MARYLAND Health Care Commission

Randolph S. Sergent, Esq, Chairman
Ben Steffen, Executive Director

MEMORANDUM

TO: Commissioners

FROM: Wynee Hawk, Director Center for Health Facilities Planning and Development

DATE: May 18, 2023

SUBJECT: University of Maryland Capital Region Health Certificate of Need for a Level III Perinatal Program/Neonatal Intensive Care Unit (NICU) in Prince George's County, Maryland (Docket No.) 23-16-2464

Dimensions Health Corporation d/b/a University of Maryland Capital Region Health, Inc. (UMCRH or applicant) is seeking a Certificate of Need (CON) application approval for Level III neonatal intensive care services at University of Maryland Capital Region Medical Center (UMCRMC or hospital). UMCRMC is an acute care hospital located in Largo, Maryland, Prince George's County. UMCRH also consists of the University of Maryland Laurel Medical Center, the University of Maryland Bowie Health Center, and the University of Maryland Capital Region Medical Group. The hospital is licensed for a total of 221 beds. Of the beds, 22 are dedicated to Obstetric and Gynecological care.

UMCRMC replaced Prince George's Hospital Center (PGHC) in 2021. UMCRMC is currently operating a Level II Special Care Nursery since its opening and is now requesting a CON to establish a Level III NICU at the hospital. UMCRMC expects that the proposed unit will treat a minimum average daily census (ADC) of 6.4 patients. There is no construction or renovation needed for the proposed project because the hospital was set up to provide Level III NICU services prior to PGHC's relinquishment of its Level III neonatal program. The applicant states that it can open the program immediately after receiving regulatory approvals. The proposed project also has no capital costs.

Based on the review of the proposed project's compliance with the Certificate of Need review criteria, and with the applicable standards in the State Health Plan, staff concludes that the project complies with the applicable standards, is needed, is a cost-effective approach to meeting the project's objectives, is viable and will have an impact that is positive with respect to the applicant's ability to provide NICU services in Prince George's County.

The conditions of the CON are as follows:

1. University of Maryland Capital Region Health will provide documentation to MHCC that it has been surveyed by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) to show compliance with the Perinatal System Standards for a Level III perinatal program and has been designated by MIEMSS as a provider of Level III perinatal service prior to implementing the Level III program.

2. After its initial survey, University of Maryland Capital Region Medical Center will maintain its MIEMSS designation in accordance with policies and procedures for periodic resurvey and re-verification of compliance with standards or this CON will become void.

IN THE MATTER OF	*	
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UNIVERSITY OF MARYLAND	*	**BEFORE THE**
	*	
CAPITAL REGION	*	**MARYLAND HEALTH**
	*	
MEDICAL CENTER-NICU	*	**CARE COMMISSION**
	*	
Docket No. 23-16-2464	*	
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STAFF REPORT AND RECOMMENDATION
May 18, 2023

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I. INTRODUCTION

Dimensions Health Corporation (Dimensions) is a not-for-profit, non-stock corporation that was founded in 1982. UMMS affiliated with Dimensions in September 2017 and through this affiliation, University of Maryland Capital Region Health was established. Dimensions Health Corporation d/b/a University of Maryland Capital Region Health, Inc. (UMCRH or applicant) is seeking a Certificate of Need (CON) for Level III neonatal intensive care services at University of Maryland Capital Region Medical Center (UMCRMC or hospital). UMCRH also consists of the University of Maryland Laurel Medical Center, the University of Maryland Bowie Health Center, and the University of Maryland Capital Region Medical Group. (DI #11, p.4).

UMCRMC is an acute care hospital located in Largo, Maryland, Prince George's County, which opened in the summer of 2021. UMCRMC replaced the former University of Maryland Prince George's Hospital Center ("PGHC"). The hospital is licensed for 221 beds, with 22 beds dedicated to Obstetric and Gynecological care. (DI #11, p.4). The Level II Special Care Nursery currently has a total of 22 beds for obstetrical and gynecological care. (DI #11, p.4). There are three other acute care hospitals in Prince George's County including Luminis Health Doctors Community Hospital, Adventist HealthCare Fort Washington Medical Center, and MedStar Southern Maryland Hospital Center[1].

A. Project Overview

The proposed project is for a Level III neonatal intensive care unit (NICU) at UMCRMC. In January 1997, the Commission granted PGHC a CON to establish a Level III NICU. In January 2015, PGHC filed an application and was approved to establish a replacement hospital. In the Fall of 2020, MIEMSS conducted a site survey of the PGHC NICU and identified "certain programmatic improvement opportunities." (DI #11 p. 25). In response to the MIEMSS surveyor's findings, PGHC developed a "comprehensive action plan," to make structural improvements to its quality oversight program. The applicant states that despite satisfying its thirty-day goals, it still decided to request a temporary suspension of Level III NICU services to "allow it to continue monitoring its progress and to focus on additional comprehensive improvements to its quality oversight structure." (DI #11, p. 25).

In October 2020, PGHC requested that MIEMSS suspend their provision of Level III Perinatal Referral Center activities[2]. (DI #11, p. 25). Per the applicant the suspension was voluntary, and MIEMSS accepted the request in October 2020. (DI #11, p. 25). Accordingly, from October 2020 until June 2021, PGHC operated as a Level II Special Care Nursery. In June 2021, PGHC relocated to the replacement hospital UMCRMC, where it has continued to operate a Level II Special Care Nursery.

PGHC did not notify MHCC that it was suspending the provision of Level III services.

[1] https://www.princegeorgescountymd.gov/ArchiveCenter/ViewFile/Item/3677

[2] In accordance to COMAR 20.08.12.14, PGHC was not to accept interfacility transfers of infants less than 1500 grams or 32 week's gestation. A table showing numbers of NICU babies who remained in care after the October 2020 suspension until discharging from the hospital as well as babies who have had to be transferred out needing a higher level of neonatal care is included in Appendix D.

When MHCC approved the CON application to relocate and replace PGHC, PGHC was a provider of NICU services and in good standing with MIEMSS as a Perinatal Referral Center. MHCC authorized UMCRMC to provide NICU services at the replacement hospital. However, in April 2021 when UMCRMC requested first use approval to open its replacement hospital, they did not notify MHCC that they would not be able to meet the terms of its CON by providing NICU services at CRMC when it opened.

MHCC became aware of the suspension in May 2022. MHCC notified UMCRMC in writing in May, August and December of 2022 stating it must obtain a new CON to introduce Level III neonatal services. (DI #1, pg. 1). UMCRMC is now requesting a CON to establish a Level III NICU at the new hospital.[3]

Prince George's County is the second most populous county in Maryland and has no other Level III neonatal programs. UMCRMC projects the proposed unit to have an average daily census (ADC) of 6.4 patients. There is no construction or renovation needed for the proposed project because UMCRMC was constructed to provide Level III NICU services prior to the suspension of its Level III neonatal program. The applicant states that it can immediately provide NICU services after receiving regulatory approvals. (DI #11, p.27).

B. Summary and Staff Recommendation

Based on the review of this application and the review of the criteria and standards, Commission staff concludes that UMCRMC has demonstrated need for a Level III NICU and has also demonstrated that it can provide this service cost effectively as part of the existing hospital. There should not be any notable negative impact on existing Level III neonatal programs.

Staff recommends approval of the project with two conditions:

1. University of Maryland Capital Region Health will provide documentation to the Commission that it has been surveyed by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) for compliance with the Perinatal System Standards for a Level III perinatal program and has been designated by MIEMSS as a Level III perinatal service provider prior to implementing the Level III program.

2. After the initial survey, University of Maryland Capital Region Medical Center will maintain its MIEMSS designation in accordance with MIEMSS policies and procedures for periodic resurvey and re-verification of compliance with standards or this CON will become void.

