

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DELAWARE HEALTH CARE COMMISSION
DELAWARE HEALTH RESOURCES BOARD
Statutory Authority: 16 Delaware Code, Section 9303 (16 Del.C. §9303)

FINAL

ORDER

Delaware Health Resources Management Plan

The Department of Health and Social Services, The Delaware Health Resources Board (The Board) initiated proceedings to adopt a revised Health Resources Management (HRMP) regulation pursuant to 16 Del.C. §9303(d)(1). The Board published its notice of the revised regulation in the November 1, 2016 Delaware *Registrar of Regulations*. A public hearing was held on December 5, 2016 in which public comments were accepted through January 5, 2017

SUMMARY OF FINAL AMENDMENT

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. The revised edition of the HRMP promotes the alignment of Delaware's existing health planning framework with statewide policy aimed at promoting health system improvement. There were no substantive changes to the revised HRMP regulation as a result of the comments received. Therefore, the Board is publishing the HRMP as final.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE AND EXPLANATION OF CHANGES

The Delaware Health Care Association, Delaware Surgery Center, St. Francis Hospital and Post Acute Medical LLC submitted comments and suggestions. The Board has considered each comment and responds as follows:

Comment 1: Section II, Activities Subject to CPR Review, No. 2, Page 6: apply the annual inflation adjustment to the \$5.8 million capital expenditure.

Response: The Board appreciates and acknowledges this comment. The Board will review the capital expenditure threshold amount at a future date.

Comment 2: Section II, Activities Subject to CPR Review, No. 4, Page 6: why isn't major medical equipment in an inpatient rehabilitation facility (IRF) not subject to review? The reference to an IRF should be deleted.

Response: The Board appreciates and acknowledges this comment. This requires a statutory change in which the Board is unable to change in regulation. The Board will review in a future revision.

Comment 3: Section III, CPR Application Procedure, Step 1, Page 8: the sentence 180 days following the data, the word data should be changed to date.

Response: Revised as recommended.

Comment 4: Section III, CPR Application Procedure, Steps 1-9, Page 8: there needs to be an additional step identified as to when copies of the application will be made available to the public. Once the application is made available, then the timeframe for requesting a public hearing should be identified. Recently, public hearings have had to be requested and impacted parties have to make their case without even knowing what is being proposed in the application, because they could not obtain a copy. There should be a requirement that the State will make copies available within a certain timeframe (currently it takes several weeks) and, based on that, set the timetable for the public hearing.

Response: The Board appreciates and acknowledges this comment. Modifications will be made in the application kit to clarify the application process for applicants.

Comment 5: Section III, CPR Application Procedure, Step 10, Page 10: the phrase or impacted party should be added after an applicant. Appeals should not be limited to just the applicant.

Response: The Board appreciates and acknowledges this comment. Revisions have been made based upon the Board's final decision and vote clarifying that an appeal can be made by any party.

Comment 6: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 11: related guiding principles, we are not sure incorporating the related guiding principles into the statutory criteria really works in this section or in others. The guiding principles do not necessarily direct the applicant as to what they need to provide the Board

and they do not necessarily tie cleanly to the statutory criteria. We would suggest keeping the related guiding principles separate and more clearly articulating what is expected from the applicant.

Response: The Board appreciates and acknowledges this comment; however, revisions will not be made. The statutory criteria (SC) and guiding principles (GP) incorporate similar Triple Aim themes.

Comment 7: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 11: the additional requirement of having to identify the names of all key professional, administrative, clinical and direct services personnel and their CVs is impractical and unlikely to add much to the application except extra paper. Since the service is proposed, it is unlikely that the staff have been hired. If personnel are identified, there is a decent likelihood they will change by the time the service is implemented. COPR is about the need for the service, not the specific individuals that will be involved.

Response: The Board appreciates and acknowledges this comment. Revisions have been made based upon the Board's final decision and vote clarifying applicants must provide a list of administrative, clinical, leadership and other positions related to the proposal as necessary.

Comment 8: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 12: section IV that outlines the Common Review Considerations for a Certificate of Public Review addresses the need of the population for the proposed project. Post-Acute believes that the efficiency of the process will be enhanced if the Plan provides guidance to applicants on how best to substantiate bed need rather than leaving the methodology solely to the discretion of each applicant.

