be made to the Superior Court any of the following:

- a. A decision of the HRB following review of a CPR application
- b. A decision of the HRB following an administrative reconsideration hearing
- c. The denial of a request for extension of a CPR pursuant to 16 Del. C. § 9307.

IV. Certificate of Public Review (CPR) Common Review Considerations

The Delaware HRB conducts CPR application reviews using three categories of consideration:

- 1. **Statutory Criteria** pursuant to 16 *Del. C.* § 9306;
- 2. A core set of **Guiding Principles** that embody the major themes of Delaware's statewide health care reform model; and
- 3. Project-specific Mathematical Need Calculations

A. Statutory Criteria and Guiding Principles

In accordance with 16 Del. C. § 9306, the Health Resources Board reviews CPR proposals according to the seven **Statutory Criteria** (SC) outlined below. As stated by Delaware Code, the HRB shall consider as appropriate at least these seven standards.

Additionally, the HRB considers CPR proposals' alignment with seven **Guiding Principles**. Guiding principles align with Delaware's statewide health care reform efforts and succinctly capture the coordinated statewide approach to achieving the vision outlined in the State Health Care Innovation Plan. Guiding principles assist CPR applicants in understanding HRB expectations and inform the HRB, itself, when conducting CPR reviews, particularly in matters where specific guidelines are lacking.

Statutory Criteria and Guiding Principles aim to achieve similar broad goals related to the distribution of statewide health resources; therefore, the current version of the HRMP appends Statutory Criteria with the Guiding Principle(s) encompassing similar themes related to health resource allocation within the state.

SC1. The relationship of the proposal to the Health Resources Management Plan (HRMP).

Each proposal shall include a detailed narrative that provides a rationale for the proposed project.

The applicant will provide their relevant certification and accreditation statuses, including Medicare certification status, Medicaid certification status, and accreditation status with the Joint Commission and/or other accrediting organizations.

Include letters that have been received in support of the proposal. Additionally, submit a list of administrative, clinical, leadership and other positions related to the proposal as necessary. Attach a copy of their Curriculum Vitae.

Each proposal seeking to add beds or expand services shall document that the applicant has a signed participation agreement with the Delaware Health Information Network (DHIN) and is submitting service records and accessing data and information from DHIN

for care coordination purposes. Each proposal seeking to establish a new health care facility shall document that the applicant shall have a signed participation agreement with the DHIN and submit service records as well as access data and information from DHIN for care coordination purposes.

Related Guiding Principles: The essential challenge faced by the HRB is striking an appropriate balance in its consideration of access, cost, and quality of care issues. Evidence that this challenge has been seriously embraced by the applicant should permeate every CPR application.

Moreover, to adapt to the long-term effects of the Affordable Care Act's changing regulatory guidelines, the board will consider and align CPR reviews with a health care delivery system in transition. Thus, the board will review CPR applications and consider the proposal's relevance to access and continuity of care, chronic disease management, use of health information technology and affiliation with the Delaware Health Information Network (DHIN), care coordination and other strategies to facilitate Delaware's transition to value-based payment models to improve overall health outcomes.

Additionally, the problem of medical indigence is extremely complex. The Delaware Health Care Commission continues to provide leadership in this area. CPR applicants are expected to contribute to the care of the medically indigent.

SC2. The need of the population for the proposed project.

Each proposal shall demonstrate a clear public need for the health care facility or services proposed by the applicant, as well as identify the population to be served by the proposed project. Specific evidence, including demographic, incidence, prevalence, outcomes, and survival data should be included. All mathematical need calculations specified for a particular category of CPR proposal shall be calculated and addressed by the applicant. All population estimates and projections for use with any criteria contained within this HRMP shall be obtained from the Delaware Population Consortium and the U.S. Census Bureau. (http://stateplanning.delaware.gov/information/dpc.shtml).

Include any supporting documents (i.e., articles, scientific studies, or reports) that corroborate the statements made in this application justifying the need for the proposal, along with a brief explanation regarding the relevance of each supporting document.

If the proposed project is expected to enhance the health status of the user population, please reference any quantitative or qualitative supporting data, including improvements in accessibility, availability, new technology, advances in medical science, and morbidity and/or mortality data.

Each proposal shall specify its plan for care of patients without private insurance coverage, as well as its plan for care of medically underserved populations with the proposed service area.

SC3. The availability of less costly and/or more effective alternatives to the proposal, including alternatives involving the use of resources located outside the state.

Each proposal should provide information about alternative providers of the proposed service, referencing the specific providers that now offer the proposed service and the impact of those parties. If alternative providers currently offer the proposed service, include financial information indicating whether these alternative providers are more or less costly in the provision of the service.

Related Guiding Principle: Given Delaware's small size and close proximity to major metropolitan referral centers, particularly in Philadelphia and Baltimore, every health care service need not be available within its borders. Potential CPR applicants are expected to take into account the availability of out-of-state, yet geographically close, resources.

SC4. The relationship of the proposal to the existing health care delivery system.

Each proposal shall describe in detail how and where the proposed patient population is currently being served. The applicant shall describe existing referral patterns in the proposed service area and satisfactorily demonstrate that the proposed project shall not result in an unnecessary duplication of existing or approved health care facilities or services.

To ensure appropriate continuity of care, accessibility, and related quality-enhancing considerations, include information regarding the applicant's established referral arrangements with other providers in the service area. The applicant will describe how their past and proposed provision of health services promote a continuum of care in Delaware's health care system.

The applicant shall also demonstrate that the proposed project will not negatively impact employment, the diversity of health care providers or patient choice in the defined service area.

SC5. The immediate and long-term viability of the proposal in terms of the applicant's access to financial, management, and other necessary resources.

The application shall satisfactorily demonstrate the financial feasibility of the proposed project. If a financial feasibility study has been performed, please include a copy of the study findings within the CPR application submission.

Provide proof of all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate, term, monthly payment, pledges and funds received to date, and letter(s) of interest or approval from a lending institution.

SC6. The anticipated effect of the proposal on the costs of and charges for health care.

The applicant shall satisfactorily demonstrate how the proposal will impact the financial strength of the health care system in the state. Specifically, the applicant will demonstrate how the proposed project will improve cost-effectiveness of health care services within the service area. The applicant will also demonstrate how the proposal will impact cost and charges to the individual(s) for health services.

Related Guiding Principles: "Historically, our cost-based reimbursement system has provided insufficient incentive for financial restraint and savings; over-utilization has frequently occurred. Cost centers were sometimes under emphasized. Projects which reflect or promote incentives for over-utilization are to be discouraged."

Strengthening market forces is a central theme in the health care reform strategy adopted by the DHCC, a theme which is embraced by the HRB. Projects resulting from or anticipated to enhance meaningful markets that ensure appropriate/adequate coverage, access and quality that is affordable are to be encouraged. Competition has often been on the basis of amenities for physicians (the medical arms race) and patients (the plushest waiting room). In meaningful markets there must be a sensitivity to elements of both cost and quality.

SC7. The anticipated effect of the proposal on the quality of health care.

Delaware's statewide health care reform model is focused on strengthening transitions of care across the health system, leading to a reduction in costly readmissions and improved quality of care.

The applicant will demonstrate how the proposed project will improve quality and accessibility of health care services within the service area, including but not limited to, the provision of or any change in the access to services for Medicaid recipients and indigent persons as well as the impact of providing services to these populations.

Related Guiding Principles: Historically, health care delivery has too often been episodic and disjointed. Projects which support a managed, coordinated approach to serving the health care needs of the person/population are encouraged.

Technology is a critical enabler to any health care transformation initiative. When implemented properly, technology solutions can achieve meaningful impact in under one year. Delaware's State Health Care Innovation Plan emphasizes the expanding roles of technology and telemedicine to achieve the Triple Aim. The HRB encourages CPR applicants to consider the impact of innovative technological advancements, especially in burgeoning areas of care such as Home and Community-Based Services (HCBS).

Prevention activities such as early detection and the promotion of healthy lifestyles are essential to any effective health care system. Delaware's statewide health care reform efforts include a number of opportunities to improve the health status of Delawareans.

The potential for a project to bring about progress in these areas will be viewed as a very positive attribute.

B. Project-Specific Mathematical Need Calculations (MNC)

The majority of activities subject to HRB review in Delaware are associated with one or more project-specific **Mathematical Need Calculations** -- quantitative guidelines used to estimate Delaware's need threshold related to the proposed project. Project-specific Mathematical Need Calculations are described later in this HRMP for each oversight category for which they exist.

CPR applicants, as well as the HRB, are reminded that estimating Delaware's future health care needs cannot be accomplished with the precision that mathematical need formulae often imply. While such formulae are essential to the CPR review process, health infrastructure planning requires more than mathematical calculations; thoughtful deliberation must occur.

Mathematical rigidity should not inhibit decision-making regarding health resource allocation throughout the state. Thus, project-specific Mathematical Need Calculations represent a necessary, but not always sufficient or all-encompassing component of the CPR decision-making process. HRB members will adopt a multi-faceted approach to CPR proposal reviews in which project-specific Mathematical Need Calculations are considered in conjunction with the Statutory Criteria and Guiding Principles described above.

V. Charity Care Policy

A. Intent

The goals of the HRMP charity care policy are to (a) promote access to care for low-income uninsured and underinsured Delawareans and (b) level the playing field between not-for-profit hospitals and freestanding health care facilities (i.e., facilities that deliver health care services and that are structurally separate and distinct from a hospital).

These goals reflect that not-for-profit, acute care hospitals use revenues generated from the provision of "profitable" services to offset the costs of providing "unprofitable" services that, nevertheless, are necessary and beneficial to society. A "profitable" service is a service for which a hospital is reimbursed an amount greater than the total cost of providing the service.

B. Defined Services

Charity care is defined as non-reimbursed charges for services to uninsured or underinsured Delawareans. Charity care may be determined prospectively or retrospectively. It does not include Medicaid or Medicare payment shortfalls or contractual allowances with third-party payers. It may include patient out-of-pocket expenses (e.g., deductibles, co-pays) for incometested patients who are uninsured or underinsured. Charity care discounts may include the provision of free care or care provided in accordance with an income-based sliding fee scale.

In addition to directly providing medical services at reduced or no cost to the medically indigent, facilities can meet their charity care requirement by facilitating the development and operation of primary medical services to indigent persons. Examples include providing a new health service (e.g., a free clinic) or making a donation to a pre-approved safety net provider approved by the HRB whose mission is to care for the medically indigent. The list of pre-approved safety net providers is available on the HRB's website:

http://dhss.delaware.gov/dhss/dhcc/hrb/dhrbhome.html

Freestanding health care facilities can also count toward their charity care contribution enabling services that make it possible for medically indigent patients to receive services at their facility whom otherwise would not be able to do so. Examples include free or reduced cost laboratory services, free or reduced cost transportation to and from the facility, and free or reduced cost home care following a surgical procedure for medically indigent patients.

C. Eligibility and Charity Care Guidelines

Patients eligible for charity care are those individuals whose annual income is less than or equal to 350 percent of the Federal Poverty Level, as published annually in the Federal Register, and who are uninsured or underinsured (i.e., overall medical expenses and/or health plan deductible equal to or exceeds 5 percent of annual income).

Freestanding health care facilities subject to the charity care provision are encouraged to accept all patients for medically necessary procedures regardless of ability to pay and strive to maintain a minimum Medicaid utilization level established by the Board.

D. Formal Charity Care Plan

As a condition of receiving a CPR, the applicant must develop a formal written charity care plan and file a copy of it with the Delaware HRB at the time of application for a CPR approval. The HRB may require that the applicant amend its charity care plan if it is determined to be unsatisfactory. If CPR approval is granted, the applicant will annually submit to the HRB a report from an independent, Delaware-licensed, certified public accountant that documents the amount of charity care they have provided during the previous fiscal year.

Charity care plans must include, but are not limited to the following:

- Explanations about the availability of charity care
- Time period and procedures for eligibility
- Applications and forms needed
- Facility location and hours during which information may be obtained by the general public

Health care facilities must notify patients of their charity care plan and their application processes. Such notice shall include visually prominent, multilingual postings. Centers shall also orally inform patients of their charity care plan. Patients who apply for charity care must be informed about the status of their application and, if approved, the level of discount for which he or she qualifies.

E. Annual Reporting Requirements

The charity care condition remains in effect over the operational life of the facility authorized by the CPR, unless otherwise notified by the Board. Freestanding health care centers approved for CPR must annually submit to the Board a report from an independent, Delaware-licensed, certified public accountant that documents the amount of charity care they have provided during the year.

Specifically, freestanding health care centers approved for CPR must, in accordance with the provisions of the federal Health Insurance Portability and Accountability Act and state law, maintain a charity care log that documents the services provided. The log must be certified as accurate by the facility administrator. The log shall include at a minimum the following data elements:

- Date of service provided
- Patient age
- ZIP code, city, and county of patient residence
- Total charges for the services provided
- Any amount charged to the patient
- Any associated physician and medical service fee (if known)

The facility shall submit a copy of the log and a summary data sheet within 180 days of the beginning of each calendar year for the previous calendar year to the Board. The form for submitting the summary information will be accessible via the Health Resources Board website. The summary data sheet shall include the following data elements:

- Date that the facility became operational
- Annual amount of total patient gross revenue collected by the facility for the fiscal year being reported
- Dollar amount and percentage of total gross patient revenue foregone to charity care
- Dollar amount written off as charity for "other", with detailed description (e.g., provided a free service, facility-covered transportation costs, etc.)
- Dollar amount and percentage of total gross revenue written off as bad debt
- Dollar amount of Medicaid gross revenue as a percentage of total gross patient revenue
- Documentation of enrollment in other Board-approved charitable programs

F. Enforcement

Failure to participate in the charity care procedures set forth by the HRB shall result in the HRB making a report to the Delaware Department of Health and Social Services designee responsible for compliance with applicable state laws and regulations, in accordance with 16 *Del. C.* § 9312. The HRB will designate all fiscal remedies for non-compliance, including pre-approved health care facilities or services to which fiscal remedies for non-compliance will be directed.

If the charity care condition is not met, the specific procedures for enforcement are as follows:

- 1. At the end of the first year of providing services to patients:
 - The facility shall provide a written explanation for why the charity care requirement was not met
 - The facility shall also appear before the Board and provide an oral presentation on why the charity care requirement was not met
 - The facility shall submit a proposed course of correction for approval by the Board

Should the Board determine that the proposed course of correction is not acceptable, the Board may require a monetary assessment equal to the amount of charity care that was to be provided during year one or the difference between what should have been provided and what was actually provided. The facility will submit this amount to a pre-approved safety net provider. A copy of the check shall be provided to the Delaware Department of Health and Social Services (please call to confirm mailing and fax address). The list of pre-approved safety net providers is available on the HRB's website: http://dhss.delaware.gov/dhss/dhcc/hrb/dhrbhome.html

2. Subsequent years:

If the charity care condition is not met in subsequent years, the facility shall submit a monetary assessment to a pre-qualified safety net provider equal to the amount of charity care that was to be provided during that fiscal year or the difference between what should have been provided

and what was actually provided. A copy of the check shall be provided to the Delaware Department of Health and Social Services (please call to confirm mailing and fax address).

This policy may be amended by the Delaware HRB as it deems appropriate and/or necessary.

VI. Supporting Resources and Documents

The following are important resources and documents which may be of assistance to applicants during the preparation of a CPR proposal:

• 16 Del. C. § 9301-9312 Health and Safety, Hospitals and Other Health Facilities

• Contact: Office of the Registrar of Regulations

Division of Research, General Assembly

P.O. Box 1401 Dover, DE 19903

Telephone: (302) 744-4114

http://delcode.delaware.gov/title16/c093/

• Delaware State Innovation Models (SIM) Initiative

 Documents include Delaware's State Health Care Innovation Plan; State Innovation Models Test Grant (abstract, project narrative, and approved project budget); CMMI SIM presentations; and summaries of public discussions

Contact: Delaware Health and Social Services

Delaware Health Care Commission Margaret O'Neill Building, Third Floor

410 Federal Street - Suite 7

Dover, DE 19901

Telephone: (302) 739-2730

http://dhss.delaware.gov/dhss/dhcc/sim.html

Delaware Population Consortium (DPC) Population Projections

Documents include DPC history, methodology, notes, and annual projections

• Contact: Office of State Planning Coordination

The Delaware Population Consortium

Haslet Armory

122 Martin Luther King Jr. Blvd. South

Dover, DE 19901

Telephone: (302) 739-3090

http://stateplanning.delaware.gov/information/dpc projections.shtml

• Delaware Nursing Home Utilization Statistics

Contact: Delaware Health and Social Services

Delaware Health Care Commission

Margaret O'Neill Building, Third Floor

410 Federal Street - Suite 7

Dover, DE 19901

Telephone: (302) 739-2730

http://dhss.delaware.gov/dhss/dhcc/hrb/nursutilizationstat.html

• Delaware Vital Statistics Annual Report

Contact: Delaware Health and Social Services

Division of Public Health

Delaware Health Statistics Center

Jesse S. Cooper Building

417 Federal Street Dover, DE 19901

Telephone: (302) 744-4700

http://www.dhss.delaware.gov/dhss/dph/hp/annrepvs.html

• Delaware Hospital Discharge Summary Report

Contact: Delaware Health and Social Services

Division of Public Health

Delaware Health Statistics Center

Jesse S. Cooper Building

417 Federal Street Dover, DE 19901

Telephone: (302) 744-4700

http://www.dhss.delaware.gov/dhss/dph/hp/hosp_dis.html

• State of Delaware State Health Assessment Goals and Strategies Report (April 2013)

Contact: Delaware Health and Social Services

Division of Public Health Jesse S. Cooper Building

417 Federal Street Dover, DE 19901

Telephone: (302) 744-4700

http://www.dhss.delaware.gov/dhss/dph/files/shagasr.pdf

VII. CPR Application: Document Property Guidelines

To facilitate efficient and thorough review of CPR applications, please limit application content to include only **required**, **relevant**, **and concise** information about the proposed project.

Strict page limits exist for each applicable section of the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website. These page limits are as follows:

Background: 2 pages

Review Considerations: 10-15 pages

Statutory Criteria Guiding Principles Project-Specific Need Criteria Additional Considerations

Financial Tables: 5 pages

Appendices: ≤10 pages

Additionally, CPR applications should adhere to the long-standing National Institutes of Health (NIH) guidelines pertaining to federal grant applications (please see below), which have been slightly adapted to meet the needs of Delaware-specific CPR applications. Specifically,

Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 12 points. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 ½" x 11). Use at least one inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses.

Use sub-headings, short paragraphs, and other techniques to make the application as easy to navigate as possible. Use bullets and numbered lists for effective organization. Indents and bold print add readability. Bolding highlights key concepts and allows reviewers to scan the pages and retrieve information quickly.

Be specific and informative, and avoid redundancies.

Use diagrams, figures and tables, and include appropriate legends, to assist the reviewers to understand complex information. These should complement the text and be appropriately inserted. Make sure the figures and labels are readable in the size they will appear in the application.

For figures, graphs, diagrams, charts, tables, figure legends, and footnotes: You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible. We suggest that you do not use a font size smaller than 9. We suggest the font Georgia for these sections, as it is the most legible at a smaller size.

(**Source**: National Institutes of Health Office of Extramural Research. 2016. *Grants & Funding: Writing Your Application*. http://grants.nih.gov/grants/writing_application.htm.)

VIII. Acute Care

A. Definition

For the purposes of this HRMP, "acute care" is defined as short-term medical or surgical services, usually provided by a hospital, for the diagnosis or the immediate treatment of patients having a brief but severe episode of illness or injury, or recovering from surgery. Acute care typically has an end goal of patient discharge as soon as they are deemed healthy and stable.

An "acute care hospital" is defined as a hospital that provides 24-hour inpatient care including medical, surgical, anesthesia, nursing, laboratory, pharmacy, and radiology services. These hospitals are also capable of providing health services on an immediate basis via an established Emergency Department.

Acute care hospitals provide services to all individuals that seek care and treatment, regardless of the individual's ability to pay for services. In Delaware, acute care hospitals are licensed as such by the Delaware Office of Health Facilities Licensing and Certification.

In contrast to an acute care hospital, a "specialty hospital" is defined as a facility offering limited specialized medical or surgical services. Specialty hospitals typically do not provide care on an immediate basis via an established Emergency Department.

B. Acute Care Hospital

For the purposes of this HRMP, an "acute care hospital" is defined as any non-federal facility licensed as such pursuant to 16 *Del. C.* §1001-1020.

In 2009, Delaware's HRB placed a moratorium on new construction of acute care hospitals. No additional hospitals offering acute care beds shall be established in the state unless or until the moratorium is rescinded.

C. Acute Care Beds

An "acute care bed" is defined as a hospital bed licensed by the Delaware Office of Health Facilities Licensing and Certification. Hospitals utilize acute care beds when providing 24-hour medical services for the diagnosis and treatment of patients across a wide range of medical conditions.

A "special purpose acute care bed" includes, but is not limited to, intensive care unit (ICU) beds, cardiac care unit (CCU) beds, and neonatal intensive care beds. Note also that for the purposes of this HRMP, hospital-based obstetric beds are considered as a separate category from hospital-based acute care beds.

D. Review Considerations for CPR Proposals Involving an Increase in Acute Care Beds

Applicants seeking an increase in acute care beds will complete the full Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website.

Statutory Criteria. Via the narrative portion of the Application, the applicant shall satisfactorily address the seven statutory criteria pursuant to 16 *Del. C.* §9306 (also refer to section III, subsection A of this HRMP for a detailed summary of the seven statutory criteria).

Guiding Principles. Applicants are also encouraged to explain the relationship of the proposed project to the seven guiding principles outlined in section III, subsection A of this HRMP.

Project-Specific Mathematical Need Calculations. The applicant will calculate its hospital-specific estimated need for acute care beds using the following formulae and explain how the proposed project is consistent with bed need projections.

Step 1: Calculate the average daily census (ADC) in the base year by dividing the base year patient days by 365 [(Base Year ADC) = (Base Year Patient Days) $\div 365$].

Step 2: Calculate projected ADC by multiplying the base year ADC by a population change factor (PCF) [(Projected ADC) = (Base Year ADC) x (PCF)].

The PCF shall represent a weighted average of projected population changes in the following age categories: less than 18; 18-64; and 65 and over. Weights will be based on the estimated percentage of acute care patient days in each age category in the base year.

Example Scenario: Calculating County-Specific PCF for Acute Care Bed Need Formulae

Age Category	Percentage Acute Care Admissions (Base Year)		5-Year Projected Population Growth (County- Specific)		Weighted Percentage of Acute Care Admissions (Projected)
Less than 18	8.2	X	1.07	=	8.774
18-64	49.1	X	1.10	=	54.010
65 and Over	42.7	X	1.18	=	50.386
	100.00				113.170

 $PCF = [(113.170) \div (100.00)] = 1.132$

Population change projections will be calculated for a five-year period, with Year 1 representing the year in which the proposed acute care beds would become licensed and staffed. Use Delaware Population Consortium (DPC) annual population projections to calculate the projected ADC, clearly identifying all underlying assumptions used.

Population estimates used in the acute care bed projections should be calculated using the following geographic areas:

• Christiana Hospital: New Castle County

St. Francis Hospital: New Castle CountyWilmington Hospital: New Castle County

• Kent General Hospital: Kent County

• Milford Memorial Hospital: Kent and Sussex Counties

Beebe Medical Center: Sussex County
 Nanticoke Memorial Hospital: Sussex County

Step 3: Calculate the projected acute care bed need by dividing projected ADC by an occupancy factor of 75% [(Projected Bed Need) = (Projected ADC) \div .750].

The applicant will provide a detailed explanation of all assumptions used in the derivation of the mathematical need calculations.

Additional Considerations. In addition to addressing statutory criteria, guiding principles, and project-specific mathematical need calculations, the CPR application for a request to increase acute care beds include the following components:

1. Actual and Projected Utilization Measures

For the last three complete fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide the following:

- a. Average Annual Admissions
- b. Average Annual Occupancy Rate
- c. Average Daily Census (including range in variability)
- d. Average Annual Patient Days

Provide a detailed explanation of all assumptions used in the derivation of the projected utilization measures. Explain any increases and/or decreases in utilization measures over the indicated time period.

The hospital shall document whether occupancy in the special purpose acute care beds is greater than 65 percent, preventing the conversion of special purpose acute care beds to acute care beds. Or, if the occupancy rate in the special purpose acute care beds is less than 65 percent, the hospital shall demonstrate whether the conversion of special purpose acute care beds to acute care beds would be insufficient to meet the hospitals total additional acute care bed need.

The hospital shall document whether during the base year (defined as the calendar year preceding the year in which the CPR proposal is submitted), its acute care occupancy rate has been higher than the target occupancy rate of 75 percent. Alternatively, the hospital will document whether its utilization of acute care beds has reached functional capacity during the base year. Functional capacity considerations will be based upon factors affecting acute care bed utilization rates such as the mix of private and semi-private rooms, patient matching limitations (e.g., for gender), or the need for medical isolation beds.

2. Actual and Projected Patient-Payer Mix

For the last three completed fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide a patient-payer breakdown detailing the percentage of patients covered by Medicare, Medicaid, TriCare, commercial insurers, workers' compensation, and those patients who are uninsured.

Provide a detailed explanation of all assumptions used in the derivation of projected patient-payer mix. Explain any increases and/or decreases in patient-payer proportions over the indicated time period.

3. Clinical Impact

The applicant will provide rationale for selecting the proposed service location.

The applicant will also describe how and where the proposed patient population is currently obtaining acute care services, including a description of existing patient admission patterns in the county in which the project is proposed.

The applicant will provide an explanation of the anticipated effect of the proposed project on existing acute care providers. The applicant will demonstrate that the projected utilization estimates under a CPR approval scenario are medically necessary and will not unnecessarily duplicate other acute care services currently established within the proposed county of service.

4. Quality Measures

The applicant hospital will document its history of providing health care services in conformity with federal and state standards. The applicant will include documented plans of action-and when applicable provide actual results and identification of steps to improve scores that serve to prevent, identify, diagnose and control the following:

- Acute myocardial infarctions sustained after admission to the hospital
- Hospital-acquired infections
- Medication errors
- Hospital-acquired pneumonia
- Re-admittance within 24 hours of discharge
- Decubitus ulcers
- Post-operative respiratory failure
- Post-operative sepsis
- Adverse medication/transfusion reactions
- Fall-related injuries

The applicant shall make available copies of reports that are required and submitted to regulatory entities.

5. Financial Information

Complete the following financial information tables in the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website:

- Estimated Capital Expenditures
- Sources of Financing
- Indicators of Financial Feasibility
- Debt Service Coverage
- Present Long-Term Debt

Prior to submission, the applicant will ensure that the application includes all pertinent financial information related to the proposed project, including, but not limited to, the following categories and subcategories: medical equipment lease/purchase, imaging equipment lease/purchase, non-medical equipment lease/purchase, land/building purchase, and construction/renovation; funding or financing sources associated with the proposal and the dollar amount of each; interest rate, term, monthly payments, pledges/funds received to date, and letters of interest/approval from lending institutions.

In reviewing CPR applications for acute care bed increases, the HRB will consider extenuating circumstances of the current health care market that influence bed need projections. A reasonable number of beds beyond the projected need for a hospital should not be considered to be inconsistent with this HRMP if it promotes greater efficiency. Likewise, proposed additions of a small number of beds which cannot be operated efficiently should not be construed as being consistent with this HRMP even if the proposed number of additional beds falls within the bed need range.

IX. Obstetric Care (Hospital-Based)

A. Definition

For the purposes of this HRMP, "obstetric care" is defined as maternity services including medical care during labor, delivery, and recovery.

B. Obstetric Care Beds

An "obstetric care bed" is defined as a hospital bed set aside for women for the purposes of delivering a baby. Such beds are staffed by trained professionals experienced in providing medical care for pregnant mothers and newborns which may include, but is not limited to, surgery, anesthesia, and blood transfusion procedures. Obstetric care beds are licensed by the Delaware Office of Health Facilities Licensing and Certification.

C. Review Considerations for CPR Proposals Involving an Increase in Obstetric Beds

Applicants seeking an increase in obstetric care beds will complete the full Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website.

Statutory Criteria. Via the narrative portion of the Application, the applicant shall satisfactorily address the seven statutory criteria pursuant to 16 *Del. C.* §9306 (also refer to section III, subsection A of this HRMP for a detailed summary of the seven statutory criteria).

Guiding Principles. Applicants are also encouraged to explain the relationship of the proposed project to the seven guiding principles outlined in section III, subsection A of this HRMP.

Project-Specific Mathematical Need Calculations. The applicant will calculate its hospital-specific estimated need for obstetric care beds using the following formulae and explain how the proposed project is consistent with bed need projections.

Step 1: Calculate the average daily census (ADC) for the base period (i.e., most recent three-year period) by dividing the base period patient days by 1,095 (the number of days in the base period; $365 \text{ days } \times 3 \text{ years} = 1,095 \text{ days}$). [(Base Period ADC) = (Base Period Patient Days) $\div 1,095$].

Step 2: Calculate projected ADC by multiplying the base period ADC by a population change factor (PCF) [(Projected ADC) = (Base Period ADC) x (PCF)].

The PCF shall represent the projected population change in the 15-44-year-old female category.