II. PROCEDURAL HISTORY

A. Review Record

[3] UM CRMC asserts that a CON is not required to resume Level III NICU services because MIEMSS has regulatory authority, pursuant to COMAR 30.08.02.09, to authorize temporary suspension. MHCC disagreed. UM CRH determined that fastest way to secure approval to resume the services is to see a CON as opposed to litigate the matter. (DI #21, p. 11)

On December 8, 2022, University of Maryland Capital Region Health filed a Letter of Intent to apply for a Certificate of Need for a Level III Perinatal Center. The 60-day waiting period was waived and the applicant filed its application for Certificate of Need on January 17, 2023. A full Record of the Review is attached in Appendix A.

B. Interested Party

There are no interested parties in this review.

C. Local Government Review and Comment

The Prince George's County Health Department submitted a letter from County Executive Angela Alsobrooks in support of the project as well as the Prince George's County Health Officer, Sanmi Areola.

D. Community Support

In addition to local government, the applicant also included letters from area hospitals and other community institutions. These letters include support of the need for the Level III NICU program from:

- Joseph Wright, M.D., Chief Health Equity Officer, University of Maryland Medical System
- Sheldon Stein, Chief Executive Officer, Mt. Washington Pediatric Hospital
- Richard Katz, M.D., Chief Medical Officer, Mt. Washington Pediatric Hospital
- Pastor John Jenkins, First Baptist Church of Glenarden

III. BACKGROUND

Maternal and Infant Health: Prince George's County

Prince George's County borders, and is considered part of the diverse Washington, D.C. metropolitan area. The County includes urban, suburban, and rural communities some of which are affluent, as well as many poorer communities with below average health outcomes. The most recent (2022) Prince George's County Community Health Assessment[4] (CHA), outlined the healthcare priorities including the social determinates of health, behavioral health, obesity/metabolic syndrome, and cancer.[5]

The Maternal and Infant Health data in the Prince George's County CHA shows that in 2020, the infant mortality rate fell to a low of 5.5 deaths per 1,000 live births, in line with the

[4]Prince George's County Community Health Assessment, 2022, available at:https://www.princegeorgescountymd.gov/ArchiveCenter/ViewFile/Item/3677, p.1
[5] https://www.princegeorgescountymd.gov/ArchiveCenter/ViewFile/Item/3677, p.5

statewide Maryland rate of 5.7. Notwithstanding that progress, in Prince George's County, the infant mortality rate was highest for Black, Non-Hispanic births at 8.0 deaths per 1,000 live births compared with the statewide rate of 9.9. Black, Non-Hispanic mothers had the highest rate of infants born at less than 37 weeks at 11.3 percent and babies with low birth weight (<2500g) at 10.9 percent. [6]

Levels of Care Perinatal Programs

Level I programs provide basic care to pregnant women and infants. These hospitals provide delivery room and normal newborn care for stable infants of 35 weeks and longer gestation.

Level II programs provide specialty care to pregnant women and infants that is specialized for moderately ill infants weighting more than 1500 grams and having had 32 weeks and longer gestation with problems that are expected to resolve rapidly.

Level III programs provide acute delivery room and NICU (Neonatal Intensive Care Unit) care for infants of all birth weights and gestational ages. These programs are staffed with board-certified subspecialists. Neonatal services provide sustained life support with multiple modes of neonatal ventilation that may include advanced respiratory support, or the use of inhaled nitric oxide.

Level IV programs provide comprehensive subspecialty obstetrical and neonatal care services for infants of all birth weights and gestational ages, including those with complex and critical illness. Board-certified neonatal-perinatal medicine subspecialists have programmatic responsibility for neonatal services. Advanced modes of neonatal ventilation and life-support are provided, including high frequency ventilation, nitric oxide, and extracorporeal membrane oxygenation.[7] A listing of Maryland Hospitals with Perinatal programs and the level of the programs is included in Exhibit B.

MIEMSS

Maryland Institute for Emergency Medical Services Systems (MIEMSS) is responsible for the evaluation and regulation of all the emergency medical services as well as the designation of hospitals to be Perinatal and Neonatal Specialty Referral Centers. MIEMSS monitors compliance and evaluates each hospital's ability to provide specialty care services. An applicant submits an application to MIEMSS and then MIEMSS conducts an on-site review, returning to survey every five years.[8] The most recent Maryland Perinatal System Standards were updated in September 2018 with a slight revision in April 2019. They state that Level I and Level II of perinatal service do not require a CON, while Level III and Level IV have a CON requirement.[9]

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[6] https://www.princegeorgescountymd.gov/ArchiveCenter/ViewFile/Item/3677

[7]The Maryland Perinatal System Standards, Revised April 2019, available at: https://health.maryland.gov/phpa/mch/Documents/perinatal_newsletters/Maryland%20Perinatal%20System%20Standards_Revised%20April%202019_FINAL.pdf

[8] https://www.miemss.org/home/hospitals/perinatal-programs

[9]https://health.maryland.gov/phpa/mch/Documents/perinatal_newsletters/Maryland%20Perinatal%20System%20Standards_Revised%20April%202019_FINAL.pdf

IV. STAFF REVIEW AND ANALYSIS

The Commission is required to make its decision in accordance with the general certificate of need review criteria at COMAR 10.24.01.08G(3)(a) through (f). The first of these six general criteria require the Commission to consider and evaluate this application according to all relevant State Health Plan (SHP) standards and policies.

A. The State Health Plan

COMAR 10.24.01.08G(3)(a) requires the Commission to consider and evaluate applications for Certificate of Need according to all relevant State Health Plan standards, policies, and projections.

The relevant State Health Plan chapters in this review are COMAR 10.24.18, *Specialized Health Care Services-Neonatal Intensive Care Services* and *COMAR 10.24.10, Acute Inpatient Services.*

COMAR 10.24.10 ACUTE CARE HOSPITAL SERVICES SECTION OF THE STATE HEALTH PLAN

.04A. GENERAL STANDARDS

The following general standards encompass Commission expectations for the delivery of acute care services by all hospitals in Maryland. Each hospital that seeks a Certificate of Need for a project covered by this Chapter of the State Health Plan must address and document its compliance with each of the following general standards as part of its Certificate of Need application.

(1) Information Regarding Charges

Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet website;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

Applicant Response

The applicant states that it has a written policy in place and includes it as Exhibit 4. The policy states that a list of services and charges will be available in writing and on the hospital website. The policy also states that the Patient Access and Financial Services departments will

distribute information on estimated charges upon request. The same department will provide education to the staff. The applicant also included its list of charges as Exhibit 14. (DI #11, Exh.4).

Staff has verified that the charges are up to date on the website and reviewed the policy in Exhibit 4, concluding the standard has been met.

(2) Charity Care Policy.

Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital; and

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

To promote financial access to hospital services, the State Health Plan requires hospitals to develop and disseminate a written policy for charity care. UMCRMC has a written policy and provided it in the CON application as Exhibit 16.

The policy states that within two business days of a patient's request for financial assistance, or an application for medical assistance, UMCRMC will provide a determination of probable eligibility. The probable eligibility determination uses a variety of sources that may include:

- Active Medical Assistance pharmacy coverage
- Low-income Medicare coverage
- Primary adult care coverage
- Homelessness
- Medical assistance/managed Medicaid
- Medicaid spenddown
- Local assistance programs,
- Patient deceased with no estate
- Eligibility under former state only Medical Assistance program

- Non-US citizens deemed non-compliant
- Non- eligible Medical Assistance services for Medical Assistance eligible patients
- Unidentified patients
- Bankruptcy
- St. Clare Outreach eligible patients
- University of Maryland St. Joseph maternity or hernia eligible patients.

In addition, the applicant states that annual public notices are published in the newspapers in the service area. Notices in English and Spanish are posted in the business office, admissions area, and emergency room as well as other areas of the hospital. (DI #11, Ex. 17). The applicant also states that a notice of the availability of charity care is part of the admissions packet and given to the patient at pre-admission and admission. Notice is also on the hospital website. (DI #11, p.17).