Response: The Board appreciates and acknowledges this comment; however, the Board agrees that estimating Delaware's future health care needs cannot be accomplished solely with the precision of mathematical formulae. As such, the Board decided to consider calculations in conjunction with statutory criteria and guiding principles. The applicant(s) must prove the need.

Comment 9: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 12: suggest adding to the end of the sentence, or another reputable source (e.g., Bureau of the Census, Claritas). DE Pop. Consortium data projects at the County level but does not project at the zip code level. It is rare that the service area in an application is defined as the County but the surrounding zip codes routinely define more.

Response: Revisions have been made to include the U.S. Bureau as a reputable source.

Comment 10: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 13: the phrase beginning including evidence until the end of the sentence should be replaced with the impact on those parties. We do not know that the fact that the project has been discussed with impacted parties has any bearing on the consideration of the application. It may give the appearance implication that since the application was discussed with the impacted party, that there is some sort of agreement or support of the project by the impacted party. Also, the phrase if such information is available should be added to the end of the last line. The information requested is not necessarily publicly available.

Response: Revisions have been made based upon the Board's final decision and vote clarifying that each proposal should provide information about alternative providers of the proposed service, referencing the specific provider 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.

Comment 11: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 13: the word that and phrase for the applicant should be deleted. The words are not additive to the requirement. The second sentence should be deleted as duplicative of the first.

Response: Revised as recommended.

Comment 12: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: individual charges should be defined or rephrased or the sentence should be deleted. Does the State want to know what the list charges will be for the service, the expected reimbursement, or the expected out-of-pocket cost to the patient?

Response: Revisions have been made based upon the Board's final decision and vote clarifying the applicant will demonstrate how the application will impact cost and charges to the individual(s) for health services.

Comment 13: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: each proposal shall describe how the applicant intends to transition from a traditional fee for service reimbursement model to a payment model that embraces value-based payments with a goal of fostering better clinical outcomes across the community, providing patient-centered care and lowering the total cost of care.

Response: The Board appreciates and acknowledges this comment. The HRMP has a section on alignment with the State Health Care Innovation Plan. Applicants should refer to this section.

Comment 14: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: third paragraph, meaningful market should be defined.

Response: Revisions have been made based upon the Board's final decision and vote clarifying projects resulting from or anticipated to enhance meaningful markets that ensure appropriate/adequate coverage, access and quality that is affordable are to be encouraged.

Comment 15: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: the sentence beginning in the past, should be deleted as non-additive.

Response: Revisions have been made based upon the Board's final decision and vote to delete the words in the past, but keep the remainder of the sentence.

Comment 16: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: the first paragraph should be restructured or deleted. It is not clear what the direction is for the applicant to respond. It is better to be clear as to what the State wants from the applicant. What is asked for in the second paragraph does not necessarily tie to what is discussed in the first paragraph.

Response: Revisions have been made based upon the Board's final decision and vote clarifying the applicant shall satisfactorily demonstrate how the proposal will impact the financial strengths of the health care system.

Comment 17: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 14: the second paragraph, the references to cost-effectiveness should be deleted as duplicative of statutory criteria six.

Response: Revised as recommended.

Comment 18: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 15: in section B, while there are calculated need methodologies for Nursing Homes, Hospitals and Freestanding Surgery Centers (FSSC), there are no such methodologies for IRFs, even though plenty of need methodologies exist in other States. It is suggested that there should be a calculated need methodology for this service.

Response: The Board appreciates and acknowledges this comment and will review in a future revision.

Comment 19: Section IV. Certificate of Public Review (CPR) Common Review Considerations, Page 15: we suggest replacing sufficient with definitive or all encompassing.

Response: Revisions have been made to the language based upon the Board's final decision and vote clarifying the project-specific mathematical need calculations represent a necessary, but not always sufficient or all-encompassing component of the CPR decision-making process.

Comment 20: Section V. Charity Care Policy, Page 16: we suggest deleting the word original and changing were to are. The sentence references original goals implying that those goals have changed, however there is nothing in this section showing any revised goals.