Example Scenario: Calculating County-Specific PCF for Obstetric Care Bed Need Formulae

Age Category	Percentage Obstetric Care Admissions (Base Period)		5-Year Projected Population Growth (County- Specific)		Weighted Percentage of Obstetric Care Admissions (Projected)
Females age 15-44	100.00	X	1.07	=	107.00
	100.00				107.00

 $PCF = [(107.00) \div (100.00)] = 1.07$

Population change projections will be calculated for a five-year period, with Year 1 representing the year in which the proposed acute care beds would become licensed and staffed. Use Delaware Population Consortium (DPC) annual population projections to calculate the projected ADC, clearly identifying all underlying assumptions used.

Population estimates used in the acute care bed projections should be calculated using the following geographic areas:

Christiana Hospital: New Castle County
 St. Francis Hospital: New Castle County
 Wilmington Hospital: New Castle County

• Kent General Hospital: Kent County

• Milford Memorial Hospital: Kent and Sussex Counties

Beebe Medical Center: Sussex County
 Nanticoke Memorial Hospital: Sussex County

Step 3: Calculate the projected obstetric care bed need by adding to the projected ADC the product of 1.96 times the square root of the projected ADC.

[(Projected Obstetric Bed Need) = (Projected ADC + $1.96\sqrt{\text{Projected ADC}}$)]

The above methodology for calculating projected obstetric bed need is based on tenets of statistical theory related to 95% confidence intervals. Using the formulae above, projected obstetric bed need is calculated with the addition of a margin of error; thus, the end result is a conservative estimate of projected obstetric bed need for Delaware hospitals in which projected bed need errors on the side of slight overestimation.

The applicant will provide a detailed explanation of all assumptions used in the derivation of the mathematical need calculations.

Additional Considerations. In addition to addressing statutory criteria, guiding principles, and project-specific mathematical need calculations, the CPR application for a request to increase obstetric care beds includes the following components:

1. Actual and Projected Utilization Measures

For the last three complete fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide the following:

- a. Average Annual Admissions
- b. Average Annual Occupancy Rate
- c. Average Daily Census (including range in variability)
- d. Average Annual Patient Days

Provide a detailed explanation of all assumptions used in the derivation of the projected utilization measures. Explain any increases and/or decreases in utilization measures over the indicated time period.

2. Actual and Projected Patient-Payer Mix

For the last three completed fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide a patient-payer breakdown detailing the percentage of patients covered by Medicare, Medicaid, TriCare, commercial insurers, worker's compensation, and those patients who are uninsured.

Provide a detailed explanation of all assumptions used in the derivation of projected patient-payer mix. Explain any increases and/or decreases in patient-payer proportions over the indicated time period.

3. Clinical Impact

The applicant will provide rationale for selecting the proposed service location.

The applicant will also describe how and where the proposed patient population is currently obtaining hospital-based obstetric care services, including a description of existing patient admission patterns in the county in which the project is proposed.

The applicant will provide an explanation of the anticipated effect of the proposed project on existing hospital-based obstetric care providers. The applicant will demonstrate that the projected utilization estimates under a CPR approval scenario are medically necessary and will not unnecessarily duplicate other obstetric care services currently established within the proposed county of service.

4. Quality Measures

The applicant hospital will document its history of providing obstetric care services in conformity with federal and state standards. The applicant will include documented plans of action-and when applicable provide actual results and identification of steps to improve scores that serve to prevent, identify, diagnose and control the following:

- Obstetric lacerations (especially 3rd and 4th degree)
- Hospital-acquired infections

- Medication errors
- Hospital-acquired pneumonia

The applicant shall make available copies of reports that are required and submitted to regulatory entities.

5. Financial Information

Complete the following financial information tables in the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website:

- Estimated Capital Expenditures
- Sources of Financing
- Indicators of Financial Feasibility
- Debt Service Coverage
- Present Long-Term Debt

Prior to submission, the applicant will ensure that the application includes all pertinent financial information related to the proposed project, including, but not limited to, the following categories and subcategories: medical equipment lease/purchase, imaging equipment lease/purchase, non-medical equipment lease/purchase, land/building purchase, and construction/renovation; funding or financing sources associated with the proposal and the dollar amount of each; interest rate, term, monthly payments, pledges/funds received to date, and letters of interest/approval from lending institutions.

In reviewing CPR applications for obstetric care bed increases, the HRB will consider extenuating circumstances of the current health care market that influence bed need projections. A reasonable number of beds beyond the projected need for a hospital should not be considered to be inconsistent with this HRMP if it promotes greater efficiency. Likewise, proposed additions of a small number of beds which cannot be operated efficiently should not be construed as being consistent with this HRMP even if the proposed number of additional beds falls within the bed need range.

X. Nursing Home Care

A. Definition

"Nursing Home" shall mean any non-federal facility licensed as such pursuant to 16 *Del. C.* 11 and more particularly 16 *Del.* Administrative Code, Section 3201.

"Nursing Home (NH) Bed" refers to all long-term care beds licensed as skilled nursing or intermediate care beds by the Delaware Office of Health Facilities and Licensing.

Skilled nursing beds are defined as beds occupied by patients who receive skilled nursing care and supportive care, and who require availability of skilled nursing care on a continuous basis. Intermediate care beds are defined as beds occupied by patients who receive skilled nursing supervision and supportive care on a recurring basis, but who do not require continuous skilled nursing care.

B. Review Considerations for CPR Proposals Involving an Increase in NH Beds

Applicants seeking an increase in nursing home beds will complete the full Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website.

Statutory Criteria. Via the narrative portion of the Application, the applicant shall satisfactorily address the seven statutory criteria pursuant to 16 *Del. C.* § 9306 (also refer to section III, subsection A of this HRMP for a detailed summary of the seven statutory criteria).

Guiding Principles. Applicants are also encouraged to explain the relationship of the proposed project to the seven guiding principles outlined in section III, subsection A of this HRMP.

Project-Specific Mathematical Need Calculations. On an annual basis, the HRB will calculate prospective 5-year nursing home bed need projections for the state and its three counties using the following formulae. The applicant will explain how the proposed project is consistent with nursing home bed need projections.

Step 1: The DHCC will annually obtain state- and county-level nursing home utilization statistics, represented by billable patient day data. These data are aggregated from monthly data submissions reported by nursing home facilities as part of the data submission requirements related to publication of the annual Delaware Nursing Home Utilization Statistics Report.

The total annual billable patient days for the state reflect the total of all billable patient days recorded by Delaware's private and public nursing home facilities. The total annual billable patient days per county reflect all of the private nursing home billable patient days for that county, as well as an admissions-based proportion of billable patient days from Delaware's public nursing home facilities.

Public nursing home facilities are available to all state residents. The supply of public nursing home billable patient days, therefore, are allocated to each of the three counties according to the percentage of patient origin. The number of public nursing home billable patient days

attributable to each county is calculated by multiplying the total number of public nursing home billable patient days by the percentage of admissions attributable to each county.

Note that while the Delaware Veterans Home (DVH; located in Milford, Delaware) operates as a private long-term care facility, for the purposes of computing nursing home bed projections only, the DVH is entered into calculations as a public nursing home. The DVH serves a unique patient population (i.e., Delawareans meeting defined military service, residency, and level of care requirements); consequently, DVH nursing home beds are not as equally accessible to the general Kent County population as are nursing home beds staffed by other private nursing homes within the county. Thus, regarding the DVH as a public nursing home for bed projection calculations only, reduces the artificial inflation of the supply of nursing home beds available to Kent County residents.

Step 2: Using the most recently-available Delaware Population Consortium (DPC) data, the DHCC will calculate projected state- and county-level population growth factors by age group (<65 years; 65-74 years; 75-84 years; and ≥85 years). Population growth factors will be calculated for the most immediate 5-year projection period, non-inclusive of the current year. For example, to calculate the 2015-2020 projected population growth factor for Delawareans age 65-74, divide the projected 2020 population of Delawareans age 65-74 by the current 2015 population of Delawareans age 65-74. Assuming positive population growth, resulting population growth factors will always be greater than 1.0.

Step 3: The DHCC will obtain the county-level proportion of nursing home admissions by age group (<65 years; 65-74 years; 75-84 years; and ≥85 years) using data aggregated from monthly data submissions provided as part of the reporting requirements related to publication of the annual Delaware Nursing Home Utilization Statistics Report.

Step 4: The DHCC will calculate state- and county-specific population change factors (PCFs). PCFs shall represent a weighted sum of projected population growth factors in the following age categories: <65 years; 65-74 years; 75-84 years; and ≥ 85 years. Weights are derived from the base year percentage of nursing home admissions attributable to each age category (<65 years; 65-74 years; 75-84 years; and ≥ 85 years). PCFs will be calculated for a projected 5-year period, non-inclusive of the current year (e.g., for nursing home bed projections calculated in 2015, the corresponding 5-year projection period is 2015-2020).

Example Scenario: Calculating PCF for Nursing Home Bed Need Formulae

Age Category	Percentage NH Admissions (Base Year)		5-Year Projected Population Growth Factors		Weighted Percentage of NH Admissions (Projected)
Less than 65	6.7	X	1.042	=	6.98
65-74	16.6	X	1.071	=	17.78
75-84	42.5	X	1.169	=	49.68
85 and over	34.2	X	1.180	=	40.36
	100.00				114.42

 $PCF = [(114.42) \div (100.00)] = 1.1442$

Step 5: The DHCC will calculate the state- and county-specific projected billable patient day (PBPD) total by multiplying the base year billable patient day total by the state- or county-specific PCF:

[(Projected Billable Patient Day Total) = (Base Year Billable Patient Day Total) x (PCF)]

Step 6: For the county in which the project is proposed, the DHCC will divide the county-level projected billable patient day (PBPD) total by 365 to derive the projected average daily census (PADC).

Step 7: The DHCC will calculate the county-specific projected bed need (PBN) by dividing the projected average daily census (PADC) by 0.90 (Delaware's desired nursing home occupancy rate).

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[(Projected Bed Need) = (Projected Average Daily Census) ÷ (0.90)]
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Step 8: The DHCC will subtract the projected bed need (PBN) from the existing inventory of beds (at the state- or county-level) to determine bed surplus or shortage for that specific 5-year projection period.

Step 9: The DHCC will calculate projected nursing home bed shortage or surplus using a five-year rolling average.

Step 10: For a county with a projected shortage of nursing home beds and a base year occupancy rate of 94 percent or greater, the bed need determination is the projected shortage rounded up to the nearest unit of 10.

Additional Considerations. In addition to addressing statutory criteria, guiding principles, and project-specific mathematical need calculations, the CPR application for a request to increase nursing home beds includes the following components:

1. Actual and Projected Utilization Measures

For the last three complete fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide the following:

- a. Average Annual Admissions
- b. Average Annual Occupancy Rate
- c. Average Daily Census (including range in variability)
- d. Average Annual Patient Days

Provide a detailed explanation of all assumptions used in the derivation of the projected utilization measures. Explain any increases and/or decreases in utilization measures over the indicated time period.

2. Actual and Projected Patient-Payer Mix

For the last three completed fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario), provide a patient-payer breakdown detailing the percentage of patients covered by Medicare, Medicaid, TriCare, commercial insurers, workers compensation, and those patients who are uninsured.

Provide a detailed explanation of all assumptions used in the derivation of projected patient-payer mix. Explain any increases and/or decreases in patient-payer proportions over the indicated time period.

3. Clinical Impact

The applicant will provide rationale for selecting the proposed service location.

The applicant will also describe how and where the proposed patient population is currently obtaining long-term care services, including a description of existing patient admission patterns in the county in which the project is proposed.

The applicant will provide an explanation of the anticipated effect of the proposed project on existing long-term care providers in the proposed service area. The applicant will demonstrate that the projected utilization estimates under a CPR approval scenario are medically necessary and will not unnecessarily duplicate other long-term care services currently established within the proposed county of service.

4. Quality Measures

The applicant facility will document its history of providing health care services in conformity with federal and state standards. The applicant will include documented plans of action-and when applicable provide actual results and identification of steps to improve scores that reduce the following:

- Percentage of residents whose need for help with daily activities has increased
- Percentage of residents who have moderate to severe pain
- Percentage of residents who lose mobility
- Percentage of residents who are physically restrained
- Percentage of residents who develop pressures sores
- Percentage of residents with a urinary tract infection
- Percentage of residents who spend most of their time in a bed or a chair
- Percentage of residents who report feeling more depressed or anxious
- Percentage of residents who lose too much weight

The applicant shall make available copies of reports that are required and submitted to regulatory entities.

5. Financial Information

Complete the following financial information tables in the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website:

- Estimated Capital Expenditures
- Sources of Financing
- Indicators of Financial Feasibility
- Debt Service Coverage
- Present Long-Term Debt

Prior to submission, the applicant will ensure that the application includes all pertinent financial information related to the proposed project, including, but not limited to, the following categories and subcategories: medical equipment lease/purchase, imaging equipment lease/purchase, non-medical equipment lease/purchase, land/building purchase, and construction/renovation; funding or financing sources associated with the proposal and the dollar amount of each; interest rate, term, monthly payments, pledges/funds received to date, and letters of interest/approval from lending institutions.

In reviewing CPR applications for nursing home bed increases, the HRB will consider extenuating circumstances of the current health care market that influence bed need projections. For example, if capacity has been so restrained that the base year ADC is felt to understate legitimate demand, an upward adjustment of projected county-level nursing home beds may be made. Conversely, if financial access to nursing homes was threatened as a result of a change in Medicaid reimbursement policy, a downward adjustment of projected bed need may be appropriate.

To the extent that new uses are proposed for nursing home beds, the need for such beds must be evaluated based on the merits demonstrated during the review of specific CPR applications. Relatedly, as Delaware's health care system works to further embrace the principle of providing health services in the least restrictive setting, the expansion of home and community-based services (HCBS) may reduce the overall need for nursing home beds within the state.

XI. Freestanding Surgery Center (FSSC)

A. Definition

Free Standing Surgical Center abbreviated as FSSC, means a facility, other than a hospital or the office of a physician, dentist or professional association thereof, which is mandated and operated for the purpose of providing surgical services and in which the expected duration of services would not exceed 23 hours 59 minutes following and admission.

FSSCs include facilities which are state-licensed or Medicare-certified, or which provide ambulatory surgery as the primary business activity and operate as a separate and independent business. In Delaware, proposed projects involving endoscopy and pain management centers do not require CPR review.

B. Review Considerations for CPR Proposals Involving the Establishment of an FSSC

Applicants seeking to establish an FSSC will complete the full Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website.

Statutory Criteria. Via the narrative portion of the Application, the applicant shall satisfactorily address the seven statutory criteria pursuant to 16 *Del. C.* § 9306 (also refer to section III, subsection A of this HRMP for a detailed summary of the seven statutory criteria).

Guiding Principles. Applicants are also encouraged to explain the relationship of the proposed project to the seven guiding principles outlined in section III, subsection A of this HRMP.

Project-Specific Mathematical Need Calculations. The applicant will calculate projected need for FSSC rooms in the county in which the project is proposed, using the following formulae. The applicant will explain how the proposed project is consistent with FSSC room need projections.

Step 1: Calculate the projected number of patients needing FSSC services by applying the most current national ambulatory surgery use rate published by the National Health Statistics Center https://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf (116.25 per 1,000 in 2006) to the current Delaware Population Consortium population estimate for the county in which the project is proposed.

Step 2: Calculate the number of surgical visits per room per year in the proposed county using the following equation and assumptions:

Number of Surgical Visits Per Room Per Year = $A \times B \times C = 2,000$

- A. Assumed Number of Surgeries Per Hour: 1
- B. Assumed Number of Hours Per Day: 8
- C. Assumed Number of Work Days Per Year: 250

Step 3: Calculate the number of surgical visits that would justify approving an additional FSSC room by multiplying the utilization percentage needed to approve a new room (70%) by the number of surgical visits per room per year obtained in Step 2.

Number of Surgical Visits that Justify Approving an Additional Room = $2,000 \times 70\% = 1,400$

Step 4: Calculate the number of FSSC rooms needed in the proposed county by dividing the number of patients needing FSSC services in the proposed county (obtained in Step 1) by the number of surgical visits that would justify approving an additional room (obtained in Step 3).

Step 5: Calculate the total number of FSSC rooms available in the county in which the project is proposed by adding the number of currently licensed FSSC rooms in the proposed county to the number of HRB-approved FSSC rooms in the proposed county.

Step 6: Calculate the surplus or deficit of FSSC rooms available in the county in which the project is proposed by subtracting the number of FSSC rooms needed in the proposed county (obtained in Step 4) from the number of FSSC rooms available in the proposed county (obtained in Step 5).

Additional Considerations. In addition to addressing statutory criteria, guiding principles, and project-specific mathematical need calculations, the CPR application for a request to establish an FSSC includes the following components:

1. Projected Utilization Measures

For the first three full years of the proposed project (under a CPR approval scenario), the applicant shall report the projected ambulatory surgery volume, by procedure type.

Provide a detailed explanation of all assumptions used in the derivation of the projected volume units. Explain any increases and/or decreases in utilization measures over the indicated time period

2. Actual and Projected Patient-Payer Mix

For the first three full years of the proposed project (under a CPR approval scenario), provide a projected patient-payer breakdown detailing the percentage of patients covered by Medicare, Medicaid, TriCare, commercial insurers, workers' compensation, and those patients who are uninsured.

Provide a detailed explanation of all assumptions used in the derivation of projected patient-payer mix. Explain any increases and/or decreases in patient-payer proportions over the indicated time period.

3. Clinical Impact

The applicant will provide rationale for selecting the proposed service location.

The applicant will also describe how and where the proposed patient population is currently obtaining ambulatory surgery services (including hospital operating and procedure rooms), including a description of existing referral patterns in the county in which the project is proposed.

The applicant will document whether patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at existing ambulatory surgery centers in the proposed service area. Applicants will also provide an explanation for any unmet need for a specific type(s) of ambulatory surgery procedure has not been reasonably addressed by providers in the county in which the project is proposed.

The applicant will provide an explanation of the anticipated effect of the proposed project on existing providers of ambulatory surgery procedures. The applicant will demonstrate that the projected number of procedures anticipated under a CPR approval scenario are medically necessary and will not unnecessarily duplicate other ambulatory surgery services currently established within the proposed county of service.

4. Quality Measures

The applicant will document its history of providing health care services in conformity with federal and state standards.

The applicant shall provide patient transfer protocols with the hospital(s) in close proximity to the proposed facility.

The applicant will identify all governmental and/or professional oversight agencies whose approval/accreditation is necessary before the applicant may initiate provision of ambulatory surgery procedures. Such oversight agencies include, but are not limited to, the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), and The Joint Commission (TJC). For each required approval/accreditation, the applicant will describe its progress toward securing such approval/accreditation.

The applicant shall make available copies of reports that are required and submitted to regulatory entities.

5. Financial Information

Complete the following financial information tables in the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website:

- Estimated Capital Expenditures
- Sources of Financing
- Indicators of Financial Feasibility

- Debt Service Coverage
- Present Long-Term Debt

Prior to submission, the applicant will ensure that the application includes all pertinent financial information related to the proposed project, including, but not limited to, the following categories and subcategories: medical equipment lease/purchase, imaging equipment lease/purchase, non-medical equipment lease/purchase, land/building purchase, and construction/renovation; funding or financing sources associated with the proposal and the dollar amount of each; interest rate, term, monthly payments, pledges/funds received to date, and letters of interest/approval from lending institutions.

In reviewing CPR applications for the establishment or increase of FSSC rooms, the HRB will consider approving more rooms than indicated by the project-specific mathematical need calculations to accommodate facilities that provide comparatively higher utilization of ambulatory surgery services due to the in-migration of out-of-state patients or a higher percentage of patient referrals from other counties for specialized outpatient surgical services.

XII. Acquisition of Major Medical Equipment

A. Definition

CPR approval is required for all major medical equipment acquisitions by health care facilities, as well as non-health care facilities, regardless of whether the proposed acquisition will result from capital expenditure, operating expense, or donation.

For the purposes of this HRMP, major medical equipment is defined as 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, operating expense, or donation which exceeds \$5,800,000 or some greater amount which has been designated by the Board following an annual adjustment for inflation;
- 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 16 *Del. C.* § 9305, along with any other information deemed necessary by the Board, shall provide the basis for exempting such a capital expenditure from review.

Examples of major medical equipment acquisitions requiring CPR approval include, but are not limited to, the following:

- "Cardiac Catheterization": a diagnostic procedure in which one or more catheters is inserted through a peripheral blood vessel in the arm or leg with x-ray guidance. Results inform providers of the functional status of a patient's heart and blood vessels.
- "Computed Tomography (CT)": a non-invasive diagnostic procedure in which a three-dimensional image of a patient's internal body structure is digitally constructed from a series of cross-sectional x-ray images made along one or more angles or axes.
- "Extracorporeal Shock Wave Lithotripsy": a technique for shattering kidney stones or gallstones with shock waves produced outside the body. Resulting small pieces of calcified stone are excreted from the body more easily than larger, intact stones. The process may involve sedatives or local anesthesia.
- "Magnetic Resonance Imaging (MRI)": a non-invasive diagnostic procedure in which the application of radio waves induces the nuclear magnetic resonance of atoms within the body, producing computerized images of internal body structures.
- "Megavoltage Radiation Therapy": a clinical modality consisting of the administration of high energy to a deep-seated cancer or cerebrovascular defect using a megavoltage radiation therapy unit (e.g., a linear accelerator).

• "Positron Emission Tomography (PET)": an imaging procedure that reveals a patient's tissue and organ functioning. Small amounts of a radioactive medication are introduced into a patient (usually via injection) and spontaneously produce positrons (positively charged electrons) as they decompose. Abnormal metabolic function is detected using a sophisticated camera that obtains sectional images of a patient's body.

B. Review Considerations for CPR Proposals Involving the Acquisition of Major Medical Equipment

Applicants seeking CPR approval for the acquisition of major equipment will complete the full Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website.

Statutory Criteria. Via the narrative portion of the Application, the applicant shall satisfactorily address the seven statutory criteria pursuant to 16 *Del. C.* § 9306 (also refer to section III, subsection A of this HRMP for a detailed summary of the seven statutory criteria).

Guiding Principles. Applicants are also encouraged to explain the relationship of the proposed project to the seven guiding principles outlined in section III, subsection A of this HRMP.

Project-Specific Considerations.

Preference will be given to applications that involve multi-institutional arrangements (via contract, agreement, ownership, or other means) between two or more agencies for the purpose of coordinating services to capitalize on geographic proximity. A member of a multi-institutional arrangement shall not establish its own service or participate in another arrangement for the intended service until the intended service is operating at sufficient capacity to achieve acceptable levels of efficiency and quality of care.

Please include any additional information related to ways in which the proposed technology could be shared on a regional basis.

A CPR application for involving the acquisition of major medical equipment will also include the following components:

1. Technology Selection Process

The applicant will submit equipment information for the proposed equipment. At a minimum, equipment information shall include the manufacturer's name, equipment make and model, unit strength of the proposed equipment, any necessary or recommended equipment upgrades or add-ons, and any other notable equipment specifications.

What is the estimated productive life of the proposed technology? What new improvements can be expected in the equipment, and over what time frame are these improvements likely to occur?

What other technologies could reasonably be expected to replace this technology, and over what time frame are these newer technologies likely to be developed?

The applicant will provide evidence of a thorough cost-benefit analysis resulting in the selection of the proposed equipment. The applicant will identify the criteria used in the equipment section process and document why the proposed equipment was selected over other types evaluated.

The applicant will verify that the physical location(s) at which the medical procedures are to be performed conform to applicable federal standards, manufacturer specifications, and relevant licensing and accreditation requirements.

2. Clinical Impact

The applicant will demonstrate, via documentation, evidence of the efficacy of the proposed equipment in the diagnosis and/or treatment of one or more known medical conditions. Please include the specific medical diagnostic groups that may benefit from the proposed medical equipment.

The applicant will detail all other service modalities currently offered by the applicant's location(s). If the proposal involves a new site of service, identify the proposed service area and the basis for its selection.

The applicant will identify all existing providers that currently utilize the proposed equipment in the county in which the project is proposed.

The applicant will also describe how and where the proposed patient population is currently obtaining health services using the proposed equipment, including existing referral patterns in the county in which the project is proposed.

The applicant will provide an explanation of the anticipated effect of the proposed equipment on existing providers currently utilizing the proposed equipment. The applicant will demonstrate that the projected number of procedures anticipated using the proposed equipment are medically necessary and will not unnecessarily duplicate other services currently established within the proposed county of service.

To what extent will the medical equipment (a) supplement existing equipment and services? (b) Replace existing equipment and services? (c) Replace staff? (d) Increase the number of support staff required to assist in the operation of the proposed equipment?

If the medical equipment is to be leased or otherwise acquired on a contractual basis, the applicant will demonstrate that the lease or contract does not require that a specific minimum number of procedures be performed.

3. Actual and Projected Service Volume

For each of the applicant's existing and proposed pieces of equipment (of the type proposed, at the proposed location only), provide the units of service by piece of equipment for the last three completed fiscal years (FYs), the current FY-to-date, and the first three full years of the proposed project (under a CPR approval scenario).

Provide a detailed explanation of all assumptions used in the derivation of projected units of service. Explain any increases and/or decreases in units of service over the indicated time period.

What is the maximum number of procedures that could be performed using the proposed equipment per day, per week, and per year? Is there a minimum number of procedures that should be performed per day, per week, or per year to maintain staff expertise?

4. Quality Measures

The applicant shall demonstrate that the proposed equipment is efficacious (i.e., successful in producing the desired result). Provide relevant articles, studies, or reports to support the need to acquire the proposed equipment.

The applicant shall verify that that the proposed equipment is certified for its intended use by the United States Food and Drug Administration (FDA). Please also indicate whether the equipment is still considered experimental.

The applicant will identify all governmental and/or professional oversight agencies (e.g., Joint Commission) whose approval/accreditation is necessary before the applicant may initiate operation of the proposed equipment. For each required approval/accreditation, the applicant will describe its progress toward securing such approval/accreditation.

The applicant shall demonstrate that all complementary diagnostic and treatment services necessary to support the proposed equipment are accessible and operational.

The applicant shall demonstrate that the physicians and clinicians who will staff the proposed equipment are qualified and adequately trained. Moreover, the applicant will demonstrate that a board-certified radiologist or other licensed physician will interpret all imaging scans performed.

The applicant will also describe the specialized training that each practitioner completed prior to their involvement with the proposed equipment. The applicant will describe its continuing education plan for physicians and clinicians staffing the proposed equipment.

The applicant will provide written protocols that have been established related to the operation of the proposed equipment. The applicant will also document its safety procedures to follow in the event of an emergency involving the equipment.

The applicant shall make available copies of reports that are required and submitted to regulatory entities.

5. Financial Information

Complete the following financial information tables in the Certificate of Public Review Application (Attachment II of the CPR Application Kit), available via the HRB website:

- Estimated Capital Expenditures
- Sources of Financing
- Indicators of Financial Feasibility
- Debt Service Coverage
- Present Long-Term Debt

Prior to submission, the applicant will ensure that the application includes all pertinent financial information related to the proposed project, including, but not limited to, the following categories and subcategories: medical equipment lease/purchase, imaging equipment lease/purchase, non-medical equipment lease/purchase, land/building purchase, and construction/renovation; funding or financing sources associated with the proposal and the dollar amount of each; interest rate, term, monthly payments, pledges/funds received to date, and letters of interest/approval from lending institutions.

Provide documentation if Medicare, Medicaid, or any private health insurer reimburses for this procedure or equipment.

The applicant will indicate if there any potential costs savings (e.g., reduced length of stay) associated with the proposed technology.

DELAWARE HEALTH RESOURCES BOARD

Certificate of Public Review Application Kit

State of Delaware

Delaware Health Care Commission

Delaware Health Resources Board

410 Federal Street, Suite 7

Dover, Delaware 19901

Adopted: April 13, 1995 Effective: May 13, 1995 Updated: July 15, 1996 Updated: June 28, 1999

Updated: December 30, 1999 Updated: May 15, 2002

Updated: February 23, 2006 Updated: July 5, 2007

Updated: December 3, 2008 Updated: August 5, 2009 Updated: January 15, 2014 Updated: October, 2, 2017

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GENERAL INSTRUCTIONS

PLEASE READ BEFORE PROCEEDING!

The Delaware Health Resources Board is required to comply with the State of Delaware Freedom of Information Act, 29 Del. C. § 10001, et seq. ("FOIA"). FOIA requires that the State of Delaware's records are public records (unless otherwise declared by FOIA or other law to be exempt from disclosure) and are subject to inspection and copying by any person upon a written request. Once an application is received by the HRB the content of the application will likely become subject to FOIA's public disclosure obligations. The HRB respects the applicant's desire to protect its intellectual property, trade secrets, and confidential business information (collectively referred to herein as "confidential business information").

In order to allow the State to assess its ability to protect an applicant's confidential business information, applicants will be permitted to designate appropriate portions of their application as confidential business information. Applicants may submit portions of a proposal considered to be confidential business information in a separate document titled "Confidential Business Information". The document must contain a letter from the applicant's legal counsel describing the document, representing in good faith that the information in each document is not "public record" as defined by 29 Del. C. § 10002, and briefly stating the reasons that each document meets the said definitions.