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

Staff reviewed data from HSCRC on the amount of uncompensated care provided by UMCRMC. The most recent Community Benefit Report at the time of the application is from fiscal year 2020. The hospital ranks in the first quartile with charity care comprising 3.22 percent of its total operating expenses. (DI #11, pp. 18-19).

Staff concludes that UMCRMC has a written charity care policy that includes a provision concerning a determination of probable eligibility, and that policy is distributed in newspapers, on their website, areas throughout the hospital and to patients as a part of the admissions packet. Additionally, UMCRMC provides charity care at 3.22 percent, meeting the charity care thresholds. Staff finds that the standard has been met.

(3) Quality of Care.
An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

Applicant Response

The hospital is licensed by the Maryland Department of Health and provided a copy of its license in their application. (DI #11, Exh. 6). The hospital is also accredited by the Joint Commission, and it included an award letter documenting the accreditation. (DI #11, Exh. 7). The hospital is in compliance with the Conditions of Participation of the Medicare and Medicaid

programs as evidenced by its licensure and accreditation. (DI #11, p.20).

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

Applicant Response

Staff notes that paragraph (b) of this standard has become outdated in recent years. To comply with the standard as it is currently being interpreted, applicants are asked to identify any below average rating on the quality reporting utilizing the data on the Commission website (based on Medicare data) and discuss its approach to resolving any below average rankings. The applicant looked at the Hospital Guide for Maryland Quality Reporting (DI #11, p.20). The hospital scored better than average or average on 47 of the 76 quality measures. There were 15 additional quality measures that did not have sufficient data for reporting due to reasons outside the applicant's control:

- Cardiac Care for not enough cases meeting criteria (one measure);
- Emergency Department for data being suppressed by the Centers for Medicare and Medicaid Services (CMS) (two measures);
- Three under Imaging for having too few cases to report (three measures);
- Infections for the number of predicted infections being under one (four measures);
- Lung Conditions for data being suppressed by CMS (two measures);
- Surgery for both case numbers being too low and for data being suppressed by CMS (three measures).

The hospital scored below average on 14 quality measures, and 62 percent of those measures were related to Patient Satisfaction. Staff verified the accuracy of this data online and the applicant provided action plans for those 14 below average measures shown in Figure 1 below, as well as a corrective action plan for each.

Figure 1: UMCRMC Below Average Quality Measures

Patient Satisfaction Survey
How often did the doctors communicate with patients?
How often did the nurses communicate with patients?
How often did the staff explain about medications before giving them to patients?
How well do patients understand their care when they leave the hospital?
Were patients given information about what to do during recovery at home?
How often did patients receive help quickly from staff?
How often was the area around the patient rooms kept quiet at night?
How do patients rate the hospital overall?
Would the patient recommend the hospital to friends and family?
Cardiac Conditions
How long with chest pain did the patient wait for transfer to another hospital for a procedure?
Emergency Department Use
Number of patients who left the emergency room without being seen.
Infections
Central-line associated blood stream infection.
Safety
Percentage of patients who received care for severe sepsis or septic shock.
How often do patients get pressure ulcers while getting care for another condition?

Source: DI #11, Exhibit 8.

Staff Analysis

Staff accessed the Hospital Guide for Maryland Quality Reporting data from the MHCC website on January 18, 2023. UMCRMC achieved one star under national ratings for both overall quality and satisfaction (ratings are one to five stars with five being the highest score). The overall star rating is based on how well the hospital performs across different areas of quality. It was the only hospital to receive the one star ranking under Satisfaction and one of only two hospitals receiving one star under Overall Quality.[10]

The Patient Satisfaction Survey, which rates a patient's experience with the hospital care, showed that 47 percent of patients "would recommend" UMCRMC. Additionally, 50 percent of the patient responses gave the hospital a rating of a 9 or 10. In comparison, the Maryland average for both these measures was 65 percent. The Patient Satisfaction Survey is based on a one-year response period. The hospital had 668 returned surveys which represented a 10 percent response rate.[11]

Notable is that the applicant scored average or above average on all seven of the Mother and Baby metrics. UMCRMC scored above average on two metrics (lower is better for both of these metrics) which showed a lower percentage (14.8% compared to Maryland overall at 17.8%) of cesarean deliveries when it is the mother's first birth and a lower percentage (0% compared to Maryland overall at 1%) of newborn deliveries scheduled one to three weeks earlier than medically necessary. UMCRMC scored average on the remaining five metrics of which three were related to complications: how often a baby is injured during delivery, and how often there are obstetric injuries to the mother after a vaginal delivery, both with and without an instrument. The other two

[10] https://healthcarequality.mhcc.maryland.gov/Hospital/Detail/34
[11] *Ibid*

average ratings were concerning delivery, including how often babies are delivered vaginally when the mother had previously delivered cesarean and percentage of births that are C-sections.

Although UMCRMC has performed low on its overall quality ranking when compared to its peers, it has met the standards minimum requirements by submitting a reasonable action plan for each of the 14 below average performance measures. Staff finds the action plans are likely to improve outcomes once they are implemented and monitored. The hospital also scored average or above average on all metrics related to Mother and Baby.

Staff recommends that the Commission find that the hospital has met the minimal requirements of the standard.

.04B. PROJECT REVIEW STANDARDS

The standards in this section are intended to guide reviews of Certificate of Need applications and exemption requests involving acute care general hospital facilities and services. An applicant and its proposed project will be evaluated for compliance with all applicable review standards. The following included project review standards are a subset of the COMAR 10.24.10 Project Review Standards, which the Commission found to be applicable to Level III NICU projects. A full list of omitted standards is included in Appendix C.

(5) Cost-Effectiveness

A proposed hospital capital project should represent the most cost-effective approach to meeting the needs that the project seeks to address.

(a) To demonstrate cost effectiveness, an applicant shall identify each primary objective of its proposed project and shall identify at least two alternative approaches that it considered for achieving these primary objectives. For each approach, the hospital must:

(i) To the extent possible, quantify the level of effectiveness of each alternative in achieving each primary objective;

(ii)Detail the capital and operational cost estimates and projections developed by the hospital for each alternative; and

(iii) Explain the basis for choosing the proposed project and rejecting alternative approaches to achieving the project's objectives.

(b) An applicant proposing a project involving limited objectives, including, but not limited to, the introduction of a new single service, the expansion of capacity for a single service, or a project limited to renovation of an existing facility for purposes of modernization, may address the cost-effectiveness of the project without undertaking the analysis outlined in (a)

above, by demonstrating that there is only one practical approach to achieving the project's objectives.

Applicant Response

PGHC provided Level III NICU services until the services were suspended in October 2020. The applicant states that UMCRMC was designed and built to provide Level III NICU services, thus, no capital expenditures are required for this project and services can begin once regulatory approvals are in place. The applicant does not address a cost-effective analysis under (a) of this standard and instead addressed section (b) on the standard, stating that there is only one practical approach to meeting the project's objectives, and that is to have Level III NICU services at UMCRMC. It states meeting this objective will provide access to higher intensity neonatal care in Prince George's County when the lack of having a Level III NICU has resulted in patients seeking care further from home, and further from their families. Therefore, the applicant reiterates that this project is the only cost-effective option because there are no additional costs to open the program and no other facility in Prince George's County is offering Level III services. (DI #11, pp. 21-22).

PGHC previously provided Level III NUCU services, the CON approved for the new hospital included a Level III NICU, and UMCRMC was constructed to continue the service. Given these factors, UMCRMC is uniquely qualified to be the most cost effective alternative because the hospital was already designed for Level III NICU care and no additional capital resources are needed. Staff concludes that the applicant has shown that this is the most cost-effective approach, and the standard has been met under subsection (b).