Response: Revised as recommended.

Comment 21: Section V. Charity Care Policy, Page 16: we recommend that charitable care include Medicare and Medicaid shortfalls. This inclusion would be consistent with Federal reporting and would reinforce, from a public policy perspective, the benefits that non-profit hospitals and others provide when caring for these populations. This approach is also consistent with the statutory purpose of the Board to support indigent care as provided in 16 Del.C. §9303.

Response: The Board acknowledges and appreciates this comment; however, Medicare and Medicaid shortfalls will not be included in charitable care.

Comment 22: Section V. Charity Care Policy, Page 17: it would be helpful to identify the actual minimum Medicaid utilization level established by the Board and incorporate that number into the plan. Currently, we are unaware that the Board has established a minimum number. The other option is to delete the phrase established by the Board.

Response: The Board appreciates and acknowledges this comment and will review in a future revision.

Comment 23: Section VII. CPR Application: Document Property Guidelines, Page 21: we believe that reducing the page limits, especially given that the Plan seeks even more information and detail than the last Plan., statutory criteria 1 requires more information on the narrative and background of the project. The project specific need criteria have added quality measures included documented plans of action for each one, detailed explanations of all assumptions used for population, utilization, payer mix and financial projections. The appendices are only allowing 10 pages but letters of support and CVs of every person involved with the proposed service are to be submitted which would easily exceed 10 pages. The page count table does not include the requirements of the Charity Care Policy, which will also add volume to the application. To suggest that the length of the applications should be limited while asking for more information from the

applicant is nonsensical.

Response: The Board appreciates and acknowledges this comment; however, changes will not be made to this section.

Comment 24: Section VII. CPR Application: Document Property Guidelines, Page 21: the second bullet point under NIH guidelines, we believe type density and margin guidelines may be too specific to address something that may not be a problem. Tables or a series of bullets may all fit on one page with a .7" bottom margin vs. split on two pages with a 1" margin where the reader may have to flip back and forth to understand the information.

Response: The Board appreciates and acknowledges this comment; however, changes will not be made to this section.

Comment 25: Section VIII. Acute Care, Page 26: quality measures, we are not sure if the State's interest is in the actual results of the quality measures, or the documented plans of action that serve to prevent, identify, diagnose and control the measures. This section does not ask the applicant's results. It wants plans for each of the 10 measures. This appears to be unnecessary additional paperwork for an audience that is primarily non-clinical. We suggest a better route may be for the applicant to share their actual results and to identify any steps it is taking to improve scores that are below average performance.

Response: The Board appreciates and acknowledges this comment. Revisions have been made based upon the Board's final decision and vote clarifying the applicant will include documented plans of action and -when applicable to provide actual results and identification of steps to improve scores and requiring applicants make available copies of reports that are required and submitted to regulatory entities. Any further changes will be considered in future revisions of the plan.

Comment 26: Section IX. Obstetric Care (Hospital- Based), Page 29: the paragraph that begins with the words the above methodology, this sentence summarizes tenets of statistical theory but does not elaborate why the applicant should use the numbers that it is required to use. The explanation in the existing Jan. 2014 Health Resources Management Plan provides a much cleaner explanation. We suggest using the language in the 2014 Plan. Further, there is no explanation as to why Kent and Sussex have a 95% Confidence Interval but New Castle County requires a 99% confidence interval. We suggest having a consistent confidence interval.

Response: The Board agrees that there should be a consistent confidence interval of 95% in all three (3) counties. Revisions have been made to adopt a 95% confidence interval.

Comment 27: Section IX. Obstetric Care (Hospital- Based), Page 30: quality measures, we are not sure if the State's interest is in the actual results of the quality measures, or the documented plans of action that serve to prevent, identify, diagnose and control the measures. This section does not ask the applicant's results. It wants plans for each of the 10 measures. This appears to be unnecessary additional paperwork for an audience that is primarily non-clinical. We suggest a better route may be for the applicant to share their actual results and to identify any steps it is taking to improve scores that are below average performance.