An applicant's allegation as to its confidential business information shall not be binding on the State. The State shall independently determine the validity of any applicant designation as set forth in this section. Any applicant submitting an application or using the procedures discussed herein expressly accepts the HRB's absolute right and duty to independently assess the legal and factual validity of any information designated as confidential business information. Accordingly, applicants assume the risk that confidential business information included within a proposal may enter the public domain.

Application: Document Property Guidelines

To facilitate efficient and thorough review of Certificate of Public Review (CPR) applications, please limit application content to include only **required**, **relevant**, **and concise** information about the proposed project.

Strict page limits exist for each applicable section of the CPR Application (Attachment II of the CPR Application Kit). These page limits are as follows:

Background: 2 pages

Review Considerations: 10-15 pages

Statutory Criteria Guiding Principles Project-Specific Need Criteria Additional Considerations

Financial Tables: 5 pages

Appendices: <10 pages

Additionally, CPR applications should adhere to the long-standing National Institutes of Health (NIH) guidelines pertaining to federal grant applications (please see below), which have been slightly adapted to meet the needs of Delaware-specific CPR applications. Specifically,

Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 12 points. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 ½" x 11). Use at least one inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses.

Use sub-headings, short paragraphs, and other techniques to make the application as easy to navigate as possible. Use bullets and numbered lists for effective organization. Indents and bold print add readability. Bolding highlights key concepts and allows reviewers to scan the pages and retrieve information quickly.

Be specific and informative, and avoid redundancies

Use diagrams, figures and tables, and include appropriate legends, to assist the reviewers to understand complex information. These should complement the text and be appropriately inserted. Make sure the figures and labels are readable in the size they will appear in the application.

For figures, graphs, diagrams, charts, tables, figure legends, and footnotes: You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible. We suggest that you do not use a font size smaller than 9. We suggest the font Georgia for these sections, as it is the most legible at a smaller size.

(**Source**: National Institutes of Health Office of Extramural Research. 2016. *Grants & Funding: Writing Your Application*. http://grants.nih.gov/grants/writing_application.htm.)

This Application Kit is intended to provide potential applicants with a clear understanding of the nature, scope and depth of the preparation expected in conjunction with the filing of an application. Further, it is intended to gather and compile the information necessary for a timely, thorough and fair evaluation of the project proposed. Not all questions will be pertinent to all proposals. Such questions can be responded to by indicating "Not Applicable." Conversely, the applicant is encouraged to submit any information that will contribute to a clearer understanding of the proposal, even if not specifically requested in the application forms. To assist the applicant in preparing an application, this Application Kit (with the exception of Section B) is available in Word format.

It is felt that the application forms are largely self-explanatory. Potential applicants having any questions concerning the forms should contact the staff at the Delaware Health Care Commission/Delaware Health Resources Board at (302) 739-2730.

Applicants unfamiliar with Delaware's Certificate of Public Review (CPR) program may want to review the statutory provisions that appear immediately following these General Instructions.

There are three distinct application forms as discussed below:

Attachment I: This is the Notice of Intent Form that precedes the filing of the actual application by at least 30 days. The information to be included is quite rudimentary. Its purpose is to allow for anticipation of various proposals so that preparatory measures can be undertaken as appropriate.

Attachment II: This is the Application itself. It cannot be filed less than 30 days from filing the Notice of Intent (Attachment I) unless the Delaware Health Resources Board agrees in writing to waive this requirement.

Attachment III: This form will be used very infrequently. It is used only in conjunction with a project required to remedy an emergency situation that threatens the safety of patients or the ability of the health facility to remain in operation.

All forms are to be submitted to the Delaware Health Care Commission/Delaware Health Resources Board at the following address:

Delaware Health Care Commission
Delaware Health Resources Board
Margaret O'Neill Building
410 Federal Street, Suite 7
Dover, Delaware 19901

Submissions are to include 12 copies, one of which shall have an <u>original signature</u>, plus an electronic version which can be sent via email.

Supporting Resources and Documents

The following are important resources and websites which may be of assistance to applicants during the preparation of a CPR proposal:

Delaware Health Care Commission

Delaware Health Resources Board

Delaware Nursing Home Utilization Statistics

Delaware Population Consortium (DPC) Population Projections

Office of Health Facilities Licensing and Certification (OHFLC)

TITLE 16

Health and Safety

Hospitals and Other Health Facilities

CHAPTER 93. HEALTH PLANNING AND RESOURCES MANAGEMENT

§ 9301 Purpose.

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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, § 1; 72 Del. Laws, c. 64, § 2.; § 9302 Definitions.

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.

61 Del. Laws, c. 393, § 1; 65 Del. Laws, c. 69, § 2; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 1, 2; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, § 2; 72 Del. Laws, c. 64, §§ 1, 3-5; 75 Del. Laws, c. 192, §§ 1, 2; 79 Del. Laws, c. 50, § 1.; § 9303 Delaware Health Resources Board.

- (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.
- 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 publicatlarge. 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.

- (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 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.

66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 3, 4; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, §§ 1, 6, 7; 75 Del. Laws, c. 192, §§ 3, 4; 78 Del. Laws, c. 394, § 1.; § 9304 Activities subject to review.

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) [Effective until Dec. 31, 2016]. Notwithstanding any other provision in this chapter to the contrary, any person who held, as of June 1, 2013, a certificate of public review issued by the Delaware Health Resources Board authorizing the construction of a 34-bed freestanding acute inpatient rehabilitation hospital in Middletown, Delaware, regardless of such certificate's date of expiration or whether the certificate has otherwise been challenged on appeal, shall not be required to obtain any additional certificate of public review pursuant to this chapter prior to the construction, development, or other establishment of freestanding acute inpatient rehabilitation hospital constructed, developed, or established pursuant to this section 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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, §§ 5, 6; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 446, §§ 3-5; 72 Del. Laws, c. 64, §§ 1, 8-11; 75 Del. Laws, c. 192, §§ 5, 6; 76 Del. Laws, c. 87, § 1; 79 Del. Laws, c. 50, §§ 2, 3.; § 9305 Procedures for review.

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 subdivision (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 subdivision (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 subdivision (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 subdivision (5) of this section. The Board may not impose fees for such a hearing. For purposes of this subdivision, 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 subdivision (5) of this section, an administrative reconsideration pursuant to subdivision (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:
Capital Expenditures
Filing 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

Filing fees shall be due 30 days after the date of notification of the beginning of review as covered under subdivision (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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 68 Del. Laws, c. 29, § 7; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1; 75 Del. Laws, c. 192, §§ 7, 8; 76 Del. Laws, c. 87, § 2.; § 9306 Review considerations.

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. 61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1.; § 9307 Period of effectiveness of Certificate of Public Review.
- (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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1.;

§ 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.
- (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 willfully 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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, § 1.;

§ 9309 Surrender, revocation and transfer of Certificate of Public Review.

- (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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 72 Del. Laws, c. 64, §§ 1, 12.;

§ 9310 Immunity.

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.

61 Del. Laws, c. 393, § 1; 66 Del. Laws, c. 90, § 1; 69 Del. Laws, c. 251, § 1; 70 Del. Laws, c. 186, § 1.;

§ 9311 Charity care.

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.

75 Del. Laws, c. 192, § 10; 76 Del. Laws, c. 87, § 3; 77 Del. Laws, c. 132, § 2.; § 9312 Charity care.

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

N O T I C E O F I N T E N T (CERTIFICATE OF PUBLIC REVIEW)

1.	Name of Applicant:	
2.	Address:	
3.	Telephone: Fax: Email:	
4.	Person to Contact:	
5.	Type of Ownership:	
	() Public	() Proprietary (Individual)
	() Private Non-profit	() Proprietary (Partnership)
		() Proprietary (Corporation)
6.	Anticipated Date of Filing Applica	tion:
7.	Estimated Capital Expenditure: \$	
8.	Please attach a brief Narrative (one	e page or less if possible) which describes the project.
9.	STATEMENT OF CERTIFICATION	ON:

knowledge and belief.

The statements and information provided herein are true and correct to the best of my

Signature of Chief Executive Officer	Date
	(Attachment II)
CERTIFICATE OF PUBLIC REV	VIEW APPLICATION
The purpose of this application is to obtain the inform pursuant to Title XVI, Chapter 93 of the Delaware Code. It issues raised to the point necessary to demonstrate that <u>need</u> for	is in the Applicant's interest to expand upon the
The application contains three (3) sections:	
A. Background Information	
B. Review Considerations	
C. Schedules	
STATEMENT OF CERTIFICATION:	
The statements and information provided in this C and correct to the best of my knowledge and belief.	Certificate of Public Review Application are true
Signature of Chief Executive Officer	Date

A. <u>BACKGROUND INFORMATION</u>

1.	Name of Applicant:
2.	Address:
3.	Telephone: Fax: Email:
4.	Person to Contact:
5.	Please attach a list of all officers and members of the governing board. If applicable, please attach a list of all individuals, corporations or other organizations having at least a 10% equity interest in the applicant organization.
6.	If the acquisition of real estate is involved, attach a copy of sales or lease agreement. If zoning changes are necessary, please provide documentation that the Applicant is in the process or obtaining all necessary waivers and clearances from zoning authorities.
7.	Does the Applicant have a contract with Blue Cross and Blue Shield of Delaware? () Yes () No
	If not, do you intend to seek? () Yes () No
8.	Has the Applicant retained (or intend to retain) a firm that provides overall management services
0.	on a contract basis? () Yes () No

If "Yes", please show the name of the firm, the services it provides, the terms of the rationale for this relationship:	e contract, and

- 9. Please attach a Schedule of Implementation. (Use separate sheet.)
- 10. Please include a copy of most recent annual audited financial statements.
- Does the Applicant have a long-range plan? () Yes () No If "Yes", include copy with this application if not previously submitted.

B. REVIEW CONSIDERATIONS

Please provide a narrative describing the project in as much detail as the Applicant feels appropriate to a proper understanding of the need for the project. The narrative should be written with an understanding that the application will be evaluated on the basis of the following statutory criteria:

The relationship of the proposal to the Health Resources Management Plan.

- The need of the population for the proposed project.
- The availability of less costly and/or more effective alternatives to the proposal including alternatives involving the use of resources located outside the State of Delaware.
- The relationship of the proposal to the existing health care delivery system.
- The immediate and long-term viability of the proposal in terms of the Applicant's access to financial, management and other necessary resources.
- The anticipated effect of the proposal on the costs of and charges for health care.
- The anticipated effect of the proposal on the quality of health care.

In the end though, the applicant should ensure that the project elements demonstrate financial viability, increase in availability and access and improve the quality of care, efficiency, appropriateness and adequacy of the service intended to be provided in the service area.

CONFORMITY OF PROJECT WITH REVIEW CRITERIA

- 1. The Health Resources Management Plan
- Please discuss the conformity of the project with the Health Resources Management Plan.
- 2. Need
- Population's need for proposed services. (Discuss in the narrative.)
- Please define the Applicant's service area and its population. (Include relevant patient origin data.)
- Summarize the relevant demographic data that contribute to a clearer understanding of the need for the service being proposed.
- Is need for the project evidenced by the extent of utilization of like and existing services in the service area?

• What utilization rates have the exiting providers been experiencing given their capacities?

3. <u>Alternatives to the project</u>

- Are there alternative providers of this service readily accessible to the
 user population? () Yes () No
 If not, how is the population currently being served?
 Include reference to specific providers that now offer the proposed service and
 include evidence that the impact of this project has been discussed with this
 provider(s).
- If "Yes", please discuss in the narrative why this project does not duplicate these resources unnecessarily.
- Are these alternative providers more costly in the provision of the service?

4. Relationship to the existing health care delivery system

- What is the applicant's relationship to the existing heath care delivery system?
- What is the anticipated impact on existing providers on the health care system?
 - Has the Applicant established referral arrangements with other providers to ensure appropriate continuity of care, accessibility and related quality enhancing considerations? () Yes () No

If "Yes", please name these providers and describe the nature of the arrangements.

5. Access to financial, management and other necessary resources

• Please demonstrate that you have resources, including health manpower, management personnel and funds for capital and operating expenditures to not only complete the project, but also keep it as a viable operation. Schedules 4, 7, 10,11,12,13 & 14 have been provided to assist you. These Schedules may also help you to assess the economic and financial viability of the project.

Will the proposed project have an impact on the costs and charges of existing health services being provided within the health care system?
7. <u>Project's effect on quality of health care</u>
• Is the applicant certified by Medicare? ()Yes() No
• If not, do you intend to seek? () Yes () No
• Is the applicant certified by Medicaid? ()Yes () No
• If not, do you intend to seek? () Yes () No
 Is the Applicant accredited by the Joint Commission on the Accreditation of Healthcare Organizations or some other accrediting organization? () Yes () No
• If not, do you intend to seek? () Yes () No
 If "Yes", and some other organization, please indicate the name of the accrediting organization:
Other Review Considerations
A. Will the project offer economies and improvements in the delivery of the service? Please describe.
B. Will the project foster competition to promote quality assurance and cost-effectiveness? Explain in the narrative.

\$

\$

\$

Please discuss the derivation of the above figures in the narrative.

Effect of project on costs and charges of health care

Financial Impact (first full year of operations):

Estimated effect on annual operating expenses

Estimated effect on annual revenues

Estimated effect on individual charges

6.

C.	Please tell us your history in Delaware of providing health services to the Medicaid patients and the medically indigent. In the absence of a history, do you propose to provide health services to that population? If so, how do you intend to reach that population?
D.	In what way(s) do you believe your past and or proposed provision of services promote a continuum of care in the health care system.
E.	Will this project enhance the health status of the user population?
iı	If "Yes", please elaborate in the narrative. If possible, please cross-reference the demographic ata mentioned above and reference any quantitative/qualitative information, including; mprovements in accessibility, availability, new technology, advances in medical science, mortality ata, morbidity data, and utilization rates of similar services elsewhere.
F.	Will this project enhance the efficiency with which the health care needs of the user population are being met? () Yes () No
	If "Yes", please discuss in the narrative. If possible, cross-reference the financial data in the Schedules and make reference to any quantitative/qualitative data information including; improvements in operating costs, the services as an alternative to more costly alternative, improvements in the financial stability of the Applicant, , more cost-effective delivery modes, etc.
G.	Has a financial feasibility study been performed? () Yes () No If "Yes" please attach a copy.
H.	Has the Applicant evaluated alternative uses to which these monies, personnel and other resources could be used and has the Applicant concluded that the proposal in this Application is a cost-effective expenditure designed to meet the health care needs of the population being served? () Yes () No .
	If "Yes", please discuss the evaluative process in the narrative.
I.	Has the Applicant evaluated alternative ways to obtain the facility change that is needed? () Yes () No
	If "Yes", please discuss in the narrative the evaluative process, the alternatives that were considered and the rationale for selecting this alternative.

Does the Applicant intend to employ energy conservation principles in the design or other J. aspects of construction? () Yes () No

If "Yes", please detail in the narrative the nature of the energy conservation program.

If "No", please outline reasons for exclusion.

- K. Will the proposed construction eliminate any architectural barriers to the handicapped?() Yes () NoIf "Yes", please discuss briefly in the narrative, the types of barriers to be eliminated.
- L. Please attach a copy of any study or analysis which has been conducted and contributed to a decision to file this application.

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-		UI	ш	w	w	

The schedules in Section-C should be completed where germane to the project being proposed or to the type of provider making application. The level of detail anticipated will vary from one type of provider to another.

Schedule 1 - PROJECT ELEMENTS

Use additional copies as needed.

A. Program Changes - (Please check where appropriate.)

Health Services Affected	New Service	Service Expansion	Merger	Closing Service

B. Facility Changes

Equipment and Functional Areas Affected	New Construction	Renovation	Lease	Purchase
Tiffeeted				

Schedule 2 - OBJECTIVES OF THIS PROPOSAL

List the objectives of the program and facility changes proposed in this application in order of relative priority to the Applicant.

1.

2.

3.

4.

5.

6.

7.

8.

9.

10.

Schedule 3 - PROGRAM CHANGE

Harlib Camai ACC 4 11	Present Capacity ²	Present Volume ²	Future Capacity ²	Future	Future Volume ³
Health Services Affected ¹	Capacity	volume -	Capacity	Volume ³ (if CN approved)	(if CN denied)

¹ For example: M/S bed, home health visits, laboratory tests.
² Expressed as patient days, tests, visits, etc. for most recent fiscal year.

Schedule 4 - <u>STATEMENT OF REVENUES AND EXPENSES</u>

Please provide the following information for each of the past two fiscal years and for the first two years of full operation of the proposed service. Please attach assumptions on which projections are based. Base projections in current dollars (no provision for inflation).

REVENUE	Year	Year	Year	Year
Gross Patient Revenue				
Less: Contractual Adjustments				
Indigent Care				
Uncollectibles & Other				
Net Patient Revenue				
Other Operating Revenue				
Net Operating Revenue				
OPERATING EXPENSES				
OTERITING EXILENSES				
Salaries and Wages				
Fringe Benefits				
Purchased Services				
a) Direct Patient Care				
b) All Others				
Energy Costs				
Supplies				
Depreciation				
Interest				
Other (Specify)				
TOTAL OPERATING EXPENSE				
Gain (loss) from operation				
Non-Operating Revenue				
Unrestricted Gifts				
Unrestricted Income from Investments				
Sale of Securities or Other Unrestricted Assets				
TOTAL NON-OPERATING REVENUE				

³ For the first full year of operation following project completion.

NET GAIN (LOSS)		

Schedule 5 - SOURCE OF REVENUE

(Most recent audited fiscal year.)

A. TOTAL OPERATIONS			
Source		Gross Revenue (Charges)	Net Revenue
Blue Cross & Blue Shield of Delaware			
Other Commercial Insurance			
Medicare			
Medicaid			
Self Pay			
Other			
TOTAL			
B. IN-PATIENT ROUTINE (IF AFFI	CTED BY PROJ	ECT AND AVAII	ABLE
Source	Patient Days	Gross Revenue (Charges)	Net Revenue
Blue Cross & Blue Shield of Delaware			
Other Commercial Insurance			
Medicare			
Medicaid			
Self Pay			
Other			
TOTAL			
C. IN-PATIENT ANCILLARY (IF A	 FFECTED BY PR	OJECT AND AV	 AILABLE)
Source	Tests/Procedures	Gross Revenue (Charges)	Net Revenue
Blue Cross & Blue Shield of Delaware			
Other Commercial Insurance			
Medicare			
Medicaid			
Self Pay			
Other			
TOTAL			

D. OUT-PATIENT ANCILLARY (IF AFFECTED BY PROJECT AND AVAILABLE)				
Source	Tests/Procedures	Gross Revenue (Charges)	Net Revenue	
Blue Cross & Blue Shield of Delaware				
Other Commercial Insurance				
Medicare				
Medicaid				
Self Pay				
Other				
TOTAL				
E. OTHER OUT-PATIENT SERVIC (IF AFFECTED BY PROJECT AND				
Source	Visits	Gross Revenue (Charges)	Net Revenue	
Blue Cross & Blue Shield of Delaware				
Other Commercial Insurance				
Medicare				
Medicaid				
Self Pay				
Other				
TOTAL				
F. EMERGENCY ROOM (IF AFFE)	L CTED BY PROJE	L CT AND AVAILA	BLE)	
Source	Visits	Gross Revenue (Charges)	Net Revenue	
Blue Cross & Blue Shield of Delaware				
Other Commercial Insurance				
Medicare				
Medicaid				
Self Pay				
Other				
TOTAL				

Schedule 5 - SOURCE OF REVENUE CONT'D

G. HOME HEALTH CARE (IF AFFECTED BY PROJECT AND AVAILABLE)					
Source	Visits	Gross Revenue	Net Revenue		
		(Charges)			
Blue Cross & Blue Shield of Delaware					
Other Commercial Insurance					
Medicare					
Medicaid					
Self Pay					
Other					
TOTAL					

SCHEDULE 6 - BED USE DATA

Please provide data below for three (3) most recent fiscal years, for services affected by the project.

Service	Year	Number of Beds	Percent Occupancy Rate	Number of Discharges	Number of Patient Days	Average Length of Stay
M/S						
OB						
OB						
PED						
ICU						
COL						
CCU						
PSYCH						
SNF/ICF						
5111/101						

SCHEDULE 6 - <u>BED USE DATA</u> (CONT'D)

Service	Year	Number of Beds	Percent Occupancy Rate	Number of Discharges	Number of Patient Days	Average Length of Stay
OTHER						
UTHER						
OTHER						
OTHER						
TOTAL						

SCHEDULE 7 - CHANGES IN STAFFING

For those services affected by this Project in which the staffing patterns are expected to change.

Personne	el Category	Present Number of Full-Time Equivalents	Present Salary & Wage Expense (Most recent	Future Number of Full-Time Equivalents (If	Future Number of Full-Time Equivalents (If	Estimated Salary & Wage Expense* (If
Department	Job Title	1	Fiscal year)	application denied)	application approved)	application approved)
				l demod)	approved)	approved)

^{*} For first year of operation following completion of the Project and stated in current dollars. Do not include fringe benefits.

SCHEDULE 8 - LOCATION OF BEDS BY FLOOR/BUILDING

Affected Service	Location*	Present # of Beds	Additions	Deletions	Future # of Beds

^{*} Please attach block diagrams identifying each building (or wing); label each (A, B, C, etc.). In Column 2 (Location) indicate where the beds are housed and the floor on which they are located (e.g., B-3). If a specific service (e.g., *M I S* beds) is located, for example, in four different locations there should be four separate entries.

${\tt SCHEDULE\,9-\underline{FACILITY\,CHANGE}}$

Functional Areas Affected*	Present	SQ Feet to be	SQ Feet to be	SQ Feet On
	Square Feet	Constructed	Renovated	Completion
Total				

^{*} Example of functional areas are: Nursing Units, Laboratory, Doctor's Office, Lobby, Medical Records, Storage, etc.

SCHEDULE 10 - ESTIMATED CAPITAL EXPENDITURE

MAXIMUM	MINIMUM	DESCRIPTION	ITEM
		Land Acquisition Costs	1.1
		Building Acquisition Costs	2.2
		Construction Contract (include bonding costs)	2.3
		(a) Site Development	
		(b) Building Cost	
		(c) Sub-Total	
		Fixed Equipment (not in contract)	2.4
		Movable Equipment	2.5
		Site Survey & Soil Investigations	2.6
		Architect/Engineering Fees	2.7
		(a) Architect	
		(b) Engineering	
		(c) Construction Management	
		(d) On-Site Representative	
		(e) Planning	
		(f) Sub-Total	

2.8	Financing and Underwriting	
2.9	Construction Loan Interest (Interest Rate = %)	
2.10	Legal Fees (and other)	
2.11	Estimated Range of Capital Expenditure	

This Schedule should be filled out using cost estimates as of the date of Application, and should not include any provision for inflation.

The range should not exceed 20% (minimum - maximum).

There should be no allowances for contingencies.

SCHEDULE 11 - SOURCES OF FINANCING

Appl	icant's Investment:		
	(a) Cash on hand	\$	
	(b) Trust or other funds	\$	_
	(c) Fund raising	\$	(d)
Other	•	\$	_
Gran	ts/Gifts		
(e.g.,	large bequeath, foundation or government grant)	\$	
Borre	owing:		
(a)			
_	(Type)		
	Principal:	\$	
	Interest Rate:		_
	Terms: (in years)		_
(b)			
_	(Type)		
	Principal:	\$	
	Interest Rate:		_
	Terms: (in years)		_
(c)			
_	(Type)		
	Principal:	\$	
	Interest Rate:		
	Terms: (in years)		
Maxi	mum project cost (Total of 1, 2 &3)	S	
Annu	al Deht Service (Interest and Principal)		

If the requisite debt service is other than the traditional level debt payments covering interest and principal, please attach a brief description of these terms.

If the proposed financing is to be used for start-up or other operating costs, please attach a brief narrative describing the extent of and rationale for this use.

SCHEDULE 12 - <u>INDICATORS OF FINANCIAL FEASIBILITY</u>

Please compute the following based upon most recent audited statement (please indicate year).

Gross Patient Re venue

SCHEDULE 13 - DEBT SERVICE COVERAGE

		Most recent 2 years			Projected*
		19	19	19	19
(1)	Revenue minus expenses:				
(2)	Interest:				
(3)	Depreciation (annual):				
	,				
(4)	Cash available for debt service (total of 1, 2 &3):				
(5)	Total Debt Service				
	Total Best Service				
(6)	Debt Service Coverage Ratio (4 divided by 5):				

^{*} First two years impacted by debt service associated with this project.

SCHEDULE 14 - PRESENT LONG TERM DEBT

Lender	Initial Date		Amount	Repayment	Interest
	of Loan	Amount	Outstanding	Amount*	Rate

^{*} If Repayment Amount is other than periodic interim payments of equal amount, outline the terms in attached narrative.

If proposed below.	d borrowing is to include refinancing of all or part of the above, so indicate in space					

SCHEDULE 15 - <u>DETAILED EQUIPMENT LISTING</u>

Please list each piece or related series of capital equipment in the table below. If the cost of individual or related series of equipment exceeds \$100,000, or constitutes a "new health service", detail the use to which the equipment will be put in the attached narrative and attach the purchase/lease agreement, if available. If the equipment is a replacement and exceeds \$100,000, please explain why existing equipment is no longer adequate in attached narrative.

Item	Nature of the Equipment	Estimated	Quantity	Price Each	Total Price	Total
		Useful				Lease Cost
		Life				per Year
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						

^{*} For example: for new beds -- 40 @ \$4,000.

DOCUMENTATION FOR APPROVAL OF "EMERGENCY SITUATION"

1.	Name of Applicant:				
2.	Date of initial contact with the Delaware Health Care Commission/Delaware Health Resources Board				
3.	Please attach a brief statement describing the nature of the "Emergency Situation."				
4.	Please attach a brief statement explaining how the "Emergency Situation" is proposed to be remedied, including the estimated capital cost involved.				
5.	Was an architect, engineer, or other consultant retained to assist the Applicant? () Yes () No				
	If "yes", please include copies of reports, recommendations, etc., issued by these consultants.				
6.	What is the expected date of completion of any necessary repairs?				
7.	Will the Applicant be filing a subsequent application to undertake more extensive capital expenditures to resolve this situation?				
O	() Yes () No				
8.	STATEMENT OF AFFIRMATION:				
	The Signatory hereby affirms that the conditions affected by this Application represent an "Emergency Situation" which threatens the safety of patients and/or the ability				

of the health facility to remain in operation.

Signature of Chief Executive Officer	Date

E-1



STATE OF DELAWARE DELAWARE HEALTH CARE COMMISSION

MARGARET O'NEILL BUILDING
410 FEDERAL STREET, SUITE 7, DOVER, DE 19901
TELEPHONE: (302) 739-2730
FAX: (302) 739-6927
www.dhss.delaware.gov/dhcc

BYLAWS OF

DELAWARE HEALTH RESOURCES BOARD

Adopted: February 27, 1995 Updated: October 13, 2016

Article I

Name, Place of Business, Purpose, Duties and Responsibilities

Section 1. <u>Name</u>-The name of this organization shall be the Delaware Health Resources Board, hereafter referred to as 'the Board'.

Section 2. <u>Place of Business-</u>The place of normal business of the Board shall be the Department of Health and Social Services, Delaware Health Care Commission, Dover, Delaware.

Section 3. <u>Purpose</u> -The purpose of the Board is to promote the cost effective and efficient use of health care resources while striving to ensure the availability of and access to high quality and appropriate health care services.

Section 4. Duties and Responsibilities -The duties and responsibilities of the Board are set forth 16 Del. C. § 9303 and shall include, but not be limited to the following:

- a. 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.
- b. Review and make decisions regarding Certificate of Public Review (CPR) applications filed pursuant to this chapter.
- c. Gather and analyze data and information needed to carry out its responsibilities.
- d. Address specific health care issues as requested by the Governor or the General Assembly.
- e. Adopt bylaws as necessary for conducting its affairs.
- f. Coordinate activities with the Delaware Health Care Commission, the Department of Health and Social Services and other groups appropriate.

Article II

Membership, Compensation

Section 1. Membership - The Board shall consist of 15 members appointed by the Governor. Appointments shall be for 3-year terms, except that the initial appointment of an individual may be less than 3 years so that one- third of the terms expires each year. Members shall serve no more than 2 full terms consecutively 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' term expire on a staggered basis. The membership shall be comprised in accordance with the provisions of 16 *Del. C.* § 9303.

Section 2. <u>Compensation</u> - 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.

Article III

Section 1. Section and Title- The Board shall consist of:

- a. Chair
- b. Vice Chair
- c. 13 other members

The Governor shall appoint one member of the Board to serve as Chair and one member to serve as Vice Chair. Both the Chair and Vice Chair shall be appointed from among the four representatives of the public-at-large. HCC staff shall serve as staff support to the Board. The Director of Policy and Planning of the HCC shall function as the Administrator Director to the Board.