(7) Construction Cost of Hospital Space

The proposed cost of a hospital construction project shall be reasonable and consistent with current industry cost experience in Maryland. The projected cost per square foot of a hospital construction project or renovation project shall be compared to the benchmark cost of good quality Class A hospital construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

Applicant Response

This standard is not applicable because the proposed project does not involve any construction.

(11) Efficiency

A hospital shall be designed to operate efficiently. Hospitals proposing to replace or expand diagnostic, or treatment facilities and services shall:

(a) Provide an analysis of each change in operational efficiency projected for each diagnostic or treatment facility and service being replaced or expanded, and document the manner in which the planning and design of the project took efficiency improvements into account; and

(b) Demonstrate that the proposed project will improve operational efficiency when the proposed replacement or expanded diagnostic or treatment facilities and services are projected to experience increases in the volume of services delivered; or

(c) Demonstrate why improvements in operational efficiency cannot be achieved.

Applicant Response

The applicant states that it is not proposing to replace or expand diagnostic or treatment facilities and services. It explains that its predecessor hospital, PGHC had provided Level III NICU services that were planned to be transferred to the new hospital before they were suspended. The new hospital was designed efficiently as substantiated by the Commission's decision to approve a CON for the replacement and relocation of PGHC to UMCRMC. The efficiencies detailed in the previous CON are still applicable, and included improved patient flow, staff workflow, staffing ratios, and supply chain management. (Dimensions Health Corporation d/b/a Price George's Hospital Center and Mt. Washington Pediatric Hospital, Inc. Docket 13-16-2351). The applicant states that since this project involves no changes to the building, and because it was designed for a Level III NICU, efficiency was in the original plan. (DI #11, pp. 22-23).

Staff concludes that while the hospital is proposing to expand its services, there have been no operational changes from the previous CON approval. The hospital was originally designed efficiently including improved patient flow, staff workflow, staffing ratios, and supply chain management. This standard has been met.

(12) Patient Safety

The design of a hospital project shall take patient safety into consideration and shall include design features that enhance and improve patient safety. A hospital proposing to replace or expand its physical plant shall provide an analysis of patient safety features include for each facility or service being replaced or expanded and document the manner in which the planning and design of the project took patient safety into account.

Applicant Response

The applicant states that the physical plant and operations of the NICU were designed with patient safety in mind. In MHCC's decision approving the CON for the replacement and relocation of PGHC to UMCRMC, the Commission found that the design of the new hospital accounted for safety. Some of the design features of the hospital included acuity adaptable rooms,

multidisciplinary workspaces, using materials that reduce infections, the ability to provide room design modifications and electronic medical records to reduce medication errors. (Dimensions Health Corporation d/b/a Price George's Hospital Center and Mt. Washington Pediatric Hospital, Inc. Docket 13-16-2351).

For this project, the applicant is not proposing to change the physical plant, and the current design supports the program's ability to accept and care for Level III neonatal patients, thus no modification to the patient safety design of the current NICU is required. (DI #11, p.23). The applicant states it has hired a dedicated perinatal safety and quality officer along with a perinatal coordinator. In addition to these new positions, the program will be run by board-certified obstetricians who have the programmatic responsibility for high-risk obstetrical services. (DI #11, p.23).

Staff concludes that the hospital has demonstrated that it has taken safety into account as part of this project and the standard has been met.

(13) Financial Feasibility

A hospital capital project shall be financially feasible and shall not jeopardize the long-term financial viability of the hospital.

(a) Financial projections filed as part of a hospital Certificate of Need application must be accompanied by a statement containing each assumption used to develop the projections.

(b) Each applicant must document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the service area population of the hospital or State Health Plan need projections, if relevant;

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant hospital or, if a new hospital, the recent experience of other similar hospitals;

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant hospital, or, if a new hospital, the recent experience of other similar hospitals; and

(iv) The hospital will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years or less of initiating operations with the exception that a hospital may receive a Certificate of Need for a project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project when the hospital can demonstrate that overall hospital

financial performance will be positive and that the services will benefit the hospital's primary service area population.

Applicant Response

The applicant states that this standard is not applicable because the project does not involve any capital expenditure. Notwithstanding, the applicant included the utilization and financial projections which show that while NICU itself is slated to have negative net income, the entire hospital is still projected to be financially viable with a positive net income of 8.6 M by 2025. The positive net income continues to grow to 21.4M through the last projected year of 2028. (DI #11, Exh. 1, Table H). Staff concludes that while this standard does not apply as this is not a capital project, the projections show the project will be financially feasible.

COMAR 10.24.18 – STATE HEALTH PLAN - SPECIALIZED HEALTH CARE SERVICES - NEONATAL INTENSIVE CARE SERVICES

.04C/D Neonatal Intensive Care Services Commission Program Policies (C) and Certificate of Need Review Standards (D)

1. Compliance with the Maryland Neonatal Intensive Care Standards

Each applicant shall demonstrate compliance with all essential requirements as defined in the most recent version of the perinatal standards, adopted by MIEMSS at COMAR 30.08.12, for the level of perinatal center specified in the application. An applicant may respond to this standard by attaching their MIEMSS' perinatal designation application.

Applicant Response

The applicant provided the background for the project and reiterated that Level III NICU services were previously provided at PGHC in Cheverly, Maryland. The MIEMSS Perinatal Designation Application is attached to the application in Exhibit 9. (DI #11, pp.25-26). MIEMSS has reviewed the hospital's application and determined that UMCRMC has met the minimal requirements for a Level III NICU on paper.

MIEMSS review of the UMCRMC's application and the Maryland Perinatal System Standards identified two weaknesses that the applicant needed to correct. UMCRMC needed to hire an additional maternal fetal medicine specialist and implement a diabetic care program. Applicant states it has hired a new maternal fetal medicine specialist that starts in April of 2023. With the addition of this specialist, the program will have two full time and one part time fetal medicine specialist. For the diabetic care program, although the hospital currently serves patients with diabetes, the applicant is currently recruiting a Certified Diabetic Educator to start a specialized program. (DI #21, p.10).

Staff Analysis

The applicant responded to this standard by attaching their MIEMSS' perinatal designation

application. Staff reviewed the comprehensive action plan in an effort to obtain more details on the corrective actions' applicant has taken to address deficiencies and enhance its neonatal program, attached in the application as Exhibit 18. In the action plan: "*Root Cause Analysis of Neonatal Deaths and Transfers to a Higher Level of Care,"* applicant conducted retrospective audits of all 2019 and 2020 cases. In the corrective action, applicant instituted a requirement that the Medical Director be notified immediately of any Hypoxic Ischemic Encephalopathy (HIE) diagnosis, neonates transferring out or neonatal deaths. For those events, NICU staff were to create an action plan, based on a root cause analysis that would then be reviewed by executive leaders for oversight. Peer reviews and chart audits of HIE cases with the Obstetrics Department were conducted to ensure collaboration reporting any discrepancies. Transfer protocols were also to be reviewed with Level IV NICU providers. Next, there was a review of current Emergency Department triage policy to ensure national standards for pregnant patient management. Staff were retrained and subsequently audited for adherence to the policy. Finally, all root cause analysis and resolution findings/discrepancies were to be reported to the Quality Improvement Committee/Quality Oversight Committee/Executive Council and Department Chair on an ongoing basis. (DI #21, Exh.18).

Staff concludes that the applicant has provided sufficient detail on its corrective actions for its perinatal program improvement and has met the minimal requirements of the MIEMSS application for Level III NICU services. In order to satisfy the standard, staff drafted two conditions for this CON. The first condition is to ensure that the applicant will notify MHCC if they are designated as a Level III NICU. The second condition will ensure that the applicant will carry this forward with its subsequent reviews, or its CON will become void.

