Delaware Health Resources Board Health Management Plan's Public Hearing

Main Administration Building

Conference Room 2CR

Herman M Holloway Sr. Health and Social Services Campus

1901 North Dupont Highway New Castle DE 19720

June 29, 2026



Agenda

I: OPENING COMMENTS

II: HEALTH RESOURCES MANAGEMENT PLAN REVISION

III: PUBLIC COMMENT

IV: ADJOURN

HEALTH RESOURCES MANAGEMENT PLAN

Health Resources Management Plan (HRMP) Revision

- Pursuant to 16 Del. C. §§ 9301 and 9303, the Department of Health and Social Services, Delaware Health Care Commission, Delaware Health Resources Board, is proposing amendments to the Health Resources Management Plan (HRMP).
- The proposed amendments update the HRMP to conform to changes made to 16 Del. C. Chapter 93 by House Bill 17 of the 153rd General Assembly, which amended the Certificate of Public Review program. Language in the HRMP that is no longer consistent with current statutory requirements is removed.
- House Bill 17 repeals the requirement that a person must apply for a certificate of public review prior to the acquisition of major medical equipment. A certificate of public review may still be required if the acquisition meets the capital expenditure threshold under § 9304(a)(2) of Title 16.
- The proposed changes to the HRMP can be reviewed on the Registrar of Regulations website in the June monthly issue.



PUBLIC COMMENT

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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 Chair

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DELAWARE HEALTH RESOURCES BOARD

Certificate of Public Review

Health Resources Management Plan

Adopted/Effective: September 11, 2017

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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.

5. <u>The acquisition of major medical equipment where total capital expenditure as defined in Section 2 (above) falls below the capital expenditure threshold.</u>

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 to16 *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 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 income-tested 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) ÷ 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)**
PCF = [(113.170) ÷ (100.00)] = 1.132					
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
	1 0 0 . 0 0				11 3.1 70

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 acute care bed need by dividing projected ADC by an occupancy factor of 75% [(Projected Bed Need) = (Projected ADC) ÷ .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 days x 3 years = 1,095 days). [(Base Period ADC) = (Base Period Patient Days) ÷ 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)
PCF = [(107.00) ÷ (100.00)] = 1.07					
Females age 15-44	100.00	X	1.07	=	107.00

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.

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

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				114

PCF = [(114.42) ÷ (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).

[(Projected Bed Need) = (Projected Average Daily Census) ÷ (0.90)]

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 podiatrist 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 x B x 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 x 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 provider 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.~~

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THANK YOU