Response: The Board appreciates and acknowledges this comment. Revisions have been made based upon the Board's final decision and vote clarifying the applicant will include documented plans of action and -when applicable to provide actual results and identification of steps to improve scores and requiring applicants make available copies of reports that are required and submitted to regulatory entities. Any further changes will be considered in future revisions of the plan.

Comment 28: Section X. Nursing Home Care, Page 35: quality measures, we are not sure if the State's interest is in the actual results of the quality measures, or the documented plans of action that serve to prevent, identify, diagnose and control the measures. This section does not ask the applicant's results. It wants plans for each of the 10 measures. This appears to be unnecessary additional paperwork for an audience that is primarily non-clinical. We suggest a better route may be for the applicant to share their actual results and to identify any steps it is taking to improve scores that are below average performance.

Response: The Board appreciates and acknowledges this comment. Revisions have been made based upon the Board's final decision and vote clarifying the applicant will include documented plans of action and -when applicable to provide actual results and identification of steps to improve scores and requiring applicants make available copies of reports that are required and submitted to regulatory entities. Any further changes will be considered in future revisions of the plan.

Comment 29: Section XI. Freestanding Surgery Center (FSSC), Page 37: section a, a FSSC is defined as a health facility that specializes in performing surgical procedures, including certain diagnostic and preventive services, in an outpatient setting. Services performed in an FSSC are billed as surgical procedures and typically represent procedures more complex than those performed in a physician's office, but not so complex as to require overnight skilled nursing care.

This definition is contradictory to what is found in the Delaware Regulations: Administrative Code: Title 16: Department of Health and Social Services; Division of Public Health: 4400 Health Systems Protection: 4405 Free Standing Surgical Centers. This regulation states: 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 maintained and operated for providing surgical services and in which the expected duration of services would not exceed 23 hours 59 minutes following an admission. Per this regulation, a FSSC if licensed may provide surgical services that require overnight skilled care. Please consider rewording the definition to align with Title 16: 4405 Free Standing Surgical Centers that allows overnight skilled care when licensure is approved through the Delaware Health and Social Services Department of Office of Health Facilities and Licensing and Certification. At present, Delaware Surgery Center is licensed by DOHFL to provide overnight care not to exceed 23 hours 59 minutes. 16 **Del.C.** §9303, states: A "freestanding surgical center" shall mean any facility licensed as such pursuant to Chapter 1 of Title 16 and particularly in the State Board of Health Regulations: Division of Public Health: 4400 Health Systems Protection: 4405 Free Standing Surgical Centers.

Response: Revised as recommended.

Comment 30: Section XI. Freestanding Surgery Center (FSSC), Page 37: section b, review considerations for CPR proposal involving the establishment of an FSSC, project-specific mathematical need calculations, the previous plan had a definition of FSSC rooms that included 65% of hospital operating and procedure rooms and all ambulatory surgery centers rooms. In the proposed plan, the hospital OR and procedure rooms are not mentioned. However, the plan references the National Ambulatory Surgery use rate published by The National Health Statistics Report of 2006, which is based upon statistical data including surgical procedures performed on an ambulatory basis in both, hospitals and freestanding surgical centers.

Response: Revisions have been made to clinical impact section for applicants to include hospital operating and procedure rooms when describing how and where the proposed patient population is currently obtaining ambulatory surgery services.

Comment 31: Section XI. Freestanding Surgery Center (FSSC), Page 37: request to add the 65% of hospital operating and procedure rooms back into the calculation. As the calculation is presented in the new plan, it will erroneously show a deficit by including hospital cases in the use rate but not in the available rooms. An oversaturated ASC market will have an impact on all facilities including the hospital. Excess capacity stemming from overbuilding of health care facilities will result in health care price inflation.

Response: The Board appreciates and acknowledges this comment and will review in a future revision.

Comment 32: Section XI. Freestanding Surgery Center (FSSC), Page 37: the reference to the ratio used is from 2006. This should be updated or, if it no longer is published, find another source. It is likely that use rates [for] FSSCs have changed dramatically since 2006.

Response: Revisions have been made based upon the Board's final decision and vote. Language has been clarified to include corrected data from the most recent report of the Centers for Disease Control and Prevention, National Center for Health Statistics, 2006 [published in 2009].