2. Minimum Unit Volume

(a) Each applicant shall document a sufficient volume of critically ill patients using the general categories identified in COMAR 10.24.18.04B(1). Each applicant shall document that the proposed neonatal intensive care unit will maintain an average daily census of at least six critically ill patients on a sustained basis. An applicant may show evidence as to why this rule should not apply to the applicant.

Applicant Response

The applicant projects that the NICU will maintain a sufficient volume of critically ill patients for Level III services and assumes the use rate will return to the average of 2018 and 2019 levels because from 2020 to current there are no NICU babies at the hospital for the applicant to provide data on. In the table below the hospital demonstrates its projections for the NICU, including that it will maintain an average daily census of approximately 6.4 patients beginning in 2024 through 2028. (DI #11, pp. 26-27).

Table IV-1: UMCRMC Level III NICU Projections

FY	2024	2025	2026	2027	2028
ALOS	16.1	16.1	16.1	16.1	16.1
Patient Days	2,327	2,326	2,324	2,323	2,322
ADC	6.4	6.4	6.4	6.4	6.4
Occupancy	70%	70%	70%	70%	70%
Bed Need	9	9	9	9	9

Source: DI #11, p.28.

(b) Each applicant for a new neonatal intensive care unit is subject to and shall document compliance with the obstetric volume requirements at COMAR 10.24.12.03B(1) and (4).

Applicant Response

The applicant states that it is currently experiencing high demand for neonatal services and has consistently met the obstetrics requirements in the State Health Plan chapter of at least 1000 cases per year in a metropolitan area. COMAR 10.24.12.03B (1) and (4). The applicant provided data showing in the last five months it has experienced an average obstetric volume of 187 cases each month, which annualized is 2239 births per year categorizing them as a high-volume program. (DI #21, p.13).

Table IV-2: UMCRMC Obstetric Volumes September 2022 to January 2023

September 2022	October 2022	November 2022	December 2022	January 2023
170	169	174	214	206

DI #21, p.13.

(c) Each applicant shall document that the value added by increased geographic access is justified by the incremental cost to the health care system based on the total cost of the service, not the rates charged for the service.

Applicant Response

The applicant reiterates that Level III services at UMCRMC will improve geographic access for the service area and will do so at a minimal cost because a Level III NICU was already planned and included in the hospital's cost structure. The only additional costs the hospital will incur will be for the nurse ratio for increased newborn census and medical supplies. (DI #11, p.27).

Staff concludes that the applicant's volume projections based on serving at least six critically ill babies per day, as well as demonstrating it is currently serving an average of 187 obstetric cases each month, annualized, are credible and exceeds the obstetrics requirement in the State Health Plan. Staff concludes that the applicant has met this standard.

3. Outreach Prevention Programs

Each applicant shall document its establishment of a program to prevent low birth weight and infant mortality with particular outreach to minority and indigent patients in the hospital's regional service area.

Applicant Response

The applicant states that the hospital strives to improve outcomes for all mothers and babies in the service area from general wellness to implementing several programs focused on prevention of low birth rate and infant mortality. These programs include a mobile care unit called the Mama and Baby Bus Program that works with shelters, a breast-feeding coalition, a domestic violence, and assault center that can assist with secure housing and a SAFE program for victims of sex and labor trafficking. (DI #11. pp.29-30).

In addition, applicant works to address broader health conditions that disproportionately affect residents in its service area. Prince George's County has 70 percent of sickle cell disease cases in Maryland. In 2023, UMCRH will open the first adult sickle cell disease program in Prince George's County, in partnership with Johns Hopkins Medical and Children's National Medical Center, funded with a grant from the Maryland Community Health Resources Commission. The Sickle Cell Disease Infusion Center and Clinic will provide services and support to adult patients living with this disease and will address the gap in access to care for this population. (DI #11, p.30). According to the CDC, pregnant women with Sickle Cell Disease are at a higher risk for preterm labor and low birth weight.[12]

Staff concludes that the applicant has demonstrated that it is providing outreach to prevent low birth weight and infant mortality in its service area with particular outreach to indigent and minority patients, and the standard has been met.

4. Data Reporting

Each applicant shall provide any statistical or other information that the Commission needs to plan for the future development of perinatal services in Maryland, as specified in COMAR 10.24.02, and demonstrate compliance with the reporting requirements specified in regulations governing the submission of uniform hospital discharge abstract data and uniform accounting data to the Health Services Cost Review Commission, including the timely reconciliation of those data elements that are common to the case-mix and financial data sets.

Applicant Response

The hospital states it will comply with its obligations to provide statistical or other information to the Commission pursuant to COMAR 10.24.02. It also states it is currently in compliance with reporting as evidenced by its performance on historical, monthly, quarterly, and annual reporting to the HSCRC. (DI #11, p.31).

The applicant has stated its intent to comply with the provision of information and staff concludes that this standard has been met.

[12] https://www.cdc.gov/ncbddd/sicklecell/documents/scd-factsheet_scd--pregnancy.pdf

5. Cost Efficiency

A hospital that applies for a Certificate of Need to provide subspecialty or comprehensive subspecialty neonatal care services will be required to enter into an agreement with the Health Services Cost Review Commission (HSCRC) outlining how the neonatal intensive care cases will be incorporated into the hospital's population global budget.

Applicant Response

The applicant states that its Level III NICU application will be incorporated into its global budget and rate order. It states that since the hospital had a previous NICU rate center there are existing historical volumes for reference, and has a neonatal intensive care approved unit rate in its current rate order. Further, regarding incorporating the NICU rate into the applicant's global budget, during the course of this CON review it was discovered that the NICU rate was never removed from the rate order, and the GBR was never reduced at the time the Level III NICU services were suspended in 2020 and thus does not need to be adjusted when the services resume. (DI #17, p.1).

Staff concludes that the standard on cost efficiency has been met.

6. Service to Minority and Indigent Populations

In the case of a comparative review of applications in which all applicants met all policies and standards, the Commission will give preference to the applicant with an established program to prevent low birth weight and infant mortality with particular outreach to minority and indigent patients in the hospital's regional service area in accordance with COMAR 10.24.18.04C(1)(d).

Applicant Response

This standard is not applicable, this is not a comparative review.

B. 10.24.01.08G(3)(b). Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served and established that the proposed project meets those needs.

Applicant Response

I. Volume projections demonstrate the need for Level III NICU services in the service area.

The hospital projects that it will maintain an average daily census of 6.4 critically ill patients in its Level III NICU. The applicant used the bed need methodology from the State Health Plan chapter for Acute Care Hospitals to project need for nine beds as shown in Table IV-1.

II. Internal maternal and infant transfer data demonstrate that Level III NICU services are needed in Prince George's County.

Applicant states that since the Level III NICU services were suspended, referrals have decreased and more mothers and infants have had to be transferred to receive a higher level of care, thus demonstrating the need for the program. Table IV-3 compares the number of mothers transported into the hospital with the number of mothers transported out of the hospital for higher-level care in 2018 through 2022.[13]

Table IV-3: UMCRMC Maternal Admissions and Transfers CY 2018 to CY 2022

	CY18	CY19	CY20	CY21	CY22
Total number of obstetric admissions	1261	1212	1324	1204	1219
Maternal admissions transferred to UMCRMC from other hospitals for a higher level of care	18	22	10	10	4
Maternal patients transferred out of UMCRMC to another hospital for specialty care.	0	1	3	19	21

Source: UMCRMC internal data.
Note: Hospital operations transferred from the PGHC campus in Cheverly to the UM-CRCM campus in Largo on June 12, 2021. CY 2021 data includes admissions and transfers to/from PGHC from January 1, 2021, through June 11, 2021, and admissions and transfers to/from UMCRMC from June 12, 2021, through December 31, 2021.