Section 2. <u>Powers and Duties of the Board Members and Staff</u> - The powers and duties of the members of the Board and staff shall be as follows:

a. <u>Chair</u> - The Chair shall preside at all meetings of the Board except the Chair may under certain circumstances designate another member to preside at a particular meeting or at a certain part of a meeting. The Chair shall cause to be called regular and special meetings of the Board in accordance with these bylaws. The Chair shall perform such other duties as the Board, from time to time, shall designate.

b. <u>Vice Chair</u> - In the absence of the Chair, the Vice Chair shall have all of the powers and duties of the Chair. The Vice Chair shall perform such other duties as the Board, from time to time, shall designate.

c. <u>HCC staff</u> - The HCC staff which support the Board shall keep or cause to be kept the minutes of the meetings of the Board, in an appropriate manner, and shall be custodian of the records. In the absence of both the Chair and Vice Chair, the Executive Director from the Health Care Commission may designate a Board member to preside at a particular meeting or at a certain part of a meeting. HCC staff shall keep or cause to be kept a record, alphabetically arranged, showing the names of the Board members, their addresses and the respective dates of their appointment as members of the Board. HCC staff shall provide reasonable access by the general public the Board's records. HCC staff shall perform other duties such as conduct research for use by the Board in evaluating applications, provide staff expertise on the CPR process, track multiple processes and deadlines associated with Board activities, staff Review Committee meetings and prepare reports.

Article IV

Meetings

Section 1. <u>Public Interest and Involvement</u> - It is the policy of the Board to encourage public interest and involvement. The Board shall operate in accordance with <u>Title 29</u>, <u>Chapter 100</u>, of the Delaware Code (Freedom of Information Act).

Section 2. <u>Regular Meetings of the Board</u> - Regular meetings of the Board will be held bi- monthly (every two months). There shall be no less than four regular meetings each calendar year. HCC staff shall send out a written notice of each regular meeting, to all members of the Board.

Section 3. Special Meetings of the Board - Special meetings of the Board may be called by the

Chair at any time and shall be called by the Chair upon written request of any 8 out of the 15 members of the Board. HCC staff shall send out a written notice of each special meeting, stating the purpose for which it is called to all members of the Board.-Such notice shall be sent to each member at least seven (7) days prior to the meeting.

Section 4. <u>Parliamentary Procedures for Board Meetings</u> - Parliamentary procedures at all meetings of the Board shall be in accordance with Roberts' Rules of Order.

Section 5. <u>Quorum</u> -The presence of at least 50 percent of the members of the Board shall constitute a quorum. There are 15 seats on the Board. A quorum must be a majority of the actual number of seats on the Board. Eight members present are needed for a quorum.

Section 6. <u>Voting</u> - All members are entitled to one vote on matters brought before the Board except when the member has a conflict of interest. The disqualification of a member from voting or a member abstaining from voting shall not affect the quorum. All matters, except as provided for in Article VI of these bylaws, shall be decided by a majority of the members present and voting. Members who abstain from voting on a particular matter are considered "present and voting" for purposes of determining a majority.

Section 7. <u>Attendance at Meetings</u> - The Board may request the Governor to declare a vacancy for any member who is absent from three consecutive meetings upon the recommendation of the membership. 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.

Section 8. <u>Conflict of Interest</u>-- Board members shall comply with <u>Title 29</u>, <u>Chapter 58</u>. of the Delaware Code (State Ethics Code). A Board member may not participate in the review or disposition of any matter in which he has a conflict of interest except to respond to questions from another Board member or any other person with official responsibility with respect to the matter. A Board member has a conflict of interest with respect to any matter when:

- a. Any action or inaction would result in a financial benefit or detriment to accrue to the Board member or a close relative (parents, spouse, children or siblings) to a greater extent than such benefit or detriment would accrue to others who are members of the same class or group of persons; or
- b. The Board member or close relative has a "financial interest" in a private enterprise (whether profit or not for profit) which enterprise or interest would be affected by any action or inaction on a matter to a lesser or greater extent than like enterprises or other interests in the same enterprise. A person has a "financial interest" in a private enterprise if: (1) He has a legal or equitable ownership interest in the enterprise of more than 10% (1% or more in the case of a corporation whose stock is regularly traded on an established securities market); (2) He is associated with the enterprise and received from the enterprise during the last calendar year or might reasonably be expected to receive from the enterprise during the current or the next calendar year income in excess of \$5,000 for services as an employee, officer, director, trustee or independent contractor; or (3) He is a creditor of a private enterprise in an amount equal to 10% or more of the debt of that enterprise (1% or more

in the case of a corporation whose securities are regularly traded on an established securities market).

c. A Board member shall declare his conflict of interest at the earliest practicable time after learning of such conflict.

Article V

Committee, Task Forces

Section 1. Appointment of Committees or Task Forces -- The Board may create such committees, task forces, or such other work or study groups at any time as may be appropriate to assist in the conduct of the affairs of the Board. Such committees or task forces shall be appointed by the Chair and may include in their membership persons other than members of the Board. Such committees or task forces shall operate accordance with Title 29, Chapter 100 of the Delaware Code (Freedom of Information Act).

Article VI

Amendments

Amendments to the Bylaws - These Bylaws may be altered, amended, repealed or added to at any regular meeting or special meeting of the Board called for that purpose, providing that ten (10) days written notice shall have been sent to each member. Such notice shall describe, at least in general terms, the alterations, amendments, or changes which are proposed to be made in the Bylaws. Public Notice shall be provided in accordance with Title 29, Chapter 100 of the Delaware Code (Freedom of Information Act). Changes shall become effective upon the affirmative vote of at least 50 percent of Board members.

HEALTH RESOURCES BOARD MEMBERS

Number of Board Members	Name Address	Professional or Public member	Position Held	Profession or Occupation	Original Appointment Date and Term Expiration
1	Brett Fallon Hockessin, DE	Public Member	Chair at Large	Morris James, LLC Attorney	Original Appointment 12/4/2017 Expiration Date
N/A	Vacant as of 10/27/2015	The Governor shall designate a Vice Chair from among the members of the Board	Vice Chair	Vacant as of 10/27/2015	Vacant as of 10/27/2015
2	Edwin Barlow New Castle, DE	Public Member	Public at Large	Retired	Original Appointment 3/22/2018 Expiration Date 3/22/2021
3	Theodore Becker Lewes, DE	Professional Member	Representative of the Delaware Health Care Commission	Mayor of Lewes	Original Appointment 9/9/2016 Expiration Date 9/9/2019
4	Michael Hackendorn Middletown, DE	Professional Member	Representative of Labor	UA local 74, President	Original Appointment 8/16/2017 Expiration Date 8/16/2020
5	Leighann Hinkle Camden-Wyoming DE	Professional Member	Representative involved in purchasing health care coverage on behalf of State employees	Deputy Director, Statewide Benefits Office, DHR	Original Appointment 2/27/2014, Reapppointment 12/01/2017 Expiration Date 12/01/2020
6	Vincent Lobo, Jr. D.O. Bethany Beach, DE	Professional Member	Representative licensed to practice medicine in Delaware	Physician	Original Appointment 7/17/2013 Expiration Date 10/18/2013
7	Elizabeth Brown, M.D. Philadelphia, PA	Professional Member	Representative from State of Delaware Department of Health and Social Services	DHSS - Medical Director for DMMA	Original Appointment 02/27/2020 Expiration Date 02/27/2023
8	Vacant as of 10/31/2019	Professional Member	Representative of a provider group other than hospitals, nursing homes or physicians	Vacant as of 10/31/2019	Vacant as of 10/31/2019
9	Julia O' Hanlon Wilmington DE 19803	Public Member	Public at Large	University of Delaware, Policy Researcher	Original Appointment 8/16/2017 Expiration Date 12/8/2018
10	Pamela Price Wilmington, DE	Professional Member	Representative of the health insurance industry	Highmark, Senior Government Affairs Representative	Original Appointment 7/31/2019 Expiration Date 7/31/2022
11	Margaret Strine Hockessin, DE	Public Member	Public at Large		Original Appointment 9/30/2019 Expiration Date 9/30/2022
12	Mark Thompson Dover, DE	Professional	Representative with knowledge and professional experience in health care administration	Medical Society, Executive Director	Original Appointment 10/18/2012 Expiration Date 10/18/2013
13	John Walsh Rehoboth Beach, DE	Public Member	Public at Large	Retired	Original Appointment 10/18/2012 Expiration Date 10/18/2015
14	Cheryl Heiks Wilmington, DE	Professional Member	Representative with knowledge and professional experience in long-term care administration	Delaware Healthcare Facilities Association, Executive Director	Original Appointment 10/7/2019 Expiration 10/7/2022
15	Vacant as of 10/18/2012	Professional Member	Representative involved in purchasing health care coverage for employers with more than 200 employees	Vacant as of 10/18/2012	Vacant as of 10/18/2012

Shaded areas indicate that a meeting was not held.

X indicates member was absent.

NA indicates member was not a member of the board, see the notes column for additional info.

DELAWARE HEALTH RESOURCES BOARD MEETING ATTENDANCE 2019

													Total	
MEMBER NAME	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Absences	Notes:
BRETT FALLON, CHAIR											Χ	Χ	2	
LYNN MORRISON	Χ					Χ			Χ		NA	NA	3	left board in Oct 2019
LEIGHANN HINKLE	Χ								Χ				2	
MARGARET STRINE	NA	NA				NA		NA					0	appointed 9/30/2019
D.R. VINCENT LOBO	Χ							Χ				Χ	3	
MARK THOMPSON								Χ			Χ	Χ	3	
PAMELA PRICE	NA	NA				NA			Χ				1	appointed 7/31/2019
JOHN WALSH													0	
MICHAEL HACKENDORN	Χ	Χ				Χ							3	
JULIA O'HANLON	Χ					Х							2	
CAROLYN MORRIS	Χ												1	
EDWIN BARLOW													0	
TED BECKER												Χ	1	
CHERYL HEIKS	NA	NA	·			NA		NA	NA				0	appointed 10/07/2019

March meeting cancelled - no new business to conduct.

April meeting cancelled - no new business to conduct.

May meeting cancelled - no quorum.

July meeting cancelled - no quorum.

October meeting cancelled - no quorum.

Page 1 of 2

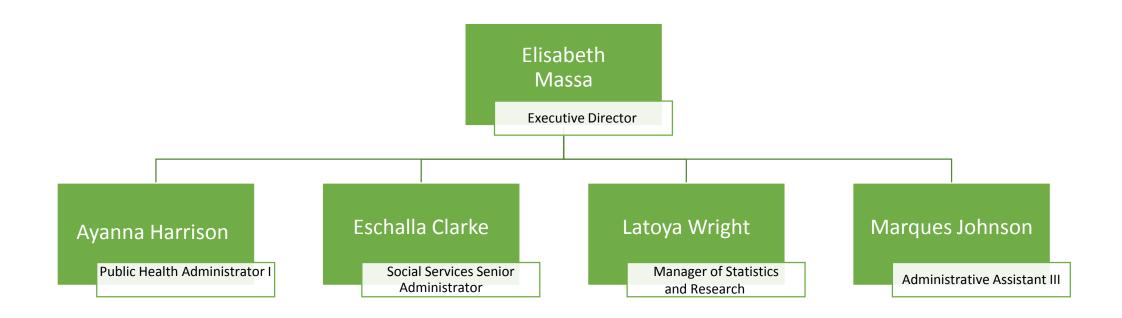
DELAWARE HEALTH RESOURCES BOARD MEETING ATTENDANCE 2020

MEMBER NAME	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Absences	Notes:
BRETT FALLON, CHAIR														
LEIGHANN HINKLE														
MARGARET STRINE														
D.R. VINCENT LOBO	Χ												1	
MARK THOMPSON														
PAMELA PRICE														
JOHN WALSH														
MICHAEL HACKENDORN														
JULIA O'HANLON														
ELIZABETH BROWN, M,D.	NA													appointed 02/27/2020
CHERYL HEIKS														_
EDWIN BARLOW														
TED BECKER														

February meeting cancelled - no quorum.

page 2 of 2

Delaware Health Care Commission Staff



JOINT SUNSET COMMITTEE 1993 FINAL REPORT HEALTH RESOURCES MANAGEMENT COUNCIL (Chapter 93, Title 16 Del. Code)

The Joint Sunset Committee has Recommended that the Health Resources Management Council be abolished (sunset), and that the Governor and General Assembly be advised of the need to develop a comprehensive health planning process. The various commissions, councils, and boards can be brought under one umbrella agency dealing with health care planning. The Joint Sunset Committee agreed that the Certificate of Need review, the development of a comprehensive health policy, the centralization of health planning, and the issue of a regionally-based health care planning process will need to be part of a comprehensive health planning process.

The Joint Sunset Committee has Recommended that the Governor and General Assembly develop a program of regulations to centralize health care planning resources under a smaller umbrella of oversight, so as to make better use of resources and to centralize the health care decision-making process. This Recommendation will be in the form of a Resolution to the General Assembly.

COMPLIANCE

Dr. William Duncan, chair of the Health Resources
Management Council, has been helpful in providing a historical
perspective for this review of the Council. Robert Welch,
Director of the Bureau of Health Planning and Resources
Management, has complied with all requests for information.

Council members, as a whole, did not cooperate with the

Sunset Review process. Eight of 18 Council members, as of June 29, 1992, and 1 former Council member, answered the individual Council member questionnaire. Those who answered the questionnaire are: Dr. William Duncan, Patrick Donahue, Robert Miller, Charles Hopkins, Dennis Klima, Gordon Pfeiffer, Robert Tremain, Roger Wick, and former member, Edith Anderson, R.N.

HISTORY

Background information on the health planning process in Delaware has been provided, in part, by Dr. Duncan and Robert Welch.

The most recent health planning efforts in Delaware, which can be documented, apparently occurred in 1960, when Governor J. Caleb Boggs asked the Welfare Council of Delaware (later known as the Community Services Council), a United Fund Agency, to undertake as a "needs" assessment, the availability of health care services with special emphasis on the poor and the elderly. The establishment of the Welfare Council, which was advisory in nature, closely paralleled the development of the Kerr-Mills legislation for the medically indigent on the federal level.

The Hill-Burton Act, which had been implemented in 1946 was administered by individual states. Grant monies and loans were provided to the states for hospital modernization and construction. As hospital bed needs were met, monies began to be directed to more out-patient services.

The State Board of Health had responsibility for application of the Hill-Burton program since its inception. With the exception of the Medical Center of Delaware, Riverside Hospital and Alfred I. duPont Institute, every

hospital in the state has received grant monies from the program. State-run facilities have received a large share of the available funds, including the Emily P. Bissell Hospital, Delaware State Hospital, the Delaware Hospital for the Chronically III and the Governor Bacon Health Center. Funds have also been used to construct and equip several State Service Centers. Hill-Burton funds also played a part in the expansion of the Delaware Curative Workshop and the establishment of the Delaware Technical and Community College Dental Clinic in Wilmington.

In 1966, Congress passed the Comprehensive Health Planning Act. While federal funding, according to many medical sources, was never sufficient, the Act, nevertheless, encouraged the active involvement of underprivileged citizens in the health planning process. The Hill-Burton functions were merged with the state Comprehensive Health Planning agency also in 1966. Dr. William O. Lamotte, Jr., who had previously chaired the Welfare Council, became chair of the statewide Comprehensive Health Planning Advisory Council. (Duncan)

Under "Section 1122 Review Program " of the 1972 Amendments to the Social Security Act, states entered into agreements with the Federal government to review capital expenditures by health care facilities. Payments for the capital costs of projects were denied by Medicare and Medicaid if projects were undertaken without the required approval.

The National Health Planning and Resources Development Act (NHPRDA) was enacted in 1975. It largely replaced the Hill-Burton and Comprehensive Health Planning programs. The Act vested greater authority over planning activities in the U.S. Department of Health and Human Services. The State Health Planning and Development Agencies (SHPDA) and Health

Systems Agencies (HSA) established under the Act were funded, almost entirely, from federal monies.

The NHPRDA mandated that states establish Certificate of Need programs, which met federal specifications. The state agencies, SHPDA and HSA, were assigned the responsibility to review and approve capital projects and make preliminary recommendations for construction, modernization and/or expansion of health care facilities.

The SHPDAs and HSAs were mandated to follow the "National Guidelines for Health Planning" established by the Act. The Act also provided for the establishment of Statewide Health Coordinating Councils. The Councils were to have final authority over individual State Health Plans. Most Councils were required to have a majority of consumers on their governing bodies.

According to information submitted, the demise of the federal law, the Federal Authorization for Health Planning, in 1986, "seemed to breathe new life into local health planning and volunteerism." Governor Castle established the Health Care Cost Management Commission by Executive Order in November, 1985. The recommendations of this Commission were enacted into law by S.B. 132, with S.A. 1, on July 2, 1987. This new law provided for a 15-member Health Resources Management Council to replace the 45-member Delaware Health Council and the 26-member Statewide Health Coordinating Council. (Duncan)

The Statewide Health Coordinating Council had been established by H.B. 956, with H.A. 2 & 3, effective June 30, 1978. Under this Act, any person proposing to offer or to develop a 'new health service' in Delaware was required to obtain a Certificate of Need. A 'new health service' included

any expenditure by or on behalf of a health care facility or health maintenance organization in excess of a threshold of between \$100,000 and \$150,000, which was established as a capital expenditure. Any expenditure by or on behalf of a health care facility or health maintenance organization for preparation expenses in excess of \$50,000 was mandated to be reviewed under this Law.

An important aspect of the law exempt from further review an approval which was granted under Section 1122 of the Social Security Act, and which was not terminated by action of the Designated Planning Agency prior to June 30, 1978.

Applicable federal laws still governed decisions for proposed new health services in the state: (Sec. 1513(b)(2) of P.L. 93-641 and Sec. 1513(b)(3) of P.L. 93-641). State decisions could not be inconsistent with federal laws.

A very important aspect of the original state law, Chapter 93, Title 16 Del. C., was an extensive section entitled Criteria for Review (Sec. 9305, 16 Del. C.). This section, which was considerably shortened by the 1987 rewrite of Chapter 93, included, for example, more detail on the relationship of the services proposed to ancillary or support services.

The 1987 rewrite of Chapter 93 also struck the Statement of Purpose contained in the original legislation: The original statement of purpose declared: "It is the policy of this State that health planning and review shall be based upon evaluation of the needs and resources of the community and the State for health facilities and services, and that participation in this decision-making process shall be accorded to both <u>interested consumers</u> and providers of health care services."

In place of the Statement of Purpose, the 1987 legislation (S. B. 132 amend. by S.A. 1) established a 15-member Health Resources Management Council.

The establishment of a Health Resources Management Council, as mentioned previously, was a Recommendation of Governor Castle's Health Care Cost Management Commission. A majority of Commission members were other than health care providers.

According to the Commission's Final Report, the HRMC will "identify needed health services and resources, determine how these services can be delivered, and evaluate whether Delaware's citizens are receiving cost-effective quality care, with attention to the long-term implications of public and private health care activities."

The original 1987 mandate to the Council included the duty (in Sec. 9303(4)(c), 16 Del. C.) to "Ensure an opportunity for public review and comment of all components of the State Health Plan." In addition, all health care provider members of the Council, when reviewing Certificates of Need, were mandated to abstain from making recommendations involving their field of health care.

According to Dr. Duncan's historical account, the 1987 law continued a Certificate of Need program, "but in scope and concept it was much more liberal than the previous law mandated by the federal government."

At this time the cap was raised on the amount of capital expenditure by a health care facility which would require a review by the Council. Previously, the amount was \$250,000; the new amount was \$750,000.

The original 1978 legislation mandated that the responsible state agencies submit in writing their findings regarding any proposed new health service for inpatients. The criteria were spelled out clearly.

The 1987 legislation, which established the Council, changed the criteria to a general statement that the written decision must include "the basis on which the decision was made."

The 1987 legislation also provided for a 5-person Appeals Board to be appointed by the Governor, who would review decisions regarding Certificate of Need applications. The 1991 revision of the statute transferred the appointment authority to the Secretary of the Department of Health and Social Services.

The original 1978 legislation included a mandate to the State Agency and Health Systems Agency to publish a report of reviews conducted under the Chapter. This is no longer required. The Bureau does publish a Certificate of Need Monthly Activity Report.

The 1987 legislation also mandated filing fees based on the amount of the capital expenditure for anticipated projects. The 1991 amendments to the law did not change these fees.

The original legislation provided that any transaction, which had the effect of conferring, transferring or assigning the controlling interest of any holder of a Certificate of Need (CON), would be subject to the same conditions applicable to transfer or assignment of the CON itself (Sec. 9309,16 Del. C.).

The report, Health Planning for Delaware, January 1987, by

the Governor's Commission on Health Care Cost Management, made the recommendations for "Improving the Current CON Process" which became part of the 1987 legislative changes. The report reviewed alternatives to the CON process and concluded that the process should not be eliminated. But, the Commission made a philosophical decision not to increase the regulatory requirements of the CON process. They concluded tightening the process "could be expected to decrease both availability of and access to health care services, without having an appreciable impact on costs or quality."

THE COUNCIL

The Health Resources Management Council (HRMC) has been established to "consider matters relating to health planning for Delaware which will help ensure access and availability of appropriate high quality health care services and promote cost-effective and efficient use of health care resources." (Sec. 9303, 16 Del. C.)

The HRMC states that it is not affected by any Federal laws and/or regulations. The Attorney General's Office has never issued an opinion that has directly affected the functioning of the HRMC.

The HRMC is covered by the Freedom of Information Act. The HRMC is not mandated to follow nor conform to the Administrative Procedures Act.

The Joint Sunset Committee has Recommended that the Health Resources Management Council be included with those agencies covered by the Administrative Procedures Act (Chapter 101, 29 Del. C.).

PURPOSE

The purpose of the Chapter, which established the Health Resources Management Council (HRMC), is "to provide a rational framework for promoting the cost-effective and efficient use of health care resources while striving to ensure the availability of and access to high quality and appropriate health care services." (Chapter 93, 16 Del. C.).

This general statement could be read to negate the need for the proliferation of Commissions which have been established, essentially, to do the same work as the HRMC. Former Governor Castle established a 9-member Health Care Commission in 1992. It is also concerned with health planning.

Certificate of Need (CON) is the approval which must be obtained from "the State Agency," which is the Bureau of Health Planning and Resource Management, before certain activities can proceed. The request for the CON approval is filed with the HRMC, where it is assigned to a Committee if it is of such complexity that a more indepth review by the HRMC is required before a decision for approval/disapproval can be made.

Certificates of Need must be obtained for the following activities:

1) The construction, acquisition, development or other establishment of a health care facility. A request for exemption from review for the acquisition of a health care facility may be granted by "the State Agency," with the concurrence of the HRMC. A notice of intent to acquire must be filed with the HRMC. Previously, the acquisition of a health care facility by acquiring the assets or a controlling equity interest was not required by the subsection, which was

changed in 1991.

- 2) Any expenditure by or on behalf of a health care facility in excess of \$750,000, which is considered a capital expenditure. Expenditures in excess of \$750,000 may be exempt by "the State Agency" (the Bureau) if the expenditure is necessary to maintain the physical structure of a facility, and not directly related to patient care. As previously, a notice of intent must be filed with "the State Agency" (the Bureau).
- 3) A change in bed capacity of a health care facility, which increases or decreases 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% of total licensed bed capacity, whichever is less, over a 2-year period.

The recent Gilpin Hall application for a Certificate of Need to expand and modernize under this section was initially recommended for rejection by the HRMC. But, an appeal panel remanded the case to the Bureau, who then granted the CON.

4) Health services offered in or through a health care facility and which were not offered on a regular basis in or through such health care facility within the 12-month period prior to the time such services would be offered, and for which the annual operating expenses exceed \$250,000 during the 1st or 2nd year of operation.

The Family Practice Services moved from the Wilmington Hospital of the Medical Center of Delaware to the old HMO Offices on Foulk Road but did not require a Certificate of Need.

Pediatric care is now concentrated at the A.I. du Pont

Institute; again, an application for Certificate of Need was not made by the Medical Center. Services were moved from one place to another; but, a CON was not required.

5) Any capital expenditure used to acquire major medical equipment. (Major medical equipment acquired by a business or industrial establishment for a dispensary or first aid station, for use by students, employees of a school or university, or by inmates and employees of a prison is not subject to review.) This section was added in the 1991 revision.

In 1992, the HRMC rejected the application for Certificate of Need of St. Francis Hospital to initiate radiation therapy service, which included the acquisition and operation of a linear accelerator and simulator to provide the services. The appeal panel upheld the decision of the HRMC; but, St. Francis has appealed the decision to Superior Court. Concurrent with this application, MCD had applied for the replacement and addition of linear accelerators. This request was granted.

<u>MEMBERSHIP</u>

The HRMC consists of 18 members appointed by the Governor for 3-year terms, with a maximum of 2 consecutive terms. All Counties must be represented, and include consumer, provider, business, government and insurer representation. A majority of members are mandated to be other than health care providers. The Governor appoints the Council's Chair and Vice-Chair. Members are uncompensated, except for reimbursement for "reasonable and necessary" expenses.

Current membership is 18:

	Apptd.	Expir.
William H. Duncan, M.D., chair Medical Administrator, recen St. Francis Hospital New Castle County		12/30/93
Roger R. Wick, vice-chair Plant Manager S. C. Johnson & Son Sussex County	12/30/87	12/30/92
Robert Netherland Health Care Specialist Delmarva Power New Castle County	8/25/92	8/25/95
Patrick Donahue, Manager Health and Welfare Plans Hercules, Inc. New Castle County	12/30/87	12/30/93
Marvin S. Gilman, Esq. Developer New Castle County	7/15/92	7/15/95
Kay E. Holmes, Exec. Director Delaware Health Care Commi New Castle County		8/22/94
Charles Hopkins, Deputy Dir. State Budget Office Kent County	12/30/90	12/30/93

Max Kenyon, CEO Principal Healthcare of Del. New Castle County	7/15/92	7/15/95
Dennis E. Klima, President Kent General Hospital Kent County	12/30/87	12/30/92
Robert F. Miller, Manager Health Care Benefits E. I. du Pont de Nemours & Co. New Castle County	3/29/90	3/29/93
Gordon A. Pfeiffer Senior Vice President Mellon Bank Delaware New Castle County	12/30/87	12/30/92
Phyllis A. Sheppard Marketing Representative A T & T New Castle County	12/30/87	12/30/93
Charles M. Smith, M.D. Medical Administrator Medical Center of Delaware New Castle County	8/22/91	8/22/94
Stephen W. Spence, Esq. Phillips, Goldman, Spence, P.A New Castle County	12/30/87 4 .	12/30/92

Janice Tildon-Burton, M.D. Private Practice Physician New Castle County	7/15/92	7/15/95
Robert E. Tremain, President HMO of Delaware New Castle County	12/30/87	12/30/93
Daniel J. Wooley, Adm. Green Meadows Retirement C Kent County	12/30/87 ommunity	12/30/92
Maureen C. Byrnes 1st Vice-Pres. MBNA New Castle County	8/25/92	8/25/95

There are 6 health care providers on the HRMC, and 4 closely allied as managers of health care plans; an additional member is a Board member of a hospital.

Only 2 women were members of the previous 15-member Council. Minorities have been underrepresented, also.

New members have been appointed to replace the members whose appointments expired in December, 1992:

	Appt'd.	Expir.
Patricia Campbell-White, pres. Jay-Gallo Realtors Sussex County	12/30/92	12/30/95
L. Glenn Davis, administrator Milford Memorial Hospital, Kent	12/30/92 County	12/30/95

Christine W. Evans, adminis. Harbor Healthcare Center Sussex County	12/30/92	12/30/95
D. Wayne Holden, vice-pres. Merrill Lynch Kent County	12/30/92	12/30/95
Sandra Kaufmann, Esq. Potter, Anderson & Corroon New Castle County	12/30/92	12/30/95

DUTIES AND RESPONSIBILITIES

The HRMC's duties as mandated by Sec. 9303(d), 16 Del. C., include, but are not limited to:

- 1) Submit to the Secretary, Health and Social Services, and Director, Planning Research and Evaluation Division, a State Health Plan. The HRMC is mandated to pursue an appropriate balance among factors such as the availability, access, quality and cost of health care services and the prevention of avoidable health problems;
- 2) Review health-related plans from agencies of state government for consistency with basic principles and goals of State Health Plan;
- 3) Ensure opportunity for public review and comment of all components of state health plan;

While the public may have had an opportunity to review and comment on the state health plan, no HRMC member can recall any input from the public when the plan was adopted.

The HRMC (or Bureau) states the the "State Health Plan is viewed as a dynamic document..." Essentially, the document serves as a primer on filing Certificates of Need (CON). All parts of the CON evaluation guidelines, established by the HRMC, previously, have not been given equal weight in considering whether or not to grant a CON, as happened during the Gilpin Hall CON application.

4) Address specific health care issues in a timely and focused fashion to provide guidance to health care decisionmakers in private and public sectors;

No information was available regarding specific health care issues addressed by the HRMC.

5) Develop specific criteria and other guidance for use in reviewing certificate of need applications;

The HRMC has accomplished this; but, the HRMC did not follow the guidelines in the Gilpin Hall CON request.

6) Review certificate of need applications and make recommendations to the state agency;

This is the area where the HRMC spends most of its time.

7) Gather and analyze data and information needed to carry out its responsibilities. Identify kinds of unavailable data so that efforts can be made to assure that legitimate data needs can be met in the future;

This work is actually done by the Bureau.

8) Adopt bylaws which incorporate adequate provisions to

assure that Council (HRMC) members shall not vote on matters in which they have a conflict of interest.