Comment 33: Section XI. Freestanding Surgery Center (FSSC), Page 38: hospital operating rooms should be included in the inventory or at least a significant fraction of rooms. For most hospitals, approximately half of their surgeries are outpatient. Given that the use rate to be used is a national ambulatory surgery use rate, presumably, irrespective of whether the surgeries are performed in a hospital or in a freestanding ASC, it would be appropriate to apply that use rate to all operating rooms that provide ambulatory surgery in the area and not just those in FSSCs.

Response: Revisions have been made to clinical impact section for applicants to include hospital operating and procedure rooms when describing how and where the proposed patient population is currently obtaining ambulatory surgery services.

Comment 34: Section XI. Freestanding Surgery Center (FSSC), Page 39: the lack of any quality measures gives the impression that FSSCs are not expected to perform to the level of hospitals or nursing homes. It seems that many of the quality measures being applied to hospitals are applicable to FSSCs (e.g., infections, medication errors, transfers to hospitals, sepsis, adverse medication reactions). FSSCs should have the same outcome expectations as other facilities.

Response: Revisions have been made based upon the Board's final decision and vote to include in this category, applicants make available copies of reports that are required and submitted to regulatory entities.

Comment 35: Section XII. Acquisition of Major Medical Equipment, Page 41: there is a need to include/add the description of the methodology/process HRB uses for determining which major medical technology the Board designates as subject to review. The process/methodology should include clearly defined criteria taking into account the advancements in the technology, changes in the reimbursement and health policy (e.g. value based purchasing, parity outpatient billing, bundle payments); as well as, contemporary clinical practices and applications. The process also should

allow participation and input from the key stakeholders. The current listed examples should be re-examined through this process. Not certain as to why CT and MRI are being listed as examples as they currently do not require COPR, unless the cost exceeds \$5.8 million. These services are considered current standard diagnostic modalities. Most states exclude them from the CON review process

Response: The Board appreciates and acknowledges this comment and will review in a future revision.

Comment 36: Section XII. Acquisition of Major Medical Equipment, Page 41: section a, second and fourth bullets, CT and MRI appear to be new additions to the medical equipment acquisition list. To our knowledge, these modalities do not currently require a COPR currently unless the cost exceeds \$5.8 million. It is not clear as to why CT and MRI are being added other than to add significant burden to the Health Resources Board, which has difficulty managing the existing COPR requests. As opposed to the other major medical equipment, these services are lower dollar investments and require non-unique skills that are plentiful in the market. Utilization controls already exist with payers and will grow under bundled payments and population health management. Those controls will be more effective than a COPR, especially given that there are no specific criteria for them that applicants must meet. Most, if not all states do not include these services as part of their CON review process.

Response: The Board appreciates and acknowledges this comment. These items are not new additions to the CPR process. PET CT and PET MRI are activities subject to CPR review.

Comment 37: General Comment, no page referenced Process for future document review, the future process for public input needs to include a comparative or redlined document so that reviewers can determine which elements of the plan have been altered from prior years. Review of this year's proposals from a comparative perspective is hampered by significant changes in format from prior years and the lack of information regarding specifically how the plan has evolved. Conceptual changes, such as guiding principles and their relationship to statutory criteria are not sufficient for review of substantive and definitional changes, which are difficult to identify in this year's document.

Response: The Board appreciates and acknowledges this comment. This revision was a complete repeal and replace. It was not feasible to provide a comparative or redlined document. The Board will provide a comparative or redlined document in the future revision process.

DECISION AND EFFECTIVE DATE

The Delaware Health Resources Board finds that the revised HRMP regulation shall be adopted with the changes as final in the form proposed. The revised HRMP will become effective ten days following publication of this Final Order in the Delaware *Registrar of Regulations*.

IT IS SO ORDERED this 1st day of August by the Delaware Department of Health and Social Services.

Kara Odom Walker, MD, MPH, MSHS
Cabinet Secretary, DHSS

***Please Note: Due to the size and formatting of the final regulation, it is not being published here. A link to a PDF version of the final regulation is provided below:**

Health Resources Management Plan (<http://regulations.delaware.gov/register/september2017/final/HRMP.pdf>)

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