Between 2018 and 2019, when the hospital had a Level III NICU, an average of 20 mothers were transferred into the hospital each year from other facilities to receive a higher level of care. In FY 2022, the transfers into the hospital have now decreased to only four transfers. The hospital states it anticipates recapturing this lost volume. Simultaneously, maternal transfers out of the hospital, which occurred rarely when the NICU was operating, have increased to 21 transfers in 2022. The hospital states that without a Level III NICU program these transfers out of the hospital are likely to continue to increase creating a larger gap in access to care in Prince George's County. (DI #11, p.34).

Although the maternal transfer numbers show an increasing gap in access, the hospital explains that this data does not show the number of pre-term mothers who would normally be routed to UMCRMC and are instead routed to facilities outside the County. The data also does not show those with high-risk pregnancies who may elect to travel outside the County to avoid the need for a transfer. (DI #11, p.35).

In addition to the ability to provide service to more mothers, the introduction of Level III services at the hospital is expected to reduce the number of infants requiring transfer to a different NICU facility to receive a higher level of care. In 2022, 43 babies went to another neonatal provider for a higher level of care, which is a 23 percent increase from its transfers in 2020 when it was operating at a Level III. (DI #11, p.35).

The applicant states it has always transferred infants to other facilities when the infant needed a higher level of care but in the past, it only had to do this for Level IV NICU babies. Currently operating as a Level II Special Care Nursery, it must also transfer when the infant

[13] The COVID-19 pandemic impacted the data beginning in March 2020.

requires a Level III NICU thus causing the number of transfers to increase. Table IV-4 compares 2020 when the hospital had a Level III NICU to the percentage of transfers out of UMCRMC since it has been a Level II Special Care Nursery. This number has increased from 8.6 percent of discharges in 2020 to 50 percent and 55.8 percent respectively in subsequent years. (DI #11, p.36).

Table IV-4: Infants Transferred from UMCRMC to a Higher Level of Care in CY 2020-2022

	CY20	CY21	CY22
Transfers to a NICU with Level III NICU services	3	11	24
Transfers to a NICU with Level IV or Level V NICU services	35	22	43
% of total transfers for higher level or specialty care UM-CRMC could have treated if Level III	8.6%	50%	55.8%

Source: UMCRMC internal data.

The applicant states that Table IV-4 shows UMCRMC could have treated at least half of the infants that it transferred to another NICU if it operated a Level III NICU instead of a Level II Special Care Nursery. It states that this demonstrates the need for a Level III program in the County. (DI #11, p.36).

III. Demographic and population health metrics in Prince George's County demonstrate a need for Level III NICU services at UMCRMC.

The applicant states that the proposed project will primarily serve Prince George's County, which has below average rankings in several key maternal-fetal metrics than the rest of Maryland. Lower performance in key metrics results in a higher likelihood of poor pregnancy outcomes that necessitate Level III NICU services. These metrics include:

- Currently scoring in the second worst quartile for poor pregnancy outcomes when compared to the rest of the State (9.6 %) for low-birth-weight babies (newborn weighing less than 2,500 grams).
- In 2019, 1.9 percent of the newborns delivered in Prince George's County were considered to have very low birth weight, which is in the 2nd worst quartile in the State.
- In 2019, 11.1 percent of the births in Prince George's County were considered pre-term which is in the lowest 25 percent of all the counties. Pre-term births require specialized medical care and may require a stay in an intensive care nursery.
- In 2019, only 53.6 percent of Prince George's County mothers received prenatal, which ranks in the bottom 25 percent of all the counties. Mothers who do not receive prenatal care are more likely to have low birth weight babies than mothers who receive early prenatal care.
- In 2019, the infant mortality rate in Prince George's County was 6.2 deaths per 1000 live births which is higher than the statewide rate of 5.9 deaths per 1000 live births. (DI #11, p.37).

The applicant states that poverty and education level can impact an individual's ability to access resources contributing to poor maternal and infant health. Thus, women living in poverty

are more likely to deliver prematurely and lack access to prenatal care. According to the Prince George's County Department of Health, in 2017, 7 percent of Black residents, 12.8 percent of Hispanic and 8.4 percent of White (non-Hispanic) residents of Prince George's County were living in poverty and approximately 12 percent of women ages 25-34 were below the poverty level. Additionally, the percentage of women of child-bearing age in Prince George's County who have a college degree (33%) was lower than that of the State (40%) and neighboring Washington, DC (60%). All these factors combined show an increased likelihood that babies born in the County will require a Level III NICU. (DI #11, p.37).

Staff Analysis

Applicant provided volume projections demonstrating that it will need nine beds and maintain a 6.4 average daily census for the NICU. In addition, the applicant reviewed the changes in discharges since the Level III NICU program was suspended and operated as a Level II Special Care Nursery. There was an increase in maternal and infant transfers from UMCRMC to other hospitals for care, and a decrease in maternal admissions for deliveries. The applicant demonstrated that this could be avoided if it could provide Level III NICU care. The applicant highlighted Prince George's County's unique community needs that resulted in a high prevalence of poor pregnancy outcomes, including low birth weight babies, pre-term births, infant mortality, and low use of prenatal care. Staff concludes that these poor outcomes along with the other data presented demonstrate the need for a Level III NICU in Prince George's County.

Staff recommends that the Commission find that the project is needed.

C. 10.24.01.08G(3)(c). Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Applicant Response

Please see the response to COMAR 10.24.10.04B(5) on Cost-Effectiveness.

D. 10.24.01.08G(3)(d). Viability of the Proposal.

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

Applicant Response

The Hospital

The applicant provided utilization and financial projections for the hospital as a whole in

Application Exhibit 1 with Tables F, G, and H. In 2022, the hospital had a negative net income of ($17,343,000). However, as reflected in the table below, UMCRMC is projected to achieve a positive net income by 2025 growing to $21,370,000 by 2028. The applicant states that the hospital CEO and administrative team have implemented ongoing performance improvements which include improvements to the management of the revenue cycle, labor management, productivity, supply chain and length of stay. The applicant states that the results of these improvements are already having a favorable impact on operational performance. (DI #21, p.15).

Table IV-5: UMCRMC FY Financial Performance Inflated (In Thousands)

	2021	2022	2023	2024	2025	2026	2027	2028
Net Operating Revenue	$385,900	$381,662	$393,985	$407,064	$418,373	$428,307	$438487	$448,916
Total Operating Expenses	$417,167	$402,352	$410,811	$410,752	$413,021	$419,240	$424,975	$431,380
Net Income*	($28,907)	($17,343)	($13,828)	($555)	$8,613	$12,491	$17,135	$21,370

Source: DI #11, Exh. 1, Table H.
*After adding in non-operating income

The applicant also included its documentation of community support for the project, as demonstrated by the letters included in Exhibit 10. The project requires no additional capital expenditure related to construction or renovation. The applicant has presented a project budget as shown in the table below that includes only legal and consulting fees that are funded by cash.

Table IV-6: Project Budget

Legal Fees	$65,000
Other Consulting Fees	$45,000
Total Fees	$110,000
Total Source of Funds-Cash	$110,000

Source: DI #21, Exh. 19, Table E.

The NICU

The hospital has not been providing Level III services since October 2020, so there is no current data to report regarding these services. However, the applicant provided utilization and financial projections for the NICU in their Application, Exhibit 1 with Tables I, J and K. The proposed NICU projections are shown in the following table (2024 is the first full year).

Table IV-7: Projected NICU Statistics*[14] (In Thousands)

	2023	2024	2025
Net Income	(3,116)	(1,914)	(1,920)
Discharges	137	147	147
Patient Days	847	2,368	2,366
Average Length of Stay	6.2	16.1	16.1
NICU Occupancy Rate	77.4%	71.9%	72%

[14] UM CRMC has not provided Level III NICU services since the suspension of those services in October 2020.

Source: DI #11 Exh.1, Tables I and J.
*The applicant provided projections through 2028 however the numbers remain constant between 2024 and 2028.
** To validate the provided data, staff reviewed fiscal year discharges further back for 2018-2020 which were 120, 143, and 133 discharges respectively, and are in line with the historic discharges in the table that the applicant expects to return to.