The 1987 legislation mandated that, in Certificate of Need applications, providers of health care shall abstain from making recommendations involving their field of health care (Sec. 9303(4)(f), 16 Del. C.). The 1988 By-laws of the HRMC defined when a member was considered to have a "conflict of interest." In keeping with the statute, a member had a conflict of interest if he/she "is an employee, trustee or board member or otherwise holds a fiduciary position with, or has a fiduciary interest in, the organization (or person) sponsoring or presenting the matter to the Council. A financial interest in any proprietary organization directly involved in an item of Council business shall also constitute a conflict of interest."

The 1992 revision of the statute loosened the prohibition on the involvement of health care providers in the CON process. The HRMC, as mandated by Sec. 9303(8) above, created and adopted its own conflict of interest provisions in its By-laws. The By-laws concerning conflict of interest were amended on July 16, 1992, after the HRMC was placed on the Sunset review schedule.

HRMC members could be considered "honorary state officials," and as such would be covered by the provisions of Chapter 58, 29 Del. C. (Ethics Code), which regulate the conduct of officers and employees of the state.

The HRMC By-laws regarding conflict of interest are lifted in part from sections of Chapter 58, 29 Del. C. (Ethics Code); but, the HRMC By-laws do not incorporate all of the prohibitions under which members would be covered by Chapter 58, 29 Del C., (Ethics). The current HRMC By-laws define a "financial interest" but do not define a "personal or private"

interest, which prohibitions are found in Chapter 58 (Ethics), Sec. 5805(a), 29 Del. C.

It is possible to identify at least 9 members of the 18-member HRMC, who are health care providers or who have an interest in the health provider community.

In November, 1992, a conflict of interest questionnaire was sent to all 18 members of the HRMC. Nine members, two of whom were appointed in August, 1992, returned the questionnaire. At least one public member has close ties to a health provider institution; and, at least two members serve on a variety of other health-related Boards and Commissions. Four persons, identified as public members, did not return the questionnaire.

The members who did return the questionnaire are: William H. Duncan, M.D., Kay Holmes, Roger R. Wick, Robert G. Netherland, Patrick C. Donahue, Marvin S. Gilman, Maureen C. Byrnes, Robert F. Miller, and Charles H. Hopkins. Dr. Duncan stated that he has declared conflicts of interest in accordance with the by-laws of the HRMC. No other conflicts of interest have been declared by those returning the questionnaire.

Those who did not return the conflict of interest questionnaire are: Max Kenyon, CEO, Principal Healthcare of Delaware; Phyllis A. Sheppard, Marketing representative, AT&T; Charles W. Smith, M.D., Medical Administrator, Medical Center of Delaware; Janice Tildon-Burton, M.D., Private Practice Physician; and Robert E. Tremain, President & CEO, HMO of Delaware.

A representative of the Attorney General's Office is not present at HRMC meetings. This was not identified as a serious matter by HRMC members.

The Joint Sunset Committee has Recommended that the Deputy Attorney General assigned to the Health Resources Management Council attend all Council meetings.

The By-laws state that any questions of conflict of interest declared by a member shall be decided by a vote of the other Council members present. An impartial, objective assessment by a Deputy Attorney General would be helpful to the Council. Conflict of interest matters should be referred to the Ethics Commission.

The Joint Sunset Committee has Recommended that members of the Health Resources Management Council, by statutory change, be brought under the State Ethics Code (Chapter 58, 29 Del. C.).

The number necessary for a quorum was not changed when the number of Council members was raised to 18.

The Joint Sunset Committee was Recommended that the members necessary for a quorum of the Health Resources Management Council be raised to 10 (ten).

CERTIFICATE OF NEED PROCEDURES

The Certificate of Need process, which occupies the greater part of the HRMC's time, consists briefly of the following:

- 1) Oral presentation made by applicant before HRMC.
- 2) Application assigned to either a staff review or to Review Committee.

- 3) Review Committee conducts public hearing, if requested.
- 4) Review Committee "generally meets with the applicant, often in conjunction with a site visit."
- 5) Review Committee formulates a recommendation to the full HRMC, which takes into consideration the seven statutory criteria (Sec. 9306, 16 Del. C.):
 - a) relationship to state health plan;
 - b) need of population for proposed project;
- c) availability of less costly and/or more effective alternatives to proposal;
- d) relationship of proposal to existing health care delivery system;
- e) immediate and long-term viability of proposal in terms of applicant's access to financial, management and other necessary resources;
- f) anticipated effect of proposal on quality of health care.
- 6) Full HRMC considers report, questions applicant, and takes final action, which constitutes recommendation to the Bureau, which renders final decision.

A review committee is appointed by the chair of the HRMC when a Certificate of Need request warrants a full review. For a recent review panel meeting only 2 of the 5-member committee was present to receive public comment on the CON request. Follow-up meetings are held which are not made public, nor are Minutes available of these follow-up meetings. Persons who testify before the review committee are also not notified of the follow-up meetings. The full HRMC votes on the recommendation of the review panel as to whether or not to approve the CON request.

The Joint Sunset Committee has Recommended that all meetings of the Health Resources Management Council, including subcommittee and review committee meetings, be posted and open to the public.

The Joint Sunset Committee has further Recommended that a quorum of subcommittee members be present for Review Committee meetings, including those at which public comment is taken.

The Joint Sunset Committee has further Recommended that Minutes be prepared for all meetings of the Health Resources Management Council, and that such Minutes be available to the public before decisions are reached by the Council as a whole.

Any person, for good cause, may request, within 30 days of date of the decision, reconsideration of any decision of the Bureau. A hearing date is set to begin 45 days from receipt of the request. The Secretary of Health and Social Services appoints a 5-person appeal panel. The appeal is on the record; but, the panel can consider additional evidence "when such evidence embodies significant changes in factors or circumstances relied upon by the State Agency in reaching its decision."

"The decision of the Appeals Board, or the State Agency after a remand from the Appeals Board, shall be considered the final decision of the State Agency." (Sec. 9305, 16 Del. C.) The decision may be appealed by the applicant to Superior Court; that appeal is also on the record.

Certificates of Need are valid for 1 year from date of approval. Sixty days prior to the expiration of the CON, the applicant must inform "the Bureau" of the project's status. A

6-month extension may be granted. The extensions are routinely approved. The Bureau may deny the extension, which can be appealed to Superior Court.

The HRMC does not set aside time on its agenda for public comment during its meetings.

The Joint Sunset Committee has Recommended that the Health Resources Management Council set a side a specific period of time for public comment at Council meetings.

The Joint Sunset Committee has Recommended that a quorum of subcommittee members of the Health Resources Management Council be present for Review Committee meetings, including those at which public comment is taken.

THE BUREAU OF HEALTH PLANNING AND RESOURCE MANAGEMENT

The HRMC is assisted in its work by the staff of the Bureau of Health Planning and Resource Management (Bureau), which is part of the Division of Management Services. The Director of the Bureau, Robert Welch, reports directly to the Director of the Division of Management Services, Wayne Bergner. The Division of Management Services was created in June, 1992, by the merger of the Division of Planning Research and Evaluation and the Division of Business Administration and General Services (DBAGS).

Unlike many other Directors, Mr. Welch is a merit system employee, as are all other positions in the Bureau (eleven, 1 vacant). Mr. Welch was interviewed by some members of the HRMC before he was chosen for his present position. An

organizational chart of the Bureau is attached.

The Bureau is the collection agency for all health data, including vital statistics, in Delaware. The statistics are used by the 3 Senior Health Planners as the basis for the State Health Plan "promulgated" by the HRMC. These statistics serve as the basis for, among others, the nursing home bed need projections, which are utilized by the HRMC in the approval/disapproval of Certificates of Need (CON).

The position of Certificate of Need Manager has been vacant since Mr. Welch moved into the position of Director of the Bureau in mid-'91. Robert Messick, Senior Health Planner, is serving as Acting Certificate of Need Manager. Mr. Messick directs the day-to-day activities of the HRMC; conducts meetings; drafts reports; and staff Committees of the HRMC. He does not take part in HRMC recommendations. A Senior Health Planner assists Mr. Messick in the CON process. The two other Planners assist Don Berry, Manager, health statistics and research, in the hospital discharge data program. Another planner under Mr. Berry is in charge of the vital statistics data.

There has been harsh criticism of the Bureau by appeal panel members appointed to review denials of Certificates of Needs by the HRMC and ultimately, the Bureau.

In a dissent from a majority opinion, an attorney member of a recent appeal panel noted that she was "greatly agitated by the Bureau's complete disregard of the increasing need of affordable health care faced by our community and its selfish and self-serving desire to reign over health care services providers as its subjects, while wasting limited and precious resources." The appeal panel member stated that "at no time" during the proceedings did the state agency act "as an

independent fact finder and decision maker." She also commented strongly on the Bureau's procedural mishandling in the case .

The Joint Sunset Committee has Recommended that the statute governing the Health Resources Management Council be amended by striking relevant sections of Chapter 93, 16 Del. C., regarding the Appeal panel.

UNIFORM HEALTH DATA ACT

On July 19, 1989, legislation signed by the Governor gave to the HRMC the mandate to "compile, correlate, analyze and develop data which it collects pursuant to this chapter" (Chapter 20, 16 Del. C., Uniform Health Data Act).

The HRMC was given a mandate to perform duties under Chapter 20, 16 Del. C. HRMC members hold full-time jobs in the private sector, and receive reimbursement only for expenses. The Chapter states that the state agency (the "Bureau") is to provide staff support for the HRMC in carrying out its activities under this Chapter, along with the already prescribed duties under Chapter 93, 16 Del. C.

The addition of the duties established under Chapter 20, 16 Del. C., brings into sharper focus the main issue in the review of the HRMC. The HRMC has not been established as an independent body with a budget and staff to do the many tasks assigned to it by law. The HRMC is totally dependent on the Bureau for all data, interpretation of data, collection of statistics, preparation and writing of reports, and compilation of the State Health Plan, among others. The HRMC has not been allotted a budget. In fact, the small amount reimbursed for expenses for HRMC members is included in the Bureau's budget.

Almost all of the HRMC's time is spent on reviewing applications for Certificates of Need. They can do no more than a cursory review of the data mandated to be collected under Chapter 20, 16 Del. C.

The data is limited to that contained in the Delaware uniform claims and billing data set (UB-82 or successor form). The information must be completed for all hospital inpatient discharges and nursing home inpatient discharges, occurring after June 30, 1991.

Chapter 20, 16 Del. C., mandates that the HRMC:

- a) "Periodically compile and disseminate reports on the data collected such as, but not limited to: Aggregate charge levels, age-specific utilization patterns, morbidity patterns, patient origin and trends in health care charges."
- b) Adopt such policies and procedures as necessary to carry out this chapter. (None have been adopted).
- c) Establish a technical advisory committee, including non-Council members, to study issues such as the collection compilation, dissemination and confidentiality of data -- and establish other committees.
- d) Issue annual reports to the General Assembly outlining actions and accomplishments as well as recommendations for changes.
- e) Study and issue reports on special medical needs, demographic characteristics, access to health care services and need for financing of health care services for the entire population or various population subgroups.

- 6) May study and issue reports on health status issues, such as:
 - a) incidence of medical and surgical procedures;
- b) mortality rates for specified diagnoses and treatments:
- c) rates of infection for specified diagnoses and treatments:
- d) morbidity rates for specified diagnoses and treatments:
- e) readmission rates for specified diagnoses and treatments; and
- f) rate of incidence for selected diagnoses and procedures.

Raw data collected is not available for public inspection, and is not considered public record under the Freedom of Information Act. Any compilations prepared and authorized by the HRMC are considered public records.

The HRMC states that, "This data will allow significant analysis of health care utilization and expenditure patterns."

According to the HRMC, preparation of this legislation (Uniform Health Data Act) has been one of its "major actions" since 1989. The statement implies that the HRMC, or the Bureau, either wrote or had significant input into the legislation, which may be why the confidentiality clause has been added. This raises the conflict of interest/ ethical issue of members having access to information not available to other health care providers or the public.

Any hospital, or nursing home, which violates any provision of Chapter 20, 16 Del. C., shall be reported, not to the HRMC, but rather to the State Board of Health. The HRMC has

no enforcement powers when there has been a violation of any provision of Chapter 20, 16 Del. C.

Information submitted by the HRMC indicates that the Bureau makes extensive use of the University of Delaware's IBM 3091 mainframe computer. This computer is used to compile the vital statistics data (birth, death, and marriage).

Recent legislation, H.B. 627, signed July, 1992, provides for the sharing of hospital discharge data, compiled by the HRMC, with the Health Care Cost Containment Committee, which is a subcommittee of the Health Care Commission. Presumably, the data referred to is not the "raw data" collected; but rather any reports issued by the HRMC.

FILING FEES

Filing fees for CON applications are set by statute in Sec. 9305(11), 16 Del. C. They are:

Capital Expenditure	Filing 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

Fees for FY'88: \$25,750; FY'89: 44,700; FY'90: \$57,900; FY'91: 38,700; FY'92: \$35,650.

Filing fees do not cover the cost of administering the CON program; but, the HRMC states they were identified as one funding source in the wake of the cessation of federal funding.

FISCAL INFORMATION

Expenditures of the Bureau for the past six fiscal years are as follows:

	FY'88	FY'89	FY'90	FY'91	FY'92	FY'93
Gen. Fund	\$227.6	\$345.6	\$435.4	\$455.7	\$394.5	\$393.4
ASF			<u>141.7</u>			
	\$227.6					

For FY'92, the Bureau expenditures for salaries and wages (excluding benefits) was \$341,484; consultants were paid \$31,370. Members of the HRMC were reimbursed \$1,282 for expenses.

JOINT SUNSET COMMITTEE 1993 FINAL REPORT

HEAL TH RESOURCES MANAGEMENT COUNCIL (Chapter 93, Title 16 Del. Code)

RECOMMENDATIONS FOR THE HEALTH RESOURCES MANAGEMENT COUNCIL_

- 1. The Joint Sunset Committee has Recommended that the Health Resources Management Council be abolished (sunset), and that the Governor and General Assembly be advised of the need to develop a comprehensive health planning process. The various commissions, councils, and boards can be brought under one umbrella agency dealing with health care planning. The Joint Sunset Committee agreed that the Certificate of Need review, the development of a comprehensive health policy, the centralization of health planning, and the issue of a regionally-based health care planning process will need to be part of a comprehensive health planning process.
- 2. The Joint Sunset Committee has Recommended that the Governor and General Assembly develop a program of regulations to centralize health care planning resources under a smaller umbrella of oversight, so as to make better use of resources and to centralize the health care decision-making process. This Recommendation will be in the form of a Resolution to the General Assembly.
- 3. The Joint Sunset Committee has Recommended that the Deputy Attorney General assigned to the Health Resources Management Council attend all Council meetings.
- 4. The Joint Sunset Committee has Recommended that the Health Resources Management Council be included under those agencies covered by the Administrative Procedures Act (Chapter 101, 29 Del. D.).
- 5. The Joint Sunset Committee has Recommended that members of the Health Resources Management Council, by statutory change, be brought under the State Ethics Code

(Chapter 58, 29 Del. C.).

- 6. The Joint Sunset Committee has Recommended that the members necessary for a quorum of the Health Resources Management Council be raised to 10 (ten).
- 7. The Joint Sunset Committee has Recommended that all meetings of the Health Resources Management Council, including subcommittee and review committee meetings, be posted and open to the public.
- 8. The Joint Sunset Committee has Recommended that Minutes be prepared for all meetings of the Health Resources Management Council, and that such Minutes be available to the public before decisions are reached by the Council as a whole.
- 9. The Joint Sunset Committee has Recommended that the statute governing the Health Resources Management Council be amended by striking relevant sections of Chapter 93, 16 Del. C., regarding the Appeal panel.
- 10. The Joint Sunset Committee has Recommended that the Health Resources Management Council set aside a specific period of time for public comment at Council meetings.
- 11. The Joint Sunset Committee has Recommended that a quorum of subcommittee members of the Health Resources Management Council be present for Review Committee meetings, including those at which public comment is taken.
- 12. The Joint Sunset Committee has Recommended that Minutes be prepared for all meetings of the Health Resources Management Council, and that such Minutes be available to the public before decisions are reached by the Council as a whole.



Joint Sunset Committee

Final Report of the Delaware Health Resources Board

DMS #1441430002 May 31, 2005

Recommendations for the Delaware Health Resources Board

The Joint Sunset Committee recommends continuance of the Delaware Health Resources Board, but only upon its meeting certain conditions or making certain modifications as identified below.

A. The Joint Sunset Committee recommends the following statutory changes:

- 1. Delete the sunset provision.
- 2. Insert a provision sunsetting the Delaware Health Resources Board on June 30, 2009.
- 3. Create legislation allowing the Delaware Health Resources Board to establish and enforce a charity care policy for free standing facilities.
- 4. Delete the statutory provision to include "1 representative designated by the Delaware Health Care Coalition."
- 5. Add one additional representative of the public-at large to the Board. This addition will increase the Board's public membership from 9 to 10 members.
- 6. Include non-traditional long term care facilities in the scope of activities subject to CPR review. For purposes of definition, non-traditional long term care facilities shall include continual care communities and other facilities identified by Department of Health and Social Services or the Delaware Health Care Commission.
- 7. Increase the 2005 capital expenditure threshold that triggers a CPR review from \$5 million to \$5.8 million, based on an annual inflation index determined by the US Dept. of Labor's Bureau of Labor Statistics.
- 8. Add a 180-day expiration date on the Notice of Intent.

B. The Joint Sunset Committee recommends that the Delaware Health Resources Board take the following action:

- 9. The Delaware Health Resources Board must comply with the statutory requirement to coordinate health planning activities with the Health Care Commission, the DHSS, and other health care organizations. (16 *Del. C.* §9303(d)(6))
- 10. The Delaware Health Resources Board shall revise the CPR application so that it directly addresses each of the statutory review criteria. (16 Del. C. §§9304, 9306)

C. The Joint Sunset Committee recommends the following action by the Division of Public Health:

11. The Division of Public Health shall create and maintain a CPR website with contact information, meeting minutes, agendas, the CPR application and CPR procedures. (16 *Del. C.* §9303(e))

DELAWARE HEALTH RESOURCES BOARD

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Background

The Delaware Health Resources Board ("Board") and the Certificate of Public Review ("CPR") program that it administers will sunset on June 30, 2005, unless legislation re-establishes it. CPRs (formerly known as Certificates of Need) are the state's stamp of approval for specific construction and expansion projects of certain health care facilities, and for the acquisition of major medical equipment. The CPR program, in existence in some form since 1972, is supposed to control health care costs, at least in theory, by squeezing out excess supply of health care services. Its history has roots in federal and state legislation.

Federal History

Federal legislation created the Comprehensive Health Planning Program in 1966 to control unnecessary or duplicative hospital investments in plant and equipment²². Six years later, the Certificate of Need concept was developed to control Medicare and Medicaid costs. Both the 1966 and 1972 federal legislation proved ineffective. Consequently, in 1974, the U.S. Congress developed a consolidated planning program requiring each state to establish a mandatory Certificate of Need (CON) process and concurrently establish a national system of local and state planning agencies. Federal funding of the CON program slowly dissolved through a series of Congressional resolutions until the mid-1980s when the Reagan administration, favoring competition versus government regulation, repealed the CON program in its entirety²³.

State History and Joint Sunset Committee Review

States responded to the federal repeal of the CON program by establishing their own health planning framework. In Delaware, Governor Castle established the Health Care Cost Containment Commission in 1985. This Commission later recommended establishing the Health Resources Management Council (HRMC) to oversee the state's health planning. The Commission's recommendation became effective with the passage of Senate Bill 132 in 1987.

Seven years later, the Joint Sunset Committee commenced a review of the HRMC. The JSC concluded, in its 1993 Final Report, that there was a need to develop a comprehensive health planning process, and that the various commissions, councils, and boards responsible for health planning should be brought under one umbrella agency for the purpose of centralizing health planning decisions. The JSC further agreed that the CON program and a regionally based health care planning process should be part of the state's comprehensive health plan. It therefore sunset the HRMC and, with passage of House Bill 331, initiated an overhaul of the CON program.

Specifically, HB 331 established the Delaware Health Resources Board to assume the functions of the HRMC as the state's overseer of the CON process. It also brought the Board under the Administrative Procedures Act and the State Ethics Code. Moreover, House Bill 331 made significant changes to the CON policies. It vested the final CON decision making power solely with the Board rather than the previous policy in which the Bureau of Health Planning and Resources made final decisions based on the HRMC recommendation. Additionally, the bill abolished the CON Appeals Board.

Other JSC recommendations made minor management modifications. These were implemented upon commencement of the Board's activities.

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²² Sunset Questionnaire, pg. 4.

²³ Ibid.

House Bill 331 included a June 30, 1996, sunset provision for the Board, and directed the Delaware Health Care Commission (DHCC) to conduct a study examining the necessity of the CON program. In response, the DHCC's Health Care Cost Containment Committee, with assistance from Dr. Frank Sloan, a nationally recognized scholar on Certificates of Need, from the Center for Health Policy Research and Education at Duke University, produced one of the most comprehensive evaluations of a state administered CON program at that time. The study concluded that, "the most prudent course of action is to allow the market to work and resort to regulation only if this approach is found to have serious limitations." The DHCC's Cost Containment Committee therefore recommended a three-year phase-out of the CON program beginning in 1996 and ending in 1999. This phase-out included raising the capital expenditures threshold from \$750,000 to \$3 million and discontinuing the review of health services and bed decreases. The gradual program phase-out was enacted through House Bill 640 in 1996.

In 1999, Senate Bill 74 delayed the sunset of the CON program until June 30, 2002 and replaced "Certificate of Need" with "Certificate of Public Review." It also continued to phase out and reduce the scope of activities subject to Board review by raising the capital expenditure threshold from \$3 million to \$5 million. The CON sunset date was delayed again -- until June 30, 2005 -- with enactment of Senate Bill 305 in May 2002.

Organization

The Board is an independent public entity. The organizational chart shows that the Board is located within the Health Systems Management Section of the Division of Public Health, Department of Health and Social Services. The Board is assigned to this agency for administrative and budgetary purposes only.²⁶

Staff

The Board is supported by 2.25 full-time merit positions from the Bureau of Health Planning and Resources Management²⁷. One position is a Management Analyst III, one position is an administrative support specialist, and .25 of the Bureau of Health Planning Director position is allocated to serving as the Board's Secretary and Chief Administrative Officer, as required by 16 Del. C. §9303(c). The Director supervises the staff assigned to the Board and the Director is supervised by the Chief of Health Systems management.

Staff size was recently reduced by 1 full time employee when the Division of Public Health realigned. The sunset questionnaire noted that the Board depends heavily on the Bureau staff to review applications and write reports in addition to performing other Board duties. The questionnaire also noted that as the size of the health care industry grows, the ability of the staff to analyze and monitor projects decreases. Staffing issues have been and will continue to be discussed with the Division of Public Health²⁸.

Staff participates in data management, health planning, and communications training opportunities.

²⁶ 16 Del. C. §9303(c).

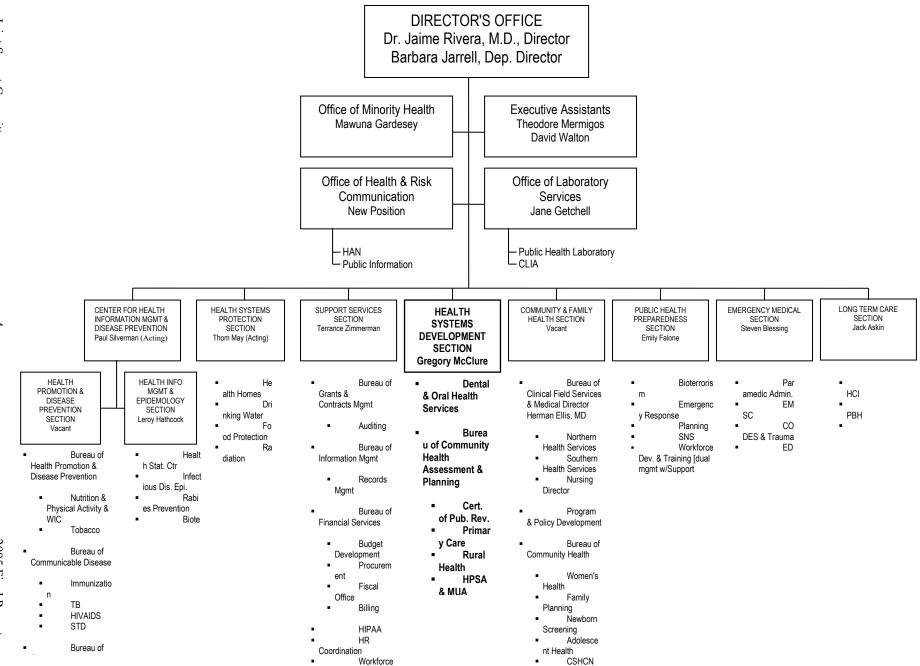
²⁴ Evaluation of Certificate of Need and Other Health Planning Mechanisms, Vol. I, pg. XV.

²⁵ Ibid, pg. vii.

²⁷ Sunset Questionnaire, pg. 14.

²⁸ Sunset Questionnaire, pg. 15.

DIVISION OF PUBLIC HEALTH



Budget

The Board's budget has changed little between Fiscal Years 2003-2005. In FY 2005, budgeted expenditures totaled \$57,052; FY 2004 actual budget was \$52,910; and FY 2003 actual budget was \$55,097. Staff salaries totaling approximately \$50,000 comprise most of the Board's budget for each fiscal year. The remaining expenditures were for phone, computer, advertising, and other professional or administrative purposes.²⁹

Mission and Goals

The Board's statutory purpose is to, "assure that there is a 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." The Board serves all Delawareans seeking health care services. It

The goals of the Board are to³²:

- Increase the accessibility, acceptability, continuity, and quality of health services provided to the residents of Delaware.
- Restrain increases in the cost of providing residents with health care services.
- Prevent unnecessary duplication of health care resources.
- Preserve and improve competition in health care in Delaware.
- Improve the health of Delawareans.

The Board noted that its goals are accomplished through statutory powers, which, in addition to administering the CPR program, include³³:

- 1. Gathering and analyzing data. The Board noted that gathering and analyzing data is performed by the Bureau of Health Resources and Planning for Board staff.³⁴
- 2. Addressing specific health care issues as requested by the Governor and General Assembly. The Board stated that it has not received any requests from the Governor or General Assembly concerning specific health care issues.³⁵
- 3. Adopting by-laws. By-laws have been adopted for conducting meetings and are explained later in this report.
- 4. Coordinating activities with the Delaware Health Care Commission (DHCC), Department of Health and Social Services (DHSS), and other related organizations. The Board noted its Health Resources Management Plan is sent to the DHCC and DHHS for their review and comment. Additionally, the Secretary to the Board attends DHCC meetings monthly and serves on a subcommittee of the DHCC. The Board's Secretary collects data for the Health Care Commission and the DHSS, if it is requested.³⁶

³¹ Sunset Ouestionnaire, pg. 10.

²⁹ Sunset Questionnaire, pg. 16.

³⁰ 16 Del. C. §9301.

³² Sunset Questionnaire, pg. 10.

³³ 16 Del. C. §9303(d) (1-6).

³⁴ Sunset Questionnaire, pg. 5.

³⁵ Ibid.

³⁶ Sunset Questionnaire, pg. 7.

Other Health Planning Agencies and Programs

Although not an exhaustive list, identified below are some other agencies or organizations that participate in health planning activities:

- The Department of Health and Social Services. All of its divisions in some way touch on health planning and management.
- Office of Health Facilities Licensing. Responsible for licensing all health care facilities and enforcing licensure standards.
- Delaware Health Care Commission. Its Community Healthcare Access Program connects the uninsured with health care services. Its Health Information network promises to improve quality of care
- Office of the Insurance Commissioner. Regulates the health insurance industry with the potential to affect costs.
- Medical Society of Delaware. It operates the VIP program, which works in conjunction with the Community Healthcare Access Program (CHAP) program, to connect the underserved with physicians.
- Community Health Clinics. Responsible for direct services to the uninsured or underinsured.
- Cancer Consortium and other issue specific task forces, which could identify health planning problems related to specific diseases.

Policymaking Structure

The Governor appoints Board members from nominees selected by the Bureau and the Board. Senate confirmation is not required.

By law, the Board should be comprised of 21 appointed members, each serving a 3-year term with no limit on the number of terms permitted. The initial appointments were staggered to avoid all terms expiring at the same time.³⁷ The Board currently consists of 19 members. The following vacancies exist: the Delaware Health Care Commission designee, and the Delaware Health Care Coalition designee. The Coalition seat has been vacant since August 1999 because the organization no longer exists. Legislation to change the statute will be required to replace this seat with another member of the public at large.

Statute designates that 12 Board members represent specific organizations which include: the Delaware Health Care Commission, Department of Health and Social Services, organized labor, health insurance, Delaware Healthcare Association, Medical Society of Delaware; Delaware Health Facilities Association, State Chamber of Commerce, Delaware Health Care Coalition, a provider group other than hospitals nursing homes or physicians, a representative purchasing health care coverage on behalf of State employees, and a representative purchasing health coverage for employers with more than 200 employees.³⁸

The remaining 9 members must be from the public. The Chair and Vice Chair are appointed from these public members.