As shown above, the financial projections show that the NICU is not expected to generate excess revenue over expenses within a reasonable planning horizon. However, the applicant reports that this is partially because most patient days are and will continue to be reimbursed by Medicaid (68.9% in 2024, the first full year of NICU operations) and a majority of Medicaid patients will generate lower operating revenues than other payment sources. In addition, the NICU is only one department within the larger hospital, and it has both the hospital and the hospital's parent company UMMS to back it financially.

UMMS

Applicant provided the Ernest and Young audited financial statements for the entire University of Maryland Medical System (UMMS) Corporation and Subsidiaries in Exhibit 11. The subsidiaries include nine total UMMS hospitals as well as its health plans and foundations. The financial statements showed total net assets of $3,276,063,000 in 2022.

HSCRC Staff Analysis

HSCRC analysis showed that the 2028 operating income is projected to be $6,876,000. However, the applicant included performance improvements of $45,300,000, and if these improvements are not achieved, it could result in an operating loss of ($38,424,000). Cash flow from operations inclusive of performance improvements in 2028 is projected to be $41,307,000 but could become a negative ($3,993,000) if improvements are not fully realized.

Nevertheless, HSCRC staff concludes that it is reasonable to forecast that the proposed project will be financially feasible. As presented in the above viability criterion Table IV-5, the hospital, even with the inclusion of Level III NICU services, is projected to be financially viable in the long term. The HSCRC opined that although the hospital projections were optimistic it still deemed them feasible:

> …if UMMS is willing to absorb any resulting losses incurred…while honoring its consolidated debt covenants, then the NICU service recommencement (which is projected to have relatively immaterial and near break-even operating results) may be deemed to be feasible. (DI #23, p.4).

Staff Analysis

The NICU itself is slated to have negative net income, losing approximately 2M annually throughout the 2028 projections. In response to these projections, the applicant states that the NICU is not a stand- alone service line but is included within the "women's services" service lines. (DI # 21, p 9). The revenue and expense tables show that the entire hospital is still projected to be

financially viable with a positive net income of 8.6 M by 2025. The positive net income continues to grow to 21.4M through the last projected year of 2028. (DI #11, Exh. 1, Table H). Staff concludes that the NICU project will not jeopardize the ability of the hospital to be profitable by 2025.

Staff concludes that although the NICU will not be profitable, it is only one service within the whole hospital. Staff also concludes that although the HSCRC characterized the applicant's projections as optimistic they still think the hospital will be able to absorb the cost especially with the backing of UMMS. Staff recommends that the Commission find that based on the data presented and the opinion of the HSCRC, the project is viable.

E. 10.24.01.08G(3)(e). Compliance with Conditions of Previous Certificates of Need.

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

Applicant Response

The applicant states that since 2000, it has obtained one CON on October 20, 2016, for the *Relocation of Prince George's Hospital Center and Mt. Washington Pediatric Hospital, Inc*. (Docket No. 13-16-2351). The applicant states that there were no conditions, and the project was completed as approved. (DI #11, p.40).

Staff notes that while the Level III NICU was an approved service in the 2016 replacement hospital CON, those services were never implemented or operationalized at the new hospital, UMCRMC. Staff finds that while UMCRMC was temporarily non-compliant by failing to provide the service and failing to notify the Commission, it appears it was crucially necessary to make structural improvements to its quality oversight program. The staff feels confident that the inclusion of the two proposed conditions will prevent similar noncompliance in the future.

F. 10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System.
An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

Applicant Response

The applicant states it wants to improve access for patients requiring Level III NICU services in the service area. The applicant also states that it does not anticipate any adverse impact on the volumes of other health care providers as a result of this project because there is no other provider for Level III NICU services in the County. The applicant has historically provided the higher level of services and as a result of the suspension of Level III services, they have experienced a volume shift to other facilities outside the County. The applicant plans to recapture

this volume, and states it will not negatively impact other providers because it will be a return to recent past utilization and referral patterns amongst providers of Level III NICU services. In addition, most of the past infants in the NICU were born at the hospital, not transferred in from other hospitals. In 2019 only seven infants were transferred in to the PGHC NICU and six of the seven were from University of Maryland hospitals. (DI #21, p.9). For transfers out, the applicant states that it currently rotates transfers between multiple facilities. In the table below it shows the number of transfers from UMCRMC to other NICUs, by facility for calendar years 2021 and 2022.

Table IV-8: UMCRMC Transfers to Other NICUs by Facility 2021 and 2022

Recipient Facility	CY 2021	CY 2022
Childrens National Medical Center	15	23
University of Maryland Medical Center	6	14
Mercy Medical Center	1	1
Georgetown	0	2
George Washington	0	1

Source: UM-CRMC Internal Data. (DI #11, p.42).

The table shows that the majority of UMCRMC's transfer patients go to Children's National Medical Center (CNMC is a Level IV NICU) and the affiliated University of Maryland Medical Center (UMMC is a Level III NICU). The table also includes transfers for pediatric subspecialty care at CNMC that the hospital does not propose to provide service to, thus demonstrating that the impact on other hospitals will not be significant. (DI #11, p.42).

The applicant references that the Commission had previously recognized that Level III NICU services at UMCRMC would not adversely impact other health care providers in its decision approving the CON application to replace PGHC, which included plans for a Level III NICU. In the prior decision, the reviewer found that "the project will substantially improve the availability and accessibility to medical services provided by a modernized hospital for the residents of Prince George's County[15]" and that the benefits outweighed any adverse impact to other providers. The prior decision also determined that the project "is likely to have a positive impact on the health care delivery system[16]."

Staff Analysis

The NICU services chapter of the SHP identifies four regional service areas for the planning of NICU services: the Western, Central, Southern, and Eastern Regions. UMCRMC is in the Southern Region. The Southern Region includes Montgomery County, Prince George's County, Calvert County, Charles County and St. Mary's County.

There are currently 15 NICUs in Maryland that are Level III or higher located in six

[15] *re Dimensions Health Corporation d/b/a Prince George's Hospital Center and Mt. Washington Pediatric Hospital, Inc.*, Docket No. 13-16-2351 (September 30, 2016)
[16] *Ibid*

jurisdictions. One is located in Anne Arundel County, three in Baltimore County, one in Frederick County, one in Howard County, three in Montgomery County and six in Baltimore City. While there are currently no NICU programs that are Level III or higher in Prince George's County, it is not clear that accessibility to NICUs would be deemed inadequate under a strict interpretation of the State Health Plan chapter for NICUs.

> The Technical Advisory Committee recommended that the basic level of perinatal services capable of handling high-risk deliveries if they happen to occur should be accessible within one half-hour in Maryland: and high-risk neonatal services should be accessible for family visiting within a travel time of two to three hours.[17]

In Maryland there are two Level III NICUs in neighboring Montgomery County, Holy Cross Hospital, and Shady Grove Medical Center. According to Google Maps, UMCRMC is 20 minutes from Silver Spring (Holy Cross), and 34 minutes from Rockville (Shady Grove). Walter Reed is a Level III located in Bethesda, but it is a military hospital, so it was not included in the analysis. UMCRMC is also in close proximity to Annapolis (22 minutes) which is the location of Anne Arundel Medical Center. Another close option for a Level III is Howard County Medical Center in Columbia, Maryland, which is 31 minutes from UMCRMC.

If Level IV services are required, Largo is 50 minutes from Baltimore (Johns Hopkins Hospital and the University of Maryland Medical Center). In neighboring Washington D.C., Children's Medical Center provides both Level III and Level IV NICU services and is 20 minutes from UMCRMC.