The Governor may remove a member. Statute does not define circumstances; however, Board By-Laws state that the Governor may "declare a vacancy" for any member who is absent from four consecutive meetings upon recommendation from the Board.

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³⁷ 16 Del. C. §9303(b).

³⁸ Ibid.

The Board members for 2004-2005 are:

Board Member Name Appointed by & Other Stipulations for Appointment		Address, City, State	Appointment Date	
Jaime H. Rivera, M.D.	Governor appointment Stipulation: designated by the Secretary, DHSS	Dover, DE 19903	Initial Appt.: Oct. 13, 2004 Term Expires: April 22, 2005	
John A.J. Forest, Jr.	Governor appointment Stipulation: designated by the Medical Society of Delaware	Dover, DE 19901	Initial Appt.: Jan. 10, 1995 Appt.: Jan. 10, 1998 Exp: Jan. 10, 2001 Appt.: April 22, 2002 Exp.: April 22, 2005 (3 terms)	
Richard D. Pack	Pack Governor appointment Stipulation: designated by the Delaware State Chamber of Commerce Milford, DE 19963		Appt.: March 12, 1998 Exp.: March 12, 2001 Appt.: April 22, 2002 Exp.: April 22, 2005	
Suzanne Raab-Long	Governor appointment Stipulation: designated by the Delaware Healthcare Association	Dover, DE 19904	(2 terms) Initial Appt.: April 19, 2004 Exp.: April 19, 2007	
Yrene E. Waldron	Governor appointment Stipulation: designated by the Delaware Health Care Facilities Assoc.	Wilmington, DE 19806	Appt.: May 13, 1999 Exp.: May 13, 2002 Appt.: June 7, 2002 Exp.: June 7, 2005 (2 terms)	
Vacant	Governor to appoint Stipulation: designated by the Delaware Health Care Coalition			
Vacant	Governor to appoint Stipulation: designated by the Delaware Health Care Commission			
Katherine R. Deitcher	Governor appointment Stipulation: rep. involved in purchasing health care coverage for employers w/over 200 employees	Wilmington, DE 19802	Initial appt.: Oct. 13, 2004 Exp.: April 22, 2005	
Dana J. Jefferson, Ph.D.	Governor appointment Stipulation: rep. involved in purchasing health care coverage on behalf of state employees	Wilmington, DE 19802	Appt.: April 22, 2002 Exp.: April 22, 2005 (1st term)	

Board Member Name	Appointed by & Other Stipulations for Appointment	Address, City, State	Appointment Date	
Timothy J. Constantine	Governor appointment Stipulation: rep. of the Health Insurance Industry	Wilmington, DE 19801	Appt.: Oct. 25, 1999 Exp.: Oct. 25, 2002 Appt.: May 12, 2003 Exp.: May 12, 2006 (3 terms)	
Thomas E. Mulhern	Governor appointment Stipulation: rep. of a provider group other than hospitals, nursing homes, physicians Wilmington, DE 19807		Initial Appt.: July 23, 2004 Exp.: July 20, 2007	
Frank Smith	Governor appointment Stipulation: rep. of organized labor	Dover, DE 19901	Appt.: June 7, 2002 Exp.: June 7, 2005 (1st term)	
Phyllis A. Sheppard (Chair)	Governor appointment Stipulation: public at large	New Castle, DE 19720	Initial appt.: Dec. 9, 1994 Appt.: Dec. 30, 1997 Exp.: Dec. 30, 2000 Appt.: April 22, 2002 Exp.: April 22, 2005 (4 terms)	
Robert F. Miller (Vice Chair: Appointed Oct. 13, 2004)	Governor appointment Stipulation: public at large	Wilmington, DE 19803	Initial appt.: Jan. 10, 1995 Appt.: Oct. 24, 2000 Exp.: Oct. 24, 2003 Appt.: Oct. 25, 2003 Exp.: April 19, 2007 (5 terms – 1 in current slot)	
		154 Fairground Rd. Harrington, DE 19952	Appt.: June 7, 2002 Exp.: June 7, 2005 (1st term)	
Joann O. Hasse	Governor appointment Stipulation: public at large	712 Kilburn Rd. Wilmington, DE 19803	Initial Appt.: Dec. 9, 1994 Appt.: March 30, 1999 Exp.: March 30, 2002 Appt.: April 22, 2002 Exp.: April 22, 2005 (4 terms)	
S. Bernard Ableman	Governor appointment Stipulation: public at large	Park Plaza 906 1100 Lovering Ave. Wilmington, DE 19806	Initial Appt.: Jan. 5, 1995 Appt.: Jan. 5, 1998 Exp.: Jan. 5, 2001 Appt.: April 22, 2002 Exp.: April 22, 2005	
Lloyd Mills, III	Governor appointment Stipulation: public at large	2 De Vries Circle Lewis, DE 19958	Initial appt.: Feb. 16, 1995 Appt.: March 30, 1999 Exp.: March 30, 2002 Appt.: April 22, 2002 Exp.: April 22, 2005 (4 terms)s	

Board Member Name	Appointed by & Other Stipulations for Appointment	Address, City, State	Appointment Date
J. Kenneth Saunders	Governor appointment Stipulation: public at large	Newark, DE 19713	Appt.: April 22, 2002 Exp.: April 22, 2005 (1st term)
Linda Heller	Governor appointment Stipulation: public at large	Wilmington, DE 19808	Appt.: May 12, 2003 Exp.: May 12, 2006 (1st term)
Richard J. Cherrin	Governor appointment Stipulation: public at large	Wilmington, DE 19803	Initial Appt.: Aug. 15, 1997 Appt.: Oct. 24, 2000 Exp.: Oct. 24, 2003 Appt.: April 19, 2004 Exp.: April 19, 2004 (3 terms – 1 in current slot)

Compensation

Board members are not compensated for anything other than travel and meals.

Committees

The Board may create committees or task forces. The Chair appoints the members and he or she may include in the membership individuals other than Board members. Currently there are two committees, the Review Committee and the Charity Care Committee. Membership on the Review Committee changes depending on the project under consideration. The Charity Care Committee was established to study and make recommendations regarding the Board's current Charity Care policy.

Meetings

By law, the Board must meet at least four times a year. For 2004, the Board has met 8 times as of September. It met 11 times in 2003; 5 times in 2002; and 7 times in 2001. A total of 13 scheduled meetings were cancelled between 2001 and 2004 due to insufficient business. None of the meetings were closed to the public.

With the exception of approving By-Law amendments, which must be approved by an affirmative vote of half of the Board, Board decisions are made by a majority of members present and voting.

To prevent conflicts of interest, the Board has adopted By-Laws with language duplicating parts of the State Ethics Code. The By-Laws explicitly state that, "a member with a conflict of interest must declare his or her conflict of interest at the earliest practicable time after learning of such conflict and must abstain from voting." By-laws state that a conflict of interest exists when:

a. Any action or inaction would result in a financial benefit or detriment to accrue to the Board member or a close relative (parent, spouse, children, or siblings) to a greater extent than such benefit or detriment would accrue to others who are members of the same class or group of persons; or

b. The Board member or close relative has a 'financial interest' in a private enterprise (whether profit or not for profit) which enterprise or interest would be affected by any action or inaction on a matter to a lesser or greater extent than like enterprises or other interests in the same enterprise. A person has a 'financial interest' in a private enterprise if: (1) He has a legal or equitable ownership interest in the enterprise or more than 10% (1% or more in the case of a corporation whose stock is regularly traded on an established securities market); (2) He is associated with the enterprise and received from the enterprise during the last calendar year, or might reasonably be expected to receive from the enterprise during the current or the next calendar year, an income in excess of \$5000 for services as an employee, officer, director, trustee or independent contractor; or (3) He is a creditor of a private enterprise in an amount equal to 10% or more of the debt of that enterprise (1% or more in the case of a corporation whose stock is regularly traded on an established securities market).

Board meeting minutes show that, during each meeting, the Chair asks members to declare any perceived conflicts of interest. In the past, Board members often recused themselves from both discussion and vote. Recent policy encourages Board members to engage in the discussions, since they are brought onto the Board based on their expertise, but they must refrain from voting.

Freedom of Information Act (FOIA)

A review of Board meeting minutes shows that the Board complies with FOIA requirements.

CPR Revisited

CPRs are required for the following activities:³⁹

1. Construction, development or other establishment of a health care facility or the acquisition of a non-profit health care facility. "Health facility" is defined to include hospitals, nursing homes, freestanding birthing centers, freestanding surgical centers and freestanding emergency centers.

Health facility <u>does not</u> include home health agencies, assisted living facilities, or in-patient hospice facilities. Home health agencies and assisted living facilities are some of the fastest growing portions of the nursing home industry. In-patient hospice facilities are a new type of facility that houses residents who are dying in a hospital type facility designed to emulate a home setting rather than providing care in the patient's home until death, as is the case with hospice services. <u>The Board, if retained, would like to add in-patient hospice facilities to the definition of "health facility"</u>.

- 2. Any capital expenditure by or on behalf of a health care facility in excess of \$5 million.
- 3. A change in bed capacity which increases the total number of beds by more than 10 beds or more than 10% of total licensed bed capacity over a two year period, whichever is greater.
- 4. The acquisition of major medical equipment, defined as medical equipment used for the diagnosis and treatment of patients and which: exceeds \$5 million, or represents medical

³⁹ 16 Del. C. §9304.

technology not available in Delaware or has been designated by the Board as being subject to review regardless of cost, such as MRIs, PETs, megavoltage radiation therapy and extracorporeal shock wave lithotripsy.

Undertaking any of the above activities without obtaining a CPR means that the organization or individual operating license will be revoked or restricted. The Board may initiate civil action and the applicant may be fined not less than \$500 but no more than \$2,500.⁴⁰

Criteria for Review

Health Resources Management Plan

One key criterion that the Board must consider in its review of a CPR application is the relationship of the project's proposal to the Health Resources Management Plan. The Plan, first adopted in 1995 and last updated in 2003, "shall address the supply of health care resources, particularly facilities and medical technologies, and the need for such resources" and "shall include a statement of principles to guide the allocation of resources and specific criteria and other guidance for use in reviewing CPR applications." ⁴¹

The most recent version of the Plan does include 7 general principles for considering a review proposal. These principles touch on: balancing cost, quality, and access; medical indigency; coordination of health care services; geographic considerations; and over-utilization. Medical technology applications in particular are supposed to be evaluated on access, cost, and quality dimensions.

Beyond these principles, much of the Plan explains projection formulas for nursing home, medical-surgical, and obstetric beds. For example, based on 2004 bed need projections and the approved supply of beds, there is a net surplus of medical surgical beds for all hospitals in the state, and New Castle County, in particular. There is a net shortage of obstetric beds at Christiana Care, Beebe Medical Center, and Nanticoke. For nursing home beds, the Plan shows a surplus of them in New Castle and Kent Counties and a 26-bed shortage in Sussex County. Additionally, the Plan has put a moratorium on the construction of additional hospitals offering medical/surgical beds or obstetric beds for the next five years.

On a related procedural matter, the Board offers an opportunity for public comments on the Plan's content. It is then submitted to the Delaware Health Care Commission for review and comment. The Plan becomes effective upon the signature of the Secretary of the Department of Health and Social Services.⁴⁵

Other Criteria

In addition to the Health Plan, the Board, in its review of a CPR application, must also consider: 1) the need of the population; 2) the availability of less costly and/or more effective alternatives to the proposal (including the use of resources located outside of the State); 3) the relationship of the proposal to the existing health care delivery system; 4) the immediate and long-term viability of the proposal in terms of the applicant's access to financial/management and other resources; 5) the anticipated effect of the proposal on the costs of and charges for health care; and 6) the anticipated effect of the proposal on the quality of health care.

⁴¹ 16 Del. C. §9303(d)(1).

⁴⁰ 16 Del. C. §9308.

⁴² Health Resources Management Plan, pg. 11.

⁴³ Health Resources Management Plan, pg. 15.

⁴⁴ Health Resources Management Plan, pg. 20.

⁴⁵ Sunset Questionnaire, pg. 5.

CPR Process

The CPR process consists of several phases and procedural steps. Timelines for task completion are established by law. 46:

- 1. <u>Notice of Intent</u>. An applicant must file a Notice of Intent at least 30 days prior to filing the application. Bargaining and negotiations take place during this pre-application phase. The notice does not expire, meaning that some projects have notices on file for years with no action, thus preventing others from engaging in a similar project. <u>The Board would like the Notice to expire after 180 days</u>.
- 2. <u>Applicant Files Application</u>. Upon receipt of the application, the Bureau of Health Resources Management has 15 days to notify the applicant as to whether the application is complete.
 - a. As a side note, the CPR Application was adopted in 1995 and last updated in May 2002. It focuses mostly on the proposal's financial feasibility. There are a few questions regarding the population served by the project and additional questions regarding programmatic changes and bed use data.
- 3. If the application is determined complete, the Bureau has 5 working days to provide notification to all health care facilities and other interested parties of the beginning of a review. The Bureau must also notify the applicant of any applicable filing fees, which are determined as follows:

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

Filing fees are deposited into the General Fund.

- 4. <u>Presentation.</u> Once the application is considered complete, the applicant makes a brief presentation to the Board and responds to questions. Staff recommends whether the Board should proceed with a staff review or use a Review Committee, to be appointed by the Chair. (Staff conducts reviews for acquisition of an existing facility, new services, equipment replacement upgrades and capital expenditures not involving direct patient care. Review Committees generally review applications for new facilities, major renovation/bed replacement projects, increased beds and emerging technology.) Review Committee or staff reports are then sent to the Board for its final decision.⁴⁷
- 5. <u>Public Hearings</u>. Anyone may request a public hearing on a CPR application within 10 days after the notification appears in the newspaper. A public hearing may also commence if anyone requests in writing reconsideration of a Board decision within 10 days of the decision.
- 6. <u>Board Decision</u>. CPR reviews must not proceed longer than 90 days from the date of notification. If a public hearing is requested, the maximum review period may be extended to 120 days.

⁴⁶ 16 Del. C. 89305.

⁴⁷ Certificate of Public Review Procedures.

Extensions may be granted up to 180 days if the Board determines an extension is necessary and it must make that determination within 30 days from the date of notification (60 days if a public hearing is requested).

- a. For emergency situations, the Chair or Vice-Chair is authorized to issue a CPR at his or her discretion but within 72 hours after receipt of the emergency application.
- b. The Bureau notifies the applicant in writing of the Board's decision and the basis for it and any conditions specifically related to the project in question. Conditions may include charity care requirements, Medicare certification, or other accreditation requirements. The applicant may appeal the Board's decision to Superior Court within 30 days following the decision.
- 7. <u>Post Decision</u>. Certificates are valid for one year. CPR recipients are required to submit progress reports to staff a month before the anniversary of the projects approval date. The Board then determines if the applicant has made sufficient progress toward project implementation. A six month extension may be granted for insufficient progress.
 - a. CPRs may also be revoked by the Board for failure to comply with conditions in a timely manner, misrepresenting the application, or loss of operating license. Applicants may also surrender the license or have it transferred.
 - b. Staff monitor CPR approved projects during the first year and after if conditions are tied to the certificate, however, according to the CPR Procedure Manual, monitoring is "generally a low priority item because of the limited resources and the competing demands of new applications."

CPR Data

- Since 1988, the Board has reviewed a total of 157 applications. It approved a total of 143 (124 approved without conditions and 19 approved with conditions) and rejected a total of 14.
- Of those rejected, 5 CPR applications were for nursing homes, 3 were for cardiac catheterization services, 1 was for a foot center, 2 related to renal dialysis centers, 2 related to radiation therapy equipment, and 1 was for MRI equipment.
- The Medical Center of Delaware, Beebe Medical Center, Alfred I. DuPont Institute, St. Francis Hospital, and Christiana Care Health Services are the health care institutions that have most frequently applied for and received CPR approval since 1988.
- Christiana Care received CPR approval for a \$114.5 million expansion and renovation project at Christiana Hospital. That was the single highest capital expenditure approved by the Board.
- CON data shows changing trends within the health facility system from construction of traditional health facilities, such as hospitals, nursing homes, and clinics, to freestanding single or multi-specialty surgical centers. Close to 20 freestanding facilities have applied for and received CPR approval since the trend began in the mid-1990s.

CPR/CON Impact on Cost, Quality, and Access

The 1996 Health Care Commission report referenced earlier concluded that there was little evidence that CONs result in a reduction of costs, and some evidence to suggest the opposite. This conclusion holds true today. Research has conclusively stated that CON laws do not effectively control overall per capita

health spending or control hospital spending⁴⁸. Additionally, Michigan, Washington, and several other recent state CON studies reached the same conclusion as the Health Care Commission. It appears that CON programs across the nation have fallen short of reaching their goals of restraining health care costs.

Research regarding the effect of CONs, or the effect of repealing CONs, on quality and access has been inconclusive. Some studies show that CON programs control quality by serving a "gatekeeper" function, essentially screening an applicant's quality record or ability to meet certain financial and staffing conditions. CON laws also attempt to improve quality by increasing the volume of services, which should result in better outcomes (practice makes perfect). Many other studies suggest CON is unnecessary as a quality control mechanism because other more recognized methods of quality controls exist (i.e., facility licensure requirements, Medicaid/Medicare accreditations, Joint Commission on the Accreditation of Hospital Organizations certification, and patient satisfaction reports).

With respect to access, proponents argue CON laws can provide financial stability to existing providers by shielding them from competition, and therefore allow them to extend access to the more expensive uninsured or underinsured populations. On the flip side, as concluded in the DHCC 1996 report, CONs may have a beneficial impact on access, but it is relatively modest compared to other governmental interventions.

In a nutshell, CON does not restrain health care costs. Its impact on improving quality and access are questionable when compared to other quality and access driven policies or programs.

CPR/CON Impact on Charity Care

Delaware's Health Resources Board periodically attaches a charity condition to its grant of a CPR certificate. This condition requires that a CPR holder set aside 2.75% of its gross revenue for charity care and then submit a report to the Board after the end of each fiscal year showing total gross charges and the amount of charges foregone.

The Board acknowledges that recent reports from most applicants show that they were unable to meet the 2.75% goal. A Charity Care subcommittee is meeting to develop ways to better ensure Charity Care provisions are met each year by these facilities.⁴⁹

Other State CPR/CON Programs

Thirty-six (36) states have a CON program. The regulatory structures vary considerably from state to state with some states regulating as few as one or two categories of services (Ohio, Nebraska, and Louisiana) while other states regulate 25 or more categories of services (Hawaii, New York, Vermont, Alaska). Maryland regulates 16 categories of services and New Jersey regulates 11.50 Delaware regulates 8 categories (acute care, ambulatory surgery centers, cardiac catheterization, lithotripsy, long term care, Position Emission Tomography, radiation therapy, and birthing centers.)

Capital and medical equipment thresholds triggering CON review also vary from state to state. Florida has no thresholds for review---anything falling into one of its 11 categories of services is reviewed. Oklahoma and Arkansas capital thresholds are the lowest at \$500,000. Massachusetts has the highest capital threshold at \$10 million. Delaware's threshold is \$5 million.

⁴⁸ Conover, Christopher and Frank A. Sloan, "Does Removing Certificate of Need Regulations Lead to a Surge in Health Care Spending?, Journal of Health Politics, Policy, and Law, Vol. 23, No.3, June 1998; and other works cited in the State of Washington Joint Legislative Audit and Review Committee report 99-1, Jan. 1999.

⁴⁹ Sunset Questionnaire, pg. 9.

⁵⁰ 2004 Relative Scope and Review Thresholds, Thomas R. Piper, Missouri CON Program.

The remaining 14 states have repealed their CON programs (AZ, CA, CO, ID, IN, KS, MN, NM, ND, PA, SD, TX, UT, and WY). Most of the repeals occurred in the mid to late 1980s (PA and ND occurred in the mid-1990s). Generally, programs were repealed because the CON program lacked legislative and public support once federal dollars were discontinued, and because these states generally believed the CON program was an administrative burden with no proven ability to control health care costs.

The effects of CON repeal on a state's health care system depends on its specific characteristics and on the state's varying market interactions; however, there is a similar scenario among the 14 states who have repealed their CON programs: after repeal, states experienced an initial rush to construct nursing homes, hospitals, and psychiatric centers but a restructured health care market, i.e., the growth of managed care and other cost cutting initiatives created a competitive environment, which generally prevented any overbuilding because facilities unable to compete simply closed.⁵¹ Nonetheless, as a precautionary measure to guard against potential increases in Medicaid costs, many of these 14 states that had repealed the CON program instituted a moratorium on the construction of nursing home beds.⁵²

Pros and Cons of the CPR Program

Pros

- The CPR program offers an opportunity for public scrutiny of and participation in decisions regarding health care facilities and services.
- CPR criteria and guiding principles provide a method of deliberately considering the health care market and community in which a facility or service is planned.
- CPR provides a way of at least considering quality and access issues.
- Board member expertise and commitment have positively contributed to the health planning process in Delaware.
- CPR is a low-cost program for the state to administer. Its budget is less than \$100,000.

Cons

- Overall, the CPR program has had difficulty achieving its goals.
- CPR was created to restrain health care costs. Research and other states' experiences has proven it does not control per capita health care spending or hospital spending.
- Quality assurances have not been attainable because of insufficient staff resources to provide ongoing project monitoring.
- CPR impact on access has been negligible.
- The CPR program's charity care policy is not applied to all projects. For those that it does apply to, the policy's 2.75% goal has not been met.
- CPRs pose significant direct and indirect costs to the applicants (i.e., filing fees, application completion, consultations, and legal fees). This could make Delaware less competitive with other states, such as Pennsylvania, which does not require a Certificate of Need.
- Consider whether the program is necessary given that almost all project applications are approved (only 14 applications have been rejected over the past 16 years).

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⁵¹ NCSL, Health Policy Tracking Service Issue Brief, December 2003.

⁵² Ibid.

Joint Sunset Committee 2012 Final Report



Delaware Health Resources Board

A Report to the Governor and the 146th General Assembly of the State of Delaware

2012 Joint Sunset Committee Members

Rep. John A. Kowalko, Jr., Chair

Sen. George H. Bunting, Jr., Vice Chair

Rep. John C. Atkins

Rep. E. Bradford Bennett

Rep. Edward S. Osienski (Interim Member)

Rep. Michael Ramone

Rep. Daniel B. Short

Sen. Michael S. Katz, M.D.

Sen. David G. Lawson

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The Sunset Law in Delaware, Chapter 102 of Title 29, enacted in 1979, provides for the periodic legislative review of state agencies, boards and commissions. The purpose of sunset review is to determine if there is a public need for an agency, board or commission and, if so, to determine if it is effectively performing to meet that need. Typically, agencies are reviewed once every six (6) years.

The Joint Sunset Committee (JSC) is responsible for guiding the sunset review process. The JSC is a bipartisan committee comprised of ten legislators. Five senators are appointed to serve on the Committee by the Senate President Pro Tempore and five representatives are appointed to serve by the Speaker of the House.

Sunset reviews are generally conducted over a ten month period commencing in July. A comprehensive review of each agency, based on statutory criteria, is performed by the JSC analyst, who subsequently prepares a preliminary report for use by the Committee members during the public hearings, which take place in February each year. Public hearings serve as a critical component of this process, as they provide an opportunity for the JSC to best determine if the agency is protecting the public's health, safety and welfare.

At the conclusion of a sunset review, the JSC may recommend the continuance, consolidation, reorganization, transfer, or termination (sunset) of an agency, board, or commission. Although the JSC has sunset several agencies since its first reviews in 1980, the more common approach has been for the Committee to work with the entity under review to formalize specific statutory and non-statutory recommendations, with the goal of improving the entity's overall performance and government accountability.

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2012 Final Recommendations: Delaware Health Resources Board

The Joint Sunset Committee recommends the Delaware Health Resources Board be continued, provided the Board is meeting certain conditions and/or making certain modifications as identified below.

- 1. For administrative and budgetary purposes only, the Delaware Health Resources Board shall be relocated to the Office of the Secretary, Department of Health and Social Services. The Delaware Health Resources Board shall function in cooperation with the Delaware Health Care Commission, as well as other state health policy activities.
- 2. Amend 16 Del. C. § 9303 (c) as follows: The Delaware Health Care Commission and the Office of the Secretary, DHSS will be responsible for the administration and staffing for the Delaware Health Resources Board.
- 3. The total composition of the Delaware Health Resources Board shall be reduced from 21 members to 15 members. The membership shall be representative of all counties in the State. The remaining positions will be as follows: 4 members to represent the public at large; public members may include, but not be limited to, representatives from business, educational and non-profit organizations; 1 rep from DHSS recommended by the Secretary of DHSS; 1 rep of labor; 1 rep of a provider group other than hospitals, nursing homes or physicians; 1 rep involved in purchasing health care coverage on behalf of state employees; 1 rep involved in purchasing health care coverage for employers with more than 200 employees; 1 rep licensed to practice medicine in Delaware; 1 rep with knowledge and professional experience in health care administration; 1 rep with knowledge and professional experience in long-term care administration; 1 rep of the Delaware Health Care Commission; and 1 rep of the health insurance industry. 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. Members are appointed 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 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.
- **4.** Amend 16 Del. C. § 9303 (d) (1) to require that when revising the Health Resources Management Plan, the Board shall conduct a public hearing and shall establish rules and regulations published in accordance with the procedures specified in the Administrative Procedures Act (29 Del C. c. 101) for reviewing Certificate of Public Review applications•

- **5.** Amend 16 Del. C. § 9903 (d) (1) to reflect that the Health Resources Management Plan should be reviewed and approved by the Delaware Health Care Commission prior to submission to the Secretary of DHSS for final written approval.
- **6.** Amend 16 Del. C. § 9304 (1) to clarify that only for-profit acquisitions of a nonprofit health care facility are subject to the Certificate of Public Review process. Not-for-profit acquisitions of another nonprofit health care facility would not require a review.
- 7. Amend 16 Del. C. § 9303 to include a section as follows: 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.
- 8. The Delaware Health Resources Board, with assistance provided by DHSS and the Delaware Health Care Commission, shall conduct a comprehensive review of 16 Del. C. c. 93 and the Certificate of Public Review program. The focus of this government efficiency review should be aimed at streamlining operations, increasing efficiency, simplifying the application process and updating the categories for review. This review shall include, but is not limited to, the following: activities subject to a review; criteria considered during a review; procedures to review; timelines/deadlines for a review; feasibility of quarterly Board meetings; documents used by the Board; application fees and fee structure; strengthening the charity care requirements; consider publishing the list of equipment triggering a review through the regulatory process; consider adding assisted living communities to CPR process; consider IT capabilities and an increased online presence. The Delaware Health Resources Board shall report the key findings identified and make recommendations to the Joint Sunset Committee by January 1, 2013.
- **9.** The Delaware Health Resources Board shall review, and revise as needed, the conflict of interest definition enumerated in the by-laws. The Board shall develop guidelines for members to use when identifying and evaluating potential conflicts of interest. Additionally, the Board shall provide its members with the opportunity to participate in a Public Integrity Commission training session no less than once per year.
- 10. The Delaware Health Resources Board, with assistance provided by the Delaware Health Care Commission, shall undertake a comprehensive review of the Health Resources Management Plan and shall update the Plan to ensure that it supports the development of health services that are cost effective, consistent with meeting consumer needs and choice, and that the standards for a Certificate of Public Review are appropriate. Public hearings and forums should be held to solicit comment from all interested stakeholders and the public at large.
- 11. The Delaware Health Resources Board shall review and revise the current by-laws governing the Board to ensure consistency with 16 Del. C. c. 93; by-laws shall be updated accordingly.

12. The Delaware Health Resources Board shall develop a toolkit for the CPR process. The toolkit should include, but not be limited to, the Board by-laws, the revised CPR applications, an overview of the CPR process outlining what applicants can expect at each step in the process, the options available for applications to be reconsidered if denied, as well as a general timeline detailing the average time needed to complete each step in the process for applications to be approved or denied by the Board. Upon completion of the toolkit, the Board shall make these documents available to the public on the Board's website.

Agency History

In 1966, the federal government created the Comprehensive Health Planning Program through the enactment of Public Law (P.L.) 89-749. This legislation authorized federal support for health planning at both the state and local levels in an attempt to control unnecessary or duplicate hospital investment in plant and equipment. In 1972, the federal government subsequently enacted P.L. 92-603, commonly referred to as Section 1122, which amended the Social Security Act to include the Certificate of Need (CON) concept for reimbursing capital expenditures due to the increase in costs of Medicaid, Medicare, and other health service programs. ¹

The inadequacies of the Comprehensive Health Planning Program as well as the ineffectiveness of Section 1122 provisions combined with the redundancy of other federally funded programs consequently led Congress to develop a consolidated planning program that required each state to establish a mandatory CON process. This legislation, P.L. 93-641, passed in the latter part of 1974 and established a national system of local and state planning agencies that required a majority of members to be consumers.²

The 1980 presidential election saw a change in administration, which ultimately resulted in limited funding for the CON program through continuing resolutions. Eventually all financial support was stopped, effectively abolishing the program in 1986 in favor of competition in the health care market place.³

Following the demise of the federal law and with the renewed interest in local health planning and volunteerism in some states, the 1985 recommendations of the Health Care Cost Management Commission, which was created pursuant to an executive order issued by then Governor Michael Castle, were enacted through Senate Bill 132 and became law on July 2, 1987. This legislation established the state-only CON program with the Health Resources Management Council (HRMC).⁴

In 1993 the Sunset Committee sunset the HRMC, allowing a year to wrap up business before June 30, 2004. This period was extended by epilogue language until September 20, 1994. House Bill 331 enacted in September 1994, established the Delaware Health Resources Board (HRB) and provided a June 30, 1996 sunset date. Following the review of the CON program by the Delaware Health Care Commission (DHCC) in July 1996, House Bill 640 was enacted which provided for the phase out of CON and a sunset date of June 30, 1999. House Bill 640 also increased the threshold which would require a review.⁵

Senate Bill 74, enacted on June 24, 1999, replaced CON with Certificate of Public Review (CPR) and delayed the sunset date until June 30, 2002. SB 74 also eliminated several categories of providers from the process of review, permitted members of the HRB to serve for more than two consecutive terms, required reviews for all acquisitions of a nonprofit health care facilities,

¹ JSC Questionnaire, Pg. 8

² JSC Questionnaire, Pg. 8

³ JSC Ouestionnaire, Pg. 8

⁴ JSC Questionnaire, Pg. 8

⁵ JSC Questionnaire, Pg. 8

and added language to make explicit that a failure to comply with conditions which may be placed on the Board's approval of an application is grounds for revocation.

In 2002, the sunset provision was extended to 2005. In accordance with the May 31, 2005 Final Report by the Joint Sunset Committee, the sunset date was further extended to June 30, 2009.

On July 8, 2009, Senate Bill 181 was signed into law, removing the sunset provision on the Delaware Health Resources Board-Certificate of Public Review program.

Joint Sunset Committee Review History

The Joint Sunset Committee (JSC) commenced a review of the HRMC in 1992. The JSC concluded in its 1993 Final Report that there was a need to develop a comprehensive health planning process and that the various commissions, councils and boards responsible for health planning should be brought under one umbrella for the purpose of centralizing health planning decisions. To date, this recommendation has not been implemented.

The JSC further agreed that the CON program and a regionally based health care planning process should be part of the state's comprehensive health plan. It therefore sunset the HRMC and with the passage of House Bill 331, initiated an overhaul of the CON program. Specifically, House Bill 331 established the HRB to assume the functions of the HRMC as the state's overseer of the CON process and made changes to CON policies. It vested the final CON decision making power solely with the Board rather than the previous policy in which the Bureau of Health Planning and Resources Management made final decisions based on HRMC recommendations. Additionally, the bill abolished the CON Appeals Board.

The JSC in its May 31, 2005 HRB Final Report made a number of recommendations, some of which were implemented through Senate Bill 181 and others which were implemented by Bureau of Health Planning and Resources Management staff. For example, Senate Bill 181 increased the dollar amount that triggers a review from \$5 million to \$5.8 million and provided the HRB with the authority to establish a charity care requirement. Staff carried out JSC recommendations to create and maintain a CPR website to facilitate public access to agendas, minutes, the CPR application and procedures.

The JSC also recommended that the HRB comply with the statutory requirement to coordinate health planning activities with the Delaware Health Care Commission (DHCC), DHSS and other health care organizations. This is partly achieved by Bureau of Health Planning and Resources Management staff attendance at DHCC meetings, and DHSS Office of Health Facilities Licensing and Certification staff attendance at HRB meetings. More importantly, coordination of HRB work with the DHCC, DHSS and other health care organizations is achieved through membership on the HRB. In early May 2011, in recognition of the need to coordinate health planning activities, Governor Markell appointed the chairperson of DHCC, the Director of the Division of Services for Aging and Adults with Physical Disabilities, as well as individuals representing hospice and the nursing profession to serve on the HRB.

Composition of the Health Resources Board

The HRB consists of 21 members appointed by the Governor. Members are appointed for three year terms and shall represent all three counties. Members appointed to a position which has been vacated prior to the end of the previous member's term shall be appointed to serve the remaining portion of the unexpired term.

The membership structure of the HRB is intended to facilitate communication among various interest groups and state agencies.⁶ Ten (10) Board members represent the public at large and cannot be involved in the delivery of health care, health care insurance or the purchasing of health care coverage for an employer with more than 200 employees.⁷

The statute stipulates that the remaining eleven (11) members represent the following: 8

- 1 representative designated by the DHCC
- 1 representative designated by the Secretary of DHSS
- 1 representative of organized labor
- 1 representative of the health insurance industry
- 1 representative designated by the Delaware Healthcare Association
- 1 representative designated by the Medical Society of Delaware
- 1 representative designated by the Delaware Health Care Facilities Association
- 1 representative of a provider group other than hospitals, nursing homes, or physicians
- 1 representative designated by the State Chamber of Commerce
- 1 representative involved in purchasing health care coverage on behalf of state employees
- 1 representative involved in purchasing health care coverage for employers with more than 200 employees.

Chairperson and Other Officers

The Governor designates a Chair and Vice Chair for the Board from among those members representing the public at large.

The Director of the Bureau of Health Planning and Resources Management in the Division of Public Health (DPH) serves as both the Secretary to the Board and Chief Administrative Officer.⁹

Removal of Members

The statute does not have express language in regards to removing members from the HRB. A member can resign their position or request not to be reappointed upon the expiration of their term. The Governor can also decline to reappoint a member whose term has expired.

⁶ JSC Questionnaire, Pg. 17

⁷ 16 Del. Code, § 9303(b)

⁸ 16 Del. Code, § 9303(b)

⁹ 16 Del. Code, § 9303 (c)

The Board's bylaws state that the HRB may request that the Governor declare a vacancy for any member who is absent from four consecutive meetings upon the recommendation of the membership. 10

Compensation and Training

Members may be reimbursed for mileage associated with their duties as Board members.¹¹ HRB members receive no additional compensation for their service.

Board members do not receive any special training opportunities; however, a survey of the HRB members was conducted in September 2011 to identify assets on the Board, with the intent to provide programmatic opportunities in which members' knowledge and expertise are shared for overall development.¹²

Health Resources Board Membership Roster

Name County/Porty	Appointment Date	Term	Expiration Date	Ovelification/Occupation
County/Party	Date	Term	Date	Qualification/Occupation
Veronica F. Rempusheski, PhD, RN, FAAN, FGSA- New Castle/	05/02/2011	1	05/02/2014	Chair- Public At Large/ Professor, Chair of Nursing Science & Coordinator, College of Health Sciences, U of D
Harold Stafford Kent/Democrat	07/01/2011	1	07/01/2014	Vice Chair- Public At Large rep/ CEO at Stafford Firm; Former DOL Secretary
Bettina Riveros New Castle/Democrat	05/02/2011	1	05/02/2014	Health Care Commission rep/ Chair DHCC, Advisor to Governor
William Love New Castle/	05/21/2011	1	12/31/2011	DHSS rep/ Director, Division of Services for Aging & Adults with Physical Disabilities
David Hollen New Castle/ Democrat	10/28/2011	1	12/31/2011	Organized labor rep/ Red Zone Properties, LLC
Vacant				Health Insurance Industry rep
Suzanne Raab-Long New Castle/Independent	04/19/2004	2	11/13/2010	DE Healthcare Association rep/ Executive Vice President, DHA

¹⁰ Bylaws of the Delaware Health Resources Board, Article IV, Section 7

¹¹ JSC Questionnaire, Pg. 29

¹² JSC Questionnaire, Pg. 29

Yrene Waldron New Castle/	05/13/1999	3	12/31/2011	DE Health Facilities Association rep/ Executive Director, DHFA
Sheila Grant New Castle/ Democrat	05/02/2011	1	05/02/2014	Provider Group rep (i.e. not hospitals, nursing homes or physician)/ Hospice Nurse Educator & VP of Hospice & Palliative Care of DE
Mark Thompson Kent/Republican	09/13/2011	1	12/31/2011	Medical Society of DE rep/ Manager of Community Relations & External Affairs Officer
Faith Rentz Kent/Democrat	04/25/2008	1	08/30/2008	State Employee Coverage rep/ Senior Health Policy Advisor, OMB
Brian Posey New Castle/Republican	05/26/2011	1	05/26/2014	Chamber of Commerce @ Large rep/ Associate State Director, AARP DE
Bedford Bruno Kent/Independent	07/05/2011	1	07/05/2014	Coverage for employers with more than 200 employees rep/ Director, Personal Care Products, Playtex at Energizes
John Walsh Sussex/Democrat	05/02/2011	1	05/02/2014	Public at Large rep/ VP, DE Manufactured Home Owners Association
Carolyn Casey New Castle/Democrat	07/01/2011	1	07/01/2014	Public at Large rep/ Director, Community Development & Housing Division NCC
Kyle Hodges New Castle/Democrat	09/13/2011	1	12/31/2011	Public at Large rep/ Director, State Council for Persons with Disabilities
Brenda Heckert Sussex/Republican	10/28/2011	1	01/05/2012	Public at Large rep/ Improvisational Performer
Gina Ward New Castle/Democrat	01/05/2012	1	05/02/2014	Public at Large rep/ St. Francis Hospital Board of Directors
Sarah Noonan New Castle/Democrat	10/26/2007	1	10/26/2010	Public at Large rep/ Deputy Director, Westside Family Healthcare

Vacant		Public at Large rep
Vacant		Public at Large rep

There are currently 3 vacancies on the Board for the following positions: 13

- Health Insurance Industry representative: Vacated 04/30/09
- Public at Large representative: HRB staff is unsure when position was vacated
- Public at Large representative: HRB staff is unsure when position was vacated

In recent years, the HRB has averaged approximately six (6) vacant positions at any given time. These vacancies have included both the designated positions and the public at large representatives. Historically, there have been very few issues with members appointed to the Board who do not regularly attend the meetings, as absences usually occurred due to a Board member's illness.¹⁴

Health Resources Board Meetings and Subcommittees

Per Article IV, Section 2 of the HRB bylaws, regular meetings of the Board will usually be held once a month; however, if there is no business to be conducted by the Board during a particular month the chairperson may cancel or postpone a meeting, provided the HRB will meet no less than four (4) times per year. ¹⁵

Article IV, Section 3 of the bylaws stipulates that the chairperson may call a special meeting at any time. Also, a special meeting shall be called by the chairperson upon the written request of any eleven (11) HRB members. ¹⁶

The Board also has the authority to create committees, task forces and work groups as outlined in Article 5, Section I in the HRB's bylaws. Members of these committees, task forces and work groups shall be appointed by the chair and may include persons who are not members of the HRB.¹⁷

Freedom of Information Act (FOIA) Compliance

The Health Resources Board is FOIA compliant. All meetings are open to the public and agendas include time for public comment. Meeting agendas are distributed by email to interested parties via a distribution list which is maintained by the Bureau of Health Planning and Resources Management. Agendas are also posted on the HRB website and the state's online Public Meeting Calendar. Tentative agendas are posted one week before each monthly meeting, with a disclaimer that they are subject to change. Minutes are developed by the staff of the Bureau of Health Planning and Resources Management and are available to the public on the web and by request as soon as they are approved by the Board. The public also has access to a variety of

¹⁴ Email from Judy Chaconas, received 12-7-11

¹³ JSC Questionnaire, Pg. 26

¹⁵ Bylaws of the Delaware Health Resources Board, Article IV, Section 2

¹⁶ Bylaws of the Delaware Health Resources Board, Article IV, Section 3

¹⁷ Bylaws of the Delaware Health Resources Board, Article V, Section 1

materials posted on the HRB website, including a description of the program, the governing statute, guiding principles, relevant reports, agency membership, the application kit, monthly activity reports and various other materials.

The Bureau of Health Planning and Resources Management within DPH promptly responds to all FOIA requests on behalf of the HRB. All documents delivered to or created by the Board are considered public information, with the exception of legal advice that is provided by the Department of Justice and is considered attorney-client privileged information. ¹⁸

The Board has entered in to executive session one time during the past three years; however, the Board does not deliberate in closed sessions. On September 16, 2011, in accordance with 29 Del. Code, §10004 (b)(4), the Board entered into executive session to receive legal advice from the Deputy Attorney General on the matter of the HRB being listed as appellee in the Notice of Appeal of the Board's decision on the application from HealthSouth Corporation.¹⁹

Administrative Procedures Act Compliance

The HRB is not expressly covered by the Administrative Procedures Act (APA), as it is not listed in 29 Del. C. § 10161 (a). However, the HRB is statutorily required to implement the APA through its regulation changes as required pursuant to 29 Del. C. § 10161(b). Nonetheless, the HRB follows the APA guidelines for hearings and case decisions and the assigned Deputy Attorney General provides guidance on these processes.²⁰

Public Integrity Act Compliance

Every meeting agenda includes a "Conflict of Interest" item, at which time HRB members are asked to declare any conflict of interest that they may have with respect to the business scheduled to be heard and/or discussed by the Board at that particular meeting.

Article IV, Section 8 of the Board's bylaws defines conflicts of interest, with specific provisions regarding financial benefits for HRB members and/or their immediate family. If a HRB member and/or their immediate family could benefit financially from participating in the consideration of certain business before the Board, that member has an obligation to recuse themselves from those proceedings.

Janet Wright, Executive Director of the Public Integrity Commission (PIC) made a presentation and led discussion at the Board's November 12, 2009 meeting. At that time, the members were instructed on how to comply with Public Integrity Act outlined in 29 Del. Code, Chapter 58. Additionally, members of the HRB have had individual consultations with the PIC's Executive Director and a Board member recently sought an official opinion from the PIC regarding a potential conflict of interest. ²¹

¹⁸ JSC Questionnaire, Pg. 14

¹⁹ JSC Questionnaire, Pg. 14

²⁰ JSC Questionnaire, Pg. 13

²¹ JSC Questionnaire, Pg. 15

Conflicts of interest do not usually hinder the ability for action to be taken on applications under consideration by the Board. However, two (2) HRB members have regularly expressed uncertainty as to what constitutes a conflict of interest. ²² One (1) member sought advice from the Executive Director of the PIC, and subsequently requested a formal opinion from the PIC on the same matter. The second HRB member has remained uncertain as to if/when they have a conflict and has asked for another presentation by the PIC before the Board. Ultimately, HRB staff anticipates that questions regarding conflicts of interest will likely re-occur in the future. ²³

There have been two (2) instances in the past three (3) years when the declaration of a conflict of interest prevented action from being taken on application that was scheduled to be heard at a specific meeting. Both instances were during the meeting held June 23, 2011, and were in regards to the HealthSouth application. As a result, two (2) votes were taken during the course of the meeting which resulted in a tie, with seven (7) members supporting the application and seven (7) members opposing. Later the PIC ruled that one HRB member, who had recused themselves from participating in the consideration of the HealthSouth application and whose request for a formal opinion from the PIC was pending at that time, could have voted on the application; however, the advice previously given by the PIC Executive Director on this issue differed from the subsequent ruling by the PIC. It is possible that had the other HRB member who had also recused themselves in regards to the HealthSouth application sought a ruling from the PIC, that member also could have voted. However, because of the uncertainly, and to err on the side of caution, neither voted during the June 23, 2011 meeting.²⁴

Health Resources Board Staff

Staff support for the HRB is provided by the Bureau of Health Planning and Resources Management in the Division of Public Health.

Public Health Administrator I (FT merit employee)

The public health administrator functions as the Director of the Bureau of Health Planning and Resources Management and, hence, Secretary and Administrative Officer to the Health Resources Board. This position ensures that HRB records and activities are recorded and filed, minutes and agendas are prepared, pertinent materials are distributed to committee members, etc. The position directs the review of applications, provides staff expertise on the CPR process, and ensures accuracy of the program mechanics. This position is funded with 100% federal appropriations received through a primary care grant.²⁵

Management Analyst III (FT merit employee)

The full-time management analyst reviews applications for technical completeness, collects information from applicants needed to assure applications are complete prior to review by the Board, staffs review committee and Board meetings, helps prepare minutes, conducts research for use by the Board in evaluating applications and prepares review committee reports. The

²² Email from Judy Chaconas, received 12-7-11

²³Email from Judy Chaconas, received 12-7-11

²⁴Email from Judy Chaconas, received 12-7-11

²⁵ JSC Questionnaire, Pg. 32

position provides staff expertise on the CPR process and helps ensure accuracy of the program mechanics. ²⁶

Management Analyst III (PT casual seasonal employee)

The casual seasonal management analyst tracks the approximately \$35,000 allocated for the program using revenue funds generated by fees collected by DPH. These funds are used for meeting refreshments, transcriptions services when needed, production of annual utilization statistical reports on Delaware nursing homes, assisted living facilities, rest residential facilities, mileage reimbursements, and other incidental costs.²⁷

Administrative Assistant I (FT merit employee)

The administrative assistant is responsible for maintaining files and tracking the multiple processes and deadlines associated with Board activities. This position is also responsible for working with Board members and the public to identify dates/locations for review committee meetings and board meetings, as well as other logistical arrangements. ²⁸

The effectiveness of the HRB has been hampered by a lack of staff assistance as the program has been downsized significantly over the years. ²⁹ Program staff members routinely communicate about three issues: ³⁰

- 1) Insufficient resources to ensure that HRB-CPR activities are appropriately recorded and managed.
- 2) Difficulty in conducting analytical research to aid the Board's decision making.
- 3) Use of federal primary care and rural health grant funds to support staff assigned to the HRB; this is not within the scope of services for which these funds are appropriated to Delaware and it diminishes the ability to focus on improving primary care and rural health.

²⁶ JSC Questionnaire, Pg. 31

²⁷ JSC Questionnaire, Pg. 31-32

²⁸ JSC Questionnaire, Pg. 32

²⁹ JSC Questionnaire, Pg. 32

³⁰ JSC Questionnaire, Pg. 32

Fiscal Information

Total operating costs for the HRB were \$170,174 in FY 2009, \$166,055 in FY 2010, and \$170,165 in FY 2011. Expected costs for FY 2012 are \$175,250.³¹ Expenditures by line item for FY 2012, FY 2011 and FY 2010 are provided in the table below.³²

FY 2012 Expenditures (Budgeted)		FY 2011 Expenditures (Actual)		FY 2010 Expenditures (Actual)	
Salaries/Fringe	\$72,738	Salaries/Fringe	\$72,063	Salaries/Fringe	\$70,079
Mileage	\$1400	Mileage	\$1297	Mileage	\$874
Other Prof Services	\$6000	Other Prof Services	\$626	Other Prof Services	\$0
Postage	\$600	Postage	\$462	Postage	\$490
Phone	\$1980	Phone	\$1980	Phone	\$1970
Computer	\$480	Computer	\$480	Computer	\$480
Advertising	\$1500	Advertising	\$1348	Advertising	\$114
Food	\$550	Food	\$812	Food	\$950
Subscription	\$638	Subscription	\$638	Subscription	\$138
Total:	\$85,886	Total:	\$79,706	Total:	\$75,095

Revenue is generated through the collection of filing fees for capital expenditure applications. All filing fees collected are deposited into the General Fund. Within five (5) working days of determining that an application is complete, the Bureau will notify the applicant of any filing fee due. Filing fees are due 30 days after the notification date for the beginning of the review and may be extended up to ten (10) additional days at the discretion of the Bureau. Applications for which the filing fee has not been paid within this timeframe are considered to be withdrawn. Below is a table outlining the capital expenditure application filing fees, for which the current fee amounts have been in place for more than 23 years.³³

Capital Expenditures	Filing 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

The total revenue generated from the filing fees was \$10,000 in FY 2009, \$17,500 in FY 2010 and \$45,000 in FY 2011. The projected revenue for FY 2012 is \$6,000, and includes one actual fee in the amount of \$3,000, as well as an anticipated fee of \$3,000 related to a letter of intent. Further projection is not feasible due to the lack of correlation between past and future submission of applications.³⁴

The Evaluation of Delaware's Certificate of Public Review Program conducted in November 2008 found that Delaware's revenue from CPR application fees significantly lags behind that of

³² JSC Questionnaire, Pg. 34-35

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³¹ JSC Questionnaire, Pg. 34

³³ 16 Del. Code, § 9305 (10)

³⁴ JSC Questionnaire, Pg. 36

other states. Upon the completion of that evaluation, the HRB was presented with several options to revise the fees; however the Board took no action at that time. In 2010, the Board reviewed another proposal to increase the fees and again did not take any action on this issue.³⁵

Per information provided by the HRB, the fee amount and structure needs to be updated and revised. The fees should be increased to cover the cost of operations, including staff positions and contractual needs. Legislative involvement and approval is necessary to revise the fees. ³⁶

Purpose, Goals and Organization

As stated in 16 Del. Code, §9301, the purpose of the HRB is to assure that there is continued 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.

The goal of the HRB is 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. ³⁷ Pursuant to 16 Del. Code, §9303 (c), HRB is constituted as an independent public instrumentality and is housed within the Bureau of Health Planning and Resources Management in DHSS for administrative and budgetary purposes only. However, effective November 1, 2011, the Bureau of Health Planning and Resources Management moved to the Director's Office in DPH. DPH Director Dr. Karyl T. Rattay, in announcing the change on October 13, 2011, wanted to help bring greater visibility and direction to one of the strategic priorities of the Division, health reform. While a new mission and vision for this Bureau is under development, it will likely include the promotion of prevention in the delivery of health care services, as well as coordinating health reform initiatives that are occurring elsewhere in the Division. ³⁸

Duties and Responsibilities

The duties and responsibilities of the HRB, pursuant to 16 Del. Code, \S 9903 (d) (1) – (6), are listed in italics below, with detailed information immediately following in regards to how the Board is meeting each of the statutorily mandated duties and responsibilities:³⁹

1) Develop a Health Resources Management Plan which shall address the supply of health care resources, particularly facilities and medical technologies, and the need for such resources.

HRB maintains a Health Resources Management Plan, last updated March 6, 2010, which includes the current supply and projected need for hospital beds and nursing home beds. It also includes a formula for determining the need for freestanding surgery centers. The methodology

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³⁵ JSC Questionnaire, Pg. 38

³⁶ JSC Questionnaire, Pg. 38

³⁷JSC Questionnaire, Pg. 16

³⁸ JSC Questionnaire, Pg. 6

³⁹ JSC Questionnaire, Pg. 20-21

used is largely based on the state's bed-to-population ratio and takes into account age-specific utilization rates, occupancy rates and predicted future population growth. The Board has identified new areas to be addressed in the Health Resources Management Plan and provides an opportunity for and consideration of public comment through the conduct of a public meeting. The statute requires the plan to then be submitted to the DHCC for review. Finally, it is sent to the Secretary of DHSS upon whose signature the Plan becomes effective.

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.

The CPR is a document issued to a successful applicant authorizing the proposer organization/individual to undertake the project that has been determined to be in the best interest of the community. Per the information provided by the HRB, CPRs are necessary in order to control the increase in health care costs while striving to ensure the availability of and access to high quality and appropriate health care services. 40

3) Gather and analyze data and information needed to carry out the Board's 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.

This work is done by Bureau staff for the Board or by Board members.

4) Address specific health care issues as requested by the Governor or the General Assembly.

To date, the Board has not received any requests to address specific health care issues from the Governor or the General Assembly.

5) Adopt bylaws as necessary for conducting its affairs.

The Board has bylaws for conducting its business and operates in compliance with both the provisions set forth in 29 Del. C. c. 58 and 29 Del. C. c. 100. The bylaws were last updated June 28, 1999.

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

Prior to the adoption of the Health Resources Management Plan, the Board coordinated with the DHCC. The Board sends the Health Resources Management Plan to DHSS for approval before adoption by the Board. The Board coordinates activities with other groups such as the Delaware Health Care Association, informally and through its membership structure.

Changes to the bylaws and the governing statute have not officially been proposed at this time; however, the bylaws should be reviewed to ensure consistency with the statute. For example, the

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⁴⁰ JSC Questionnaire, Pg. 20-21

bylaws currently limit the number of terms a member can serve, while term limitations are not addressed in the governing statute.⁴¹

There is an on-going conversation about the need to either discontinue or make significant changes to the HRB - CPR program. If continued, the Health Resources Management Plan should also be reviewed and updated along with other relevant documents (application kit, statutorily set list of health facilities subject to review, the review criteria and process of review, fee structure, etc.).⁴²

DHSS believes the HRB and the CPR process should be components of a comprehensive health planning system in Delaware. DHSS is interested in working with the HRB to review the current Health Resources Management Plan to determine if the plan supports the development of health services that are cost effective and are consistent with meeting consumer needs and choice (e.g. the growing consumer demand for home-based services).⁴³

Per the information provided in the JSC questionnaire, the Governor also recognizes the need to make sure the HRB has all its members appointed and that the Board needs to retain its vitality over time. Consistent with this, the Governor has recently made several new appointments, which will bring new ideas and skills the Board needs.⁴⁴

CPR Review Process

A CPR is required for the following activities:⁴⁵

- The construction, acquisition, development, or other establishment of a health care facility or the acquisition of a nonprofit care facility.
- Any expenditure by or on behalf of a health care facility, not including a medical office building, in excess of \$5,800,000, which is considered a capital expenditure. Expenditures in excess of \$5,800,000 may be exempt from review if they are necessary to maintain the physical structure of a facility and are not directly related to patient care.
- 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 one physical or site to another) by more than 10 beds or is more than 10% of total licensed bed capacity, whichever is less, over a 2-year period.
- The acquisition of major medical equipment; does not include the replacement of major medical equipment nor major medical equipment acquired by a business or industrial establishment for a dispensary or first aid station, for use by students, employees of a school or university or by inmates and employees of a prison.

⁴¹ JSC Questionnaire, Pg. 10

⁴² JSC Questionnaire, Pg. 10

⁴³ JSC Questionnaire, Pg. 10

⁴⁴ JSC Questionnaire, Pg. 10

⁴⁵ JSC Questionnaire, Pg. 39

Notice of Intent/Applications for Review

At least 30 days prior to submitting an application, applicants are required to submit a notice of intent in regards to the scope and nature of the project to the Bureau of Health Planning and Resources Management. Applications can be submitted less than 30 days from the submission of the notice, with the written approval by the HRB. A notice of intent expires if an application is not received within 180 days. 46

Deadlines and Time Limitations

Upon receipt of an application, the Bureau has a maximum of fifteen (15) days to notify the applicant as to whether or not their application is considered complete. ⁴⁷ If incomplete, applicant will be notified as such and will be advised of the additional information that is required to complete the application. ⁴⁸

Agency Review/Notification

Within five (5) working days after determining an application is complete, the Bureau will provide written notification of the beginning of a review. Notification shall be sent directly to all health care facilities and all others who request direct notification. A notice is also placed in the newspaper which also serves as both the public notice and the official date of notification. ⁴⁹ Applications are required to be reviewed within 90 days of notification. If a public hearing is requested, the review period is extended to 120 days. The HRB may also extend the review period up to 180 days to allow for the development of appropriate review criteria or to facilitate the simultaneous review of similar applications. The maximum review period can be extended as mutually agreed to in writing by the Board and the applicant. ⁵⁰

In conducting reviews, the Board considers the following:⁵¹

- (1) The relationship of the proposal to the Health Resources Management 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.
- (4) Including alternatives involving the use of resources located outside the state.
- (5) The relationship of the proposal to the existing health care delivery system.
- (6) The immediate and long-term viability of the proposal in terms of the applicant's access to financial, management and other necessary resources.
- (7) The anticipated effect of the proposal on the costs of and charges for health care.
- (8) The anticipated effect of the proposal on the quality of health care.

⁴⁶ 16 Del. Code, § 9305 (1)

⁴⁷ 16 Del. Code, § 9305 (3)

⁴⁸ 16 Del. Code, § 9305 (3)

⁴⁹ 16 Del. Code, § 9305 (4)

⁵⁰ 16 Del. Code, § 9305 (3)

⁵¹ 16 Del. Code, § 9306

With respect to applications submitted to address an emergent situation, the Chair or Vice Chair of the HRB is authorized to render a decision stating if the application is a true emergency and if the application will or will not be approved. The Chair or Vice Chair shall have discretion with respect to the decision making process and is required to render a decision within 72 hours.⁵²

Public Hearing in the Course of a Review

Within ten (10) days after the date of notification, a public hearing can be requested by any person in writing. A public hearing notice will be published in the newspaper, and the hearing will take place within fourteen (14) days of the publication. Any person is permitted to speak at the public hearing.⁵³

Findings

Upon the completion of an application review, the Bureau shall notify the applicants and other interested parties in writing regarding the HRB's decision, including the basis on which the decision was made. Decisions can be conditional (e.g. requirements for a charity care policy, participation in the Delaware Medicaid Program, sliding fee scale for indigent uninsured patients, etc.) but the conditions must be related to the specific project in question.⁵⁴

Administrative Reconsideration/Appeal

Requests for administrative reconsideration must be received within ten (10) days of the Board's decision and any hearing for the purposes of reconsideration must commence within 45 days of the request. In order for an administrative hearing to be granted, a person must show there is new evidence to consider that previously was not available which significantly changes the factors the Board relied upon to render its decision, or prove that the Board did not follow the established protocol set forth in the governing statute or bylaws.⁵⁵

A decision by the HRB following the review of an application may be appealed within 30 days to Superior Court. Such appeal shall be on the record. As currently written, and upheld by the courts, the statute limits the right of appeal to the applicant.⁵⁶

CPR-Period of Effectiveness

A CPR shall be valid for one (1) year from the date such approval was granted. At least 30 days prior to the expiration of the CPR, the applicant shall inform the Board in writing of the project's status. The Board will determine if sufficient progress has been made for the CPR to continue in effect. If sufficient progress has not been made, the applicant may submit a request in writing to the Board for a six (6) month extension. The HRB 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 16 Del. Code, § 9305(8).

⁵² 16 Del. Code, § 9305 (3)

⁵³ 16 Del. Code, § 9305 (6)

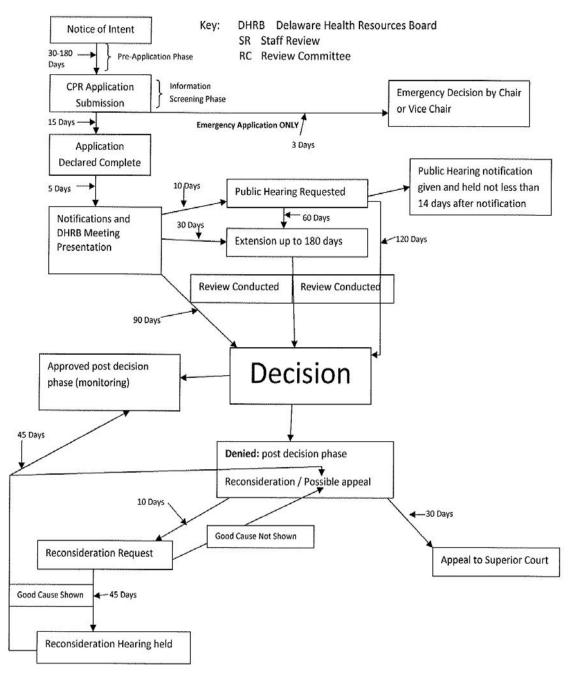
⁵⁴ 16 Del. Code, § 9305 (5)

⁵⁵ 16 Del. Code, § 9305 (7)

⁵⁶ JSC Questionnaire, Pg. 42

⁵⁷ JSC Questionnaire, Pg. 41

CPR Review Process



I:\BHPRM\DHRB\Flow Chart CPR Process\2011 Algorithm Document\CPR Review Process 9-27-11 ks.doc

CPR Program Data

	2008	2009	2010	2011
Notice of Intent Letters Receiv	ed			
Construction, development or other establishment of health care facility	0	2	2	1
Acquisition of a nonprofit health care facility	0	0	1	0
Capital Expenditures in excess of \$5.8 million	1	1	0	1
Change in bed capacity	0	2	2	3
Acquisition of major medical equipment	1	0	2	1
Applications Received				
Construction, development or other establishment of health care facility	0	1	1	2
Acquisition of a nonprofit health care facility	0	0	0	0
Capital Expenditures in excess of \$5.8 million	1	1	0	1
Change in bed capacity	0	0	2	3
Acquisition of major medical equipment	1	0	1	0
Public Hearings Requested				
Construction, development or other establishment of health care facility	0	0	0	1
Acquisition of a nonprofit health care facility	0	0	0	0
Capital Expenditures in excess of \$5.8 million	0	0	0	0
Change in bed capacity	0	0	0	0
Acquisition of major medical equipment	0	0	0	0
Applications Approved	•			•
Construction, development or other establishment of health care facility	0	0	2	2
Acquisition of a nonprofit health care facility	0	0	1	0
Capital Expenditures in excess of \$5.8 million	1	1	0	0
Change in bed capacity	0	0	2	1
Acquisition of major medical equipment	1	0	1	0
Applications Denied				
Construction, development or other establishment of health care facility	0	0	0	0
Acquisition of a nonprofit health care facility	0	0	0	0
Capital Expenditures in excess of \$5.8 million	0	0	0	0
Change in bed capacity	0	0	0	0
Acquisition of major medical equipment	0	0	0	0
Requests for Administrative Reconsi	deration			
Construction, development or other establishment of health care facility	0	0	0	1
Acquisition of a nonprofit health care facility	0	0	0	0
Capital Expenditures in excess of \$5.8 million	0	0	0	0
Change in bed capacity	0	0	0	0
Acquisition of major medical equipment	0	0	0	0
Appeals filed in Superior Cou				
Construction, development or other establishment of health care facility	0	0	0	1
Acquisition of a nonprofit health care facility	0	0	0	0
Capital Expenditures in excess of \$5.8 million	0	0	0	0
Change in bed capacity	0	0	0	0
Acquisition of major medical equipment	0	0	0	0

CON/CPR Programs in Other States

Currently, there are 14 states without and 36 states with a CON/CPR program. The states without a CON/CPR program rely on the free market as well as licensure and regulations to ensure quality. Business entities establish new facilities, expand existing ones and purchase medical equipment at their own risk. Licensing does slow growth, as it can take months and sometimes years to be surveyed, pass inspection and become licensed. In Idaho, it can take up to two (2)

years before a new nursing home is inspected and Minnesota currently has a moratorium on nursing homes. ⁵⁸ If there is a critical need for a certain type of facility in a particular location, such a facility may float to the top of the inspection list, which is part of the licensure process, while others wait in line. Some states issue a Request for Applications when there is a critical need for a particular type of facility. ⁵⁹

In Pennsylvania, CON activities were transferred to the state's licensure and regulations divisions in 1996; however licensure and regulations divisions do not get involved in need analysis. Instead, the hope is that entities have evaluated how they are going to secure enough patients to be successful.

In the state of Washington, the Ninth Circuit Court of Appeals has lent some credibility to a lawsuit filed by a hospital against the state's Department of Health. The lawsuit alleges that a CON regulation unreasonably burdens interstate commerce and so violates the Constitution's "dormant" Commerce Clause, which grants Congress authority to regulate interstate commerce, thereby limiting the ability of states to do so. In the decision issued August 22, 2011, the court of appeals ruled state certificate of need regulations will be struck down as unconstitutional if they impose more than an incidental burden on interstate commerce. After the ruling, the case was sent back to district court where the hospital will have the burden of proving that the state's disputed CON regulation imposes a burden on interstate commerce that is clearly excessive in relation to the putative local benefits of such regulation. ⁶⁰

A research brief released in May 2011 found that various stakeholders from states with CON programs across the country thought their state's program tended to be influenced heavily by political relationships. This held true for every state, with the exception of Michigan. Respondents from Michigan cited several elements of the state's CON apparatus that contribute to greater objectivity and transparency. Michigan divides responsibility for setting CON review standards and the actual review of CON applications between an appointed commission and the State Department of Community Health, respectively. The commission members include representatives of hospitals, physicians, health care providers, employers and labor. Researchers also cited Michigan with having the most systematic approach to evaluating and updating CON requirements. The appointed CON commission evaluates the review standards for modification on a three-year rotating schedule and has the authority to recommend revisions to the list of covered clinical services subject to CON review. Finally, Michigan recently shifted to an electronic filing system, and the response to this was overwhelmingly positive because of increased transparency and efficiency of the process overall. 61

Reviews/Audits of Delaware's CON/CPR Process

In 1996, the DHCC put forth a recommendation, which resulted from the *Evaluation of Certificate of Need and Other Health Planning Mechanisms* report by the Cost Containment Committee, to eliminate the CON program in gradual phases. The review concluded that

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⁵⁸ JSC Questionnaire, Pg. 46

⁵⁹ JSC Questionnaire, Pg. 46

⁶⁰ Court Holds Certificate of Need Laws May Be Unconstitutional by Douglas Ross & Charles White, 8/23/11

⁶¹ Health Care Certificate-of-Need Laws: Policy or Politics? By Tracy Yee, Lucy Stark, Amelia Bond, Emily Carrier- May 2011

sufficient evidence did not exist to demonstrate that CON contains costs. The effort to eliminate the CON process failed, as the hospital association lobbied for its continuation. Instead, legislation was passed that changed the program from a CON to a CPR and increased the dollar amount threshold that triggers a CPR from \$750,000 to \$5.8 million. Additionally, the activities subject to review were somewhat reduced as well. 62

The *Delaware Certificate of Public Review Policy Options Review*, dated November 2008, provided information needed by DPH in the formation of an opinion to share with the JSC on how to manage the impending sunset of the CPR program. The following abbreviated list of recommendations is the product of the 2008 review:⁶³

- Recommendation 1: DHSS should propose legislation that allows for a two year review of health planning systems for the purpose of devising a plan for a fully coordinated and comprehensive health planning process.
- Recommendation 2 (Option A): If CPR is to be continued, it is recommended that a mechanism for determining system costs be devised. Lowering thresholds for CPR is one way to move toward this goal.
- Recommendation 2 (Option B): If CPR is discontinued, some mechanism needs to be devised for assuring consumer access to medical health care "goods" and that some procedures should be rendered in high-volume environment should be considered.
- Recommendation 3: If CPR is maintained, consider extending CPR to services, not facilities and technology, and add assisted living as a reviewed service.

Secondary Recommendations included:⁶⁴

- Recommendation 5: Close the loop-hole which allows for adding other specialties on to a single specialty certificate.
- Recommendation 6: Mandate annual updates to Health Resource Board Plan with population trends, inpatient and outpatient utilization data, and cost analyses.
- ➤ Recommendation 7: A sub-group should immediately be convened to study nursing home capacity and make recommendations to stimulate capacity so that consumer choice and quality is more likely to occur.

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⁶² JSC Questionnaire, Pg. 47

⁶³ JSC Questionnaire, Pg. 23

⁶⁴ JSC Questionnaire, Pg. 23-24

CON/CPR Programs: Pro vs. Con

>	Some believe that health care is not like other businesses that can be regulated by market forces alone. A large portion of health care services are paid for by the government. The government does not pay market prices and not every line of health care services is profitable, thus market forces alone do not always allocate health resources appropriately or equitably. 65	À	Others believe that market competition will have a positive influence on containing costs and improving the quality of care. There is a move toward consumers purchasing health savings accounts with larger deductibles, leading to increased price awareness and sensitivity, as well as an interest in improved transparency of health care costs. 66
A	There is a general perception that the CPR Program may have a "sentinel effect" by discouraging new service providers who might otherwise be tempted to build health care facilities in Delaware if they knew they did not have to undergo the CPR process and the agency's scrutiny. ⁶⁷	A	The CPR Program has a history of approving almost every application that comes before it. In the past five years there have been no denials. ⁶⁸
<i>\(\)</i>	Some believe that the CPR Program could be used as a tool to limit the number of nursing homes in the state of Delaware. ⁶⁹	>	Elimination of the agency would have a positive impact on the ability of the DHSS/Division of Public Health to carryout activities designed to improve the delivery of preventive and primary care and focus on health system change, including the development of medical homes. ⁷⁰
>	For-profit acquisitions of not-for-profit health care facilities also may be discouraged by the CPR Program's existence. ⁷¹	A	Staff assigned to the CPR Program would be able to devote their time to working on health care reform, primary care and prevention. 72
A	Very recently, the Board has begun using the CPR Program to make significant changes to the health system by attaching conditions to the approval of applications (e.g. charitable care requirements, coordinated outreach, etc.).	A	It has long been known that the fees do not cover the salary of staff designated to support the Board nor do they cover the cost of contractual research that could be provided, if funds were available, to inform Board decisions. ⁷⁴

⁶⁵ JSC Questionnaire, Pg. 45

⁶⁶ JSC Questionnaire, Pg. 45 67 JSC Questionnaire, Pg. 45

⁶⁸ JSC Questionnaire, Pg. 47

⁶⁹ JSC Questionnaire, Pg. 46

JSC Questionnaire, Pg. 51
 JSC Questionnaire, Pg. 47

⁷² JSC Questionnaire, Pg. 51

⁷³ JSC Questionnaire, Pg. 47

⁷⁴ JSC Questionnaire, Pg. 38

A	The CPR process provides an opportunity for the public to become aware of and weigh in on major health care developments. This is particularly evident during the review of contested applications (e.g. the establishment of a surgery center in Seaford and an inpatient rehabilitation hospital in Middletown.).	A	In 1996, the DHCC's Cost Containment Committee reviewed the Delaware CON Program and recommended that the program be phased out. The review concluded that sufficient evidence does not exist to demonstrate that CON contains costs. 76
>	There is concern that elimination of CON would result in a surge of new health facilities, including freestanding surgery centers, and that Delaware hospitals would face increased competition from for profit hospitals. ⁷⁷	A	Research conducted in regards to the success of CON/CPR Programs has been inconclusive, and often produced disparate findings. ⁷⁸
>	There is research evidence that the death rate among patients who have cardiac surgery is higher in states without certificate of need. This is because the certificate of need process can help to keep such procedures in high volume hospitals. ⁷⁹	>	CON Programs tend to be influenced heavily by political relationships, such as provider's clout, organizational size, or overall wealth and resources, rather than policy objectives. ⁸⁰
^	Some experts have concluded that CON/CPR regulations do protect access to safety net hospitals and access to care in rural communities. ⁸¹	>	Hospitals typically view CON/CPR regulations opportunistically and are more likely to use this process to block competitors. 82
A	CON Programs set standards for project planning, which helps to ensure access to care and quality standards. 83	A	Most physicians likely view the CON process as overly restrictive, delaying access to the most advanced equipment and making it difficult to recruit top-tier specialists. ⁸⁴

Complaints

A formal complaint would be presented in the form of an appeal of a decision by the Board. Appeals are managed by the Department of Justice and the courts. In the last three years, the Board has not received any written complaints from applicants or members of the public.⁸⁵

Recently, an attorney for an applicant shared their concerns that the CPR program, including the process for having an application deemed complete and the review process itself, required too much detail and was too lengthy. ⁸⁶

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75 JSC Questionnaire, Pg. 50
76 JSC Questionnaire, Pg. 24
77 JSC Questionnaire, Pg. 50
78 Health Care Certificate-of-Need Laws: Policy or Politics?, Pg. 2
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In addition, the ruling on voting on an application that resulted in two (2) tie votes generated confusion and complaints. Using a "new standard" for achieving a quorum (majority of 21 statutory members, as opposed to appointed members) has also resulted in verbal complaints, from an applicant and Board members.

Accomplishments

Per the HRB, below is a list of the three most significant accomplishments of the Board:⁸⁷

- HRB historically has taken pride in its ability to review and make decisions on detailed applications within timelines set forth in the statute with the intent of achieving the best possible outcomes for Delawareans. The process is often very difficult as the Board must review not only the information provided by the applicants but also conduct its own independent research so as to assess the full impact of a proposed project on the broader effort to ensure access to a high quality, cost efficient health care system.
- Development of a Charity Care Policy and Charity Care Implementation Requirements for freestanding health care facilities and incorporation of these materials into the Health Resources Management Plan.
- Development of Freestanding Surgery Center "need" criteria, and incorporation of such into the Health Resources Management Plan.

Challenges

Per the HRB, below is a list of the top challenges the Board is currently facing:⁸⁸

- The statute calls for the Director of the Bureau of Health Planning and Resources Management to function as the Secretary to the Board and its Chief Administrative Officer. The individual in this position is funded 100% with federal funds through the Primary Care Services Resource Coordination and Development Grant. Ideally, this individual would spend the bulk of their time working on activities to improve the delivery of primary care and on health prevention activities. Instead, 85-90% of her time is consumed by activities to support the CPR program and the HRB. Similarly, the administrative specialist assigned to the Board is fully funded with federal grant funds provided to Delaware for other purposes. More staff and/or funding are also needed to develop analytic reports, develop methodology to determine need and perform other activities for the Board to inform its decision making.
- As a statutory Board of 21 members, achieving a quorum requires 11 members. Recusals do not count toward a quorum. The Board's bylaws state that the "presence of at least 50 percent of the members of the Board shall constitute a quorum," and the Board has

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⁸⁷ JSC Questionnaire, Pg. 17- 18

⁸⁸ JSC Questionnaire, Pg. 18-19

interpreted this to mean 50 percent of appointed members. Decisions on applications in the past have been made using the definition of quorum in the bylaws; however, a recent opinion by the Deputy Attorney General clarified that a majority of the statutory members is needed to meet the quorum requirement.

- The statute lists a minimum of seven (7) factors that must be considered during the review of an application. In some cases the items are difficult to assess. For example, Review Criteria #6 is the "anticipated effect of the proposal on the costs of and charges for health care." This is of critical importance given the present cost of health care; however it is challenging to gauge and there is much debate over whether the establishment of a health service will increase the demand for a service, and thereby increase health care costs and charges. There is also significant discussion regarding the role of competition in the marketplace. Review Criteria #7 requires the Board to consider the "anticipated effect of the proposal on the quality of health care", which is also difficult to gauge and ideally is assessed through licensure, inspection and accreditation.
- 16 Del. Code §9305 (8) has been interpreted by the courts to mean that only an applicant can appeal a Board decision.
- There is a technical error in 16 Del. Code, §9304 (1), which lists the type of activities subject to review including "the acquisition of a nonprofit health care facility." The historical purpose of this clause was to assure that for-profit acquisitions of not-for-profit facilities were reviewed, but not not-for-profit acquisitions of another not-for-profit. The thinking behind this was that for-profit facilities are mostly interested in making a profit and may not be as focused on charitable care or community benefit as a not-for-profit. However, several years ago it was determined by a Deputy Attorney General that technically all acquisitions of not-for-profits were subject to review.

Opportunities for Improvement

Per the HRB, below is a list of possible opportunities for improvement:⁸⁹

- Additional staff resources are needed to meet the responsibilities of the Board, including the need to develop analytic reports for the Board to inform its decision making. Also, effort should be made to identify staff persons whose budget positions are funded by General Funds or increase application filing fees to cover the operations which include the salaries of staff positions that support the CPR program and the Board. The fees have never been increased and pursuant to 16 Del. Code §9305 (10), all filing fees are deposited into the General Fund.
- Evaluate the purposes of the CPR program, the activities that are subject to review and the review criteria considered during the course of a review. Revise as necessary to assure that the CPR program supports and is in synch with the state's health policy goals.

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⁸⁹ JSC Questionnaire, Pg. 19

- Appoint members to fill the vacancies on the Board. There has been discussion about reducing the size of the HRB; however, it has also been noted that the current composition set forth in statute is carefully balanced, with eleven (11) members designated by organizations and ten (10) members representing the public at large.
- Revise the timelines and deadlines in the statute to enable the Board to meet quarterly instead of monthly. Procedures to review, including deadlines and time limitations in the statute, currently require the HRB to meet monthly in order to conduct business in a manner that is in compliance with the law.



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CPR Procedures

- 1. Applicant files Notice of Intent, found within the CPR Application Kit.
- Applicant files application. When application is determined to be complete, there is notification of the beginning of the review (Public Notice, etc.).
- 3. At the first meeting of the Delaware Health Resources Board after an application is determined complete, there is an overview presentation by the applicant and an opportunity for questions. At this meeting the application is assigned as a staff review or a Review Committee is appointed.
- 4. If a public hearing is requested, this is conducted by Review Committee.
- 5. Review Committee meets with the applicant and deliberates as necessary to formulate a recommendation to the Board.
- 6. Review Committee report is submitted to the Board. The Board makes the decision.
 From the date of notification referred to in step 2 above, generally the maximum review period is 90 days. There are exceptions, such as a public hearing is requested or it is mutually acceptable to the Board and the applicant.



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Delaware Health Resources Board

The Delaware Health Resources Board (HRB) Certificate of Public Review (CPR) program, like other national Certificate of Need (CON) programs, originated to regulate the number of beds in hospitals and nursing homes and essentially prevent excessive purchasing of expensive equipment. Per the Joint Sunset Committee 2012 Final Report the Delaware Health Resources Board (HRB) transitioned from the Division of Public Health to the Department Health and Social Services, Office of the Secretary, the Delaware Health Care Commission (HCC). The HCC provides the administration and staffing for the board and the CPR program which is regulated through the Delaware Code 16 Del. Code 9301 . The primary goal for the CPR process is to control health care cost through a formal review process used to ensure public scrutiny of certain health care developments in the state. These reviews are focused on balancing concerns for access, cost and quality. A Letter of Intent begins the CPR process and interested applicants will find the entire process, start to finish, on this website.

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Featured News

- Health Resources Management Plan (HRMP) Final Draft incorporating public comments, as approved by the Health Care Commission on July 6, 2017.
 - Public comments derived from the Registrar of Regulation process.
- · Delaware Regulations: Monthly Register of Regulations: Delaware Health Resources Management Plan.

Certificate of Public Review Application Information

- · Health Resource Management Plan (Printable PDF)
- Guiding Principles
- CPR Procedures
- · Requirements for a CPR
- · Major Medical Equipment
- · CPR Criteria
- Letter of Intent Submission Form
- CPR Application Kit
- Application Fees
- · Frequently Asked Questions

State Board Regulatory Information

- Title 16 Statute
- · HRB Board Members
- · Board Bylaws
- · Board Meeting Schedule
- · Board Minutes, Agendas & Notices
- · Other Resources and Helpful Links
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Reports and Publications

- Monthly Activity Reports
- · Nursing Home Utilization Statistics Reports
- Assisted Living Utilization Statistics Reports
- Meeting Presentations
- CPR Application Decisions
- · Annual Reports







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Guiding Principles

The following general principles are intended to assist potential Certificate of Public Review (CPR) applicants in understanding the Board's expectations and also to assist the Board itself in conducting CPR reviews, particularly in matters where specific guidelines are lacking.

- The essential challenge faced by the Board is striking an appropriate balance in its consideration of access, cost and quality of care issues. Evidence that this challenge has been seriously embraced by the applicant should permeate every CPR application.
- The problem of medical indigency is extremely complex. The Delaware Health Care Commission continues
 to provide leadership in this area. CPR applicants are expected to contribute to the care of the medically
 indigent.
- Historically, health care delivery has too often been episodic and disjointed. Projects which support a
 managed, coordinated approach to serving the health care needs of the person/population are to be
 encouraged.
- Given Delaware's small size and close proximity to major metropolitan referral centers, particularly in Philadelphia and Baltimore, every health care service need not be available within its borders. Potential CPR applicants are expected to take into account the availability of out-of-state resources.
- · Historically, our cost-based reimbursement system has provided little incentive for financial restraint; over-





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CPR applicants are expected to take into account the availability of out-of-state resources.

- Historically, our cost-based reimbursement system has provided little incentive for financial restraint; overutilization has been encouraged. Revenue centers, not cost centers, were generally emphasized. Projects which reflect or promote incentives for over-utilization (including self-referral) are to be discouraged.
- Strengthening market forces is a central theme in the health care reform strategy adopted by the Delaware Health Care Commission, a theme which is embraced by the Board. Projects resulting from or anticipated to enhance meaningful markets are to be encouraged. In the past, "competition" has often been on the basis of amenities for physicians (the medical arms race) and patients (the plushest waiting room). In meaningful markets there must be a sensitivity to elements of both cost and quality.
- Prevention activities such as early detection and the promotion of healthy lifestyles are essential to any
 effective health care system. The Choose Health Delaware State Health Care Innovation Plan identifies a
 number of opportunities to improve the health status of Delawareans. The potential for a project to bring
 about progress in these areas will be viewed as a very positive attribute.



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Requirement for a Certificate of Public Review

In Delaware, a Certificate of Public Review (CPR) is required for 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, not including a medical office building, in excess of \$5,800,000, which is considered a capital expenditure. Expenditures in excess of \$5,800,000 may be exempt from review if they are necessary to maintain the physical structure of a facility and are not directly related to patient care.
- 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 one physical or site to another) by more than 10 beds or is more than 10% of total licensed bed capacity, whichever is less, over a 2-year period.
- 4. The acquisition of major medical equipment; does not include the replacement of major medical equipment nor major medical equipment acquired by a business or industrial establishment for a dispensary or first aid station, for use by students, employees of a school or university or by inmates and employees of a prison.



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Major Medical Equipment

Title 16, Chapter 93 of the Delaware Code requires that a Certificate of Public Review be obtained prior to the acquisition of "major medical equipment." This requirement is irrespective of whether the acquisition is made by a "health care facility."

Major medical equipment is defined as follows:

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:

- 1. 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;
- 2. Represents medical technology which is not yet available in Delaware; or
- 3. Represents medical technology which has been designated by the Board as being subject to review.

The following medical technologies have been designated by the Delaware Health Resources Board as being subject to review per (3.) above:

- · Cardiac Catheterization
- · Megavoltage Radiation Therapy
- · Extracorporeal Shock Wave Lithotripsy
- · Positron Emission Tomography (PET)

os://dhss.delaware.gov/dhss/ddds/





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CPR Criteria

Certificate of Public Review Statute

As stated in the 16 Del. Code §9301, the purpose of the HRB is to assure that there is continued 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. Through the efforts of the HRB, the state focuses on balancing concerns for cost, access, and quality that is in the best interest of Delawareans. In conducting reviews under the HRMP, the HRB must consider seven (7) statutorily mandated criteria:

- 1. Relationship of the Proposal to the Health Resources Management 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;
- 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 on the Proposal on the Costs of and Charges for Health Care;
- 7. and The anticipated effect of the proposal on the quality of health care.





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Certificate of Public Review Application Fees

Certificate of Public Review applications must be accompanied by an application filing fee. Pursuant to Chapter93 Health Planning and Resources Management, §9305, application fees shall be determined from the following table:

Capital Expenditures	Application Fee
Less than \$ 500,000	\$100
\$500,000 to \$999,999	\$750
\$1,000,000 to \$4,999,999	\$3000
\$5,000,000 to \$9,999,999	\$7500
\$10,000,000 and over	\$10,000

Filing fees shall be due 30 days after the date of notification of the beginning of review as covered under §9305 subdivision (4). 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. Make checks payable to: Treasurer, State of Delaware and remit to the Delaware Health Care Commission, 410 Federal Street, Suite 7, Margaret O'Neill Building, Third Floor, Dover, DE 19901



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Frequently Asked Questions(FAQs)

1. What activities are subject to Certificate of Public Review?

The activities subject to review are: The construction, development or other establishment of a health care facility or the acquisition of a nonprofit health care facility; Any expenditure by or on behalf of a health care facility in excess of \$5,800,000, or some greater amount; 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; 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. For more information visit the HRB website at: www.dhss.delaware.gov/dhss/dhcc/hrb/cprphome.html.

2. How do I file a Certificate of Public Review application?

Notice of Intent must be submitted at least 30 days but not more than 180 days prior to submitting an application. The Notice of Intent and CPR Application can also be found within the CPR Application Kit.

3. What is the entire process for submitting a Certificate of Public Review application and how long does it take?

Notice of Intent starts the process and must be filed first followed by a subsequent application. The CPR process and deadlines/time limitations can be found in the Title 16 Statute at delcode.delaware.gov/title16/c093/index.shtml.

4. What are the application fees to file a CPR application?

The application fees to file an application are:

Capital Expenditures

- Less than \$500k = \$100
- \$500k 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





5. How are the applications determined?

The applications are reviewed in accordance to review considerations pursuant to Title 16 Statute §9306.

6. Who do I contact to find out information about my Certificate of Public Review application?

To find out information about your application please contact the Health Resources Board Staff at the Delaware Health Care Commission or call 302-739-2730.

7. How do I obtain a copy of a CPR application filed by other facilities?

You can obtain a copy of a CPR application filed by contacting the Health Care Commission's office at 302-739-2730.

8. Are Assisted Living Facilities subject to the Certificate of Public Review process?

No, Assisted Living Facilities are not subject to the CPR process. More information on activities subject to review can be found at: delcode.delaware.gov/title16/c093/index.shtml.

9. How do I withdraw a CPR application?

To withdraw a CPR application, please submit the request in writing to the Delaware Health Care Commission, Health Resources Board, 410 Federal Street Suite 7, Margaret O'Neill Building, Dover, DE 19901.

10. Where do I submit my documentation to file a Certificate of Public Review application?

Documentation to file a Certificate of Public Review application can be submitted to the Delaware Health Care Commission, Health Resources Board, 410 Federal Street Suite 7, Margaret O'Neill Building, Dover, DE 19901.



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Certificate of Public Review Statute

All HRB correspondence, forms and applications* should be sent to the Delaware Health Care Commission/Delaware Health Resources Board at the following address:

Delaware Health Care Commission

Delaware Health Resources Board Margaret O'Neill Building 410 Federal Street, Suite 7 Dover, Delaware 19901

*Application submissions require one (1) hard copy of the completed application via USPS, FedEx or UPS with an <u>original signature</u>, plus one (1) electronic version (CD).

Phone, Fax and Email Contact: Main Office: (302) 739-2730 Fax: (302) 739-6927

Email*: DHCC@delaware.gov

HRB Staff from the Health Care Commission:

Latoya Wright: Latoya.Wright@delaware.gov
 Manager of Statistics and Research

Elisabeth Massa: Elisabeth.Massa@delaware.gov

Executive Director

Letter of Intent

NOTICE OF INTENT CERTIFICATE OF PUBLIC REVIEW

1.	Name of Applicant:
2.	Address:
3.	Telephone: Fax: Email:
4.	Person to Contact:
5.	Type of Ownership:
	 () Public () Proprietary (Individual) () Private Non-profit () Proprietary (Partnership) () Proprietary (Corporation)
6.	Anticipated Date of Filing Application:
7.	Estimated Capital Expenditure: \$
8.	Please attach a brief Narrative (one page or less if possible) which describes the project.
9.	STATEMENT OF CERTIFICATION:
	The statements and information provided herein are true and correct to the best of my knowledge and belief.
	Signature of Chief Executive Officer Date