Table IV-9: Time and Distance from UMCRMC to the Alternate Hospital's City

Hospital and Jurisdiction	Time/Distance from UMCRMC
Montgomery County	
UMCRMC	0/0
Holy Cross in Silver Spring	20 minutes/17.1 miles
Shady Grove Medical Center in Rockville	34 minutes/29.9 miles
Anne Arundel County	
Anne Arundel Medical Center in Annapolis	22 minutes/21.8 miles
Howard County	
Howard County Medical Center in Columbia	31 minutes/ 29.2 miles
Washington D.C.	
Children's Medical Center	20 minutes/12.8 miles

MHCC Staff Analysis

Part of the Impact criterion focuses on access to care. Although staff analysis has shown that the residents of Prince George's County currently already have access to multiple NICU programs within a 30-minute drive, there is no other NICU in Prince George's County. The applicant has demonstrated in the Need criterion that Prince George's County has unique health needs because of higher rates for pre-term deliveries and lower birth rates. Because NICU services

[17] COMAR 10.24.18 Neonatal Intensive Care Services Chapter of the State Health Plan, p. 16

historically existed at PGHC, staff are confident that there should be a return to historical volumes without negatively impacting other NICU programs. Staff recommends that the Commission find that the project impact will be positive, and applicant has met this criterion.

VI. SUMMARY AND STAFF RECOMMENDATION

Based on the staff's review of this application it is recommended the Commission find that UMCRMC has demonstrated a need, the cost-effectiveness, and the financial feasibility of proposed Level III perinatal services. The implementation of this project should not have a significant negative impact on existing Level III NICU programs. Staff recommends approval of the project with the following two conditions:

1. University of Maryland Capital Region Health will provide documentation to MHCC that it has been surveyed by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) to show compliance with the Perinatal System Standards for a Level III perinatal program and has been designated by MIEMSS as a provider of Level III perinatal service prior to implementing the Level III program.

2. After its initial survey, University of Maryland Capital Region Medical Center will maintain its MIEMSS designation in accordance with policies and procedures for periodic resurvey and re-verification of compliance with standards or this CON will become void.

IN THE MATTER OF	*	
	*	
UNIVERSITY OF MARYLAND	*	**BEFORE THE**
	*	
CAPITAL REGION	*	**MARYLAND HEALTH**
	*	
MEDICAL CENTER-NICU	*	**CARE COMMISSION**
	*	
Docket No. 23-16-2464	*	
	*	

****

FINAL ORDER

Based on the analysis and findings in this Recommended Decision, it is this 18th day of May 2023:

ORDERED that the application for Certificate of Need by University of Maryland Capital Region Medical Center Docket No. 23-16-2464, for a Level III Perinatal Program is **APPROVED,** subject to the following two conditions:

1. University of Maryland Capital Region Health will provide documentation to MHCC that it has been surveyed by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) to show compliance with the Perinatal System Standards for a Level III perinatal program and has been designated by MIEMSS as a provider of Level III perinatal service prior to implementing the Level III program.

2. After its initial survey, University of Maryland Capital Region Medical Center will maintain its MIEMSS designation in accordance with policies and procedures for periodic resurvey and re-verification of compliance with standards or this CON will become void.

MARYLAND HEALTH CARE COMMISSION

May 18, 2023

APPENDIX A:
RECORD OF THE REVIEW

Docket Item #	Description	Date
1	MHCC memo to hospital, stating awareness of the ceased operation of its NICU	5/4/2022
2	Applicant attorneys to MHCC, memo on discussion of the NICU	8/8/2022
3	MHCC to applicant attorney memo on regulatory requirements	8/26/2022
4	MHCC to hospital, CON is required for project, will waive 60 day waiting period	12/2/2022
5	Letter of intent received and acknowledged	12/8/2022
6	Applicant attorney to MHCC, request 60-day waiting period waived	12/8/2022
7	MHCC to applicant attorney, MHCC will waive the 60-day waiting period	12/9/2022
8	Maryland Register publication soliciting additional LOI's for NICU services in Southern HPR	12/14/2022
9	Applicant attorney to MHCC requesting waiver of select standards	12/14/2022
10	MHCC to applicant attorney, MHCC will not waive select standards	12/21/2022
11	Certificate of Need application	1/17/2023
12	MHCC to hospital acknowledging receipt of application for review.	1/18/2023
13	Washington Times-notice of application	1/19/2023
14	Maryland Register-notice of application	1/19/2023
15	Receipt Washington Times	1/20/2023
16	MHCC sends completeness questions	2/1/2023
17	Email HSCRC NICU Rates	2/10/2023
18	HSCRC Supplemental Completeness Questions	2/13/2023
19	Email HSCRC NICU rates Level II only	2/16/2023
20	Applicant requests extension on completeness questions until 2/28/2023 and MHCC granted	2/17/2023
21	Applicant responses to completeness received	2/28/2023
22	Applicant responses to HSCRC questions received	3/1/2023
23	HSCRC memo on feasibility received	3/6/2023
24	Formal start of application will be 3/24/23	3/8/2023
25	Request to publish docketing notice Maryland Register	3/8/2023
26	Request to publish docketing notice Washington Times	3/8/2023
27	Request Local Health Planning Comments	3/8/2023
28	Formal start of review published in Washington Times	3/10/2023

APPENDIX B:

MARYLAND HOSPITAL SPECIALTY REFERRAL CENTER PERINATAL PROGRAMS

APPENDIX B: Maryland Hospital Specialty Referral Center Perinatal Programs by Jurisdiction and Program Level

Jurisdiction	Hospital	Program Level
Frederick County	Frederick Memorial Hospital	Level III
Anne Arundel County	Anne Arundel Medical Center	Level III
	Baltimore Washington Medical Center	Level II
Baltimore City	Johns Hopkins Hospital	Level IV
	University of Maryland	Level III
	Johns Hopkins Bayview	Level III
	Mercy Medical Center	Level III
	Saint Agnes Hospital	Level III
	Sinai Hospital of Baltimore	Level III
	MedStar Harbor Hospital	Level II
Baltimore County	MedStar Franklin Square Hospital	Level III
	Greater Baltimore Medical Center	Level III
	Saint Joseph Medical Center	Level III
Carroll County	Carroll Hospital Center	Level II
Harford County	Upper Chesapeake Medical Center	Level II
Howard County	Howard County General Hospital	Level III
Montgomery County	Holy Cross Hospital	Level III
	Shady Grove Adventist Hospital	Level III
	Walter Reed	Level III
	White Oak Medical Center	Level II
Prince George's County	MedStar Southern Maryland Hospital	Level II
	UM Capitol Regional Health	Level II
St. Mary's County	St. Mary's Hospital	Level I

Source: https://www.miemss.org/home/hospitals/specialty-referral-centers

APPENDIX C:
PROJECT REVIEW STANDARDS

APPENDIX C: PROJECT REVIEW STANDARDS ACUTE CARE HOSPITAL SERVICES 10.24.10.04B[18]

(Bold indicates the standard was included in the review)

Geographic Accessibility
Identification of Bed Need and Addition of Beds
Minimum Average Daily Census for Establishment of a Pediatric Unit
Adverse Impact
Cost-Effectiveness
Burden of Proof Regarding Need
Construction Cost of Hospital Space
Construction Cost of Non-Hospital Space
Inpatient Nursing Unit Space
Rate Reduction Agreement
Efficiency
Patient Safety
Financial Feasibility
Emergency Department Treatment Capacity and Space
Emergency Department Expansion
Shell Space

[18] The standards in this section are intended to guide reviews of Certificate of Need applications and exemption requests involving acute care general hospital facilities and services. An applicant and its proposed project will be evaluated for compliance with all applicable review standards.

APPENDIX D:
UTILIZATION NOVEMBER 2020 TO CURRENT

Perinatal Babies Cared for by Weeks and Gestational Age at PGHC and UMCRMC November 2020 to January 2023

11/1/20-6/11/21	BW <1500g but GA >32 weeks	BW >1500g but GA <32 weeks	Both BW <1500g and GA <32 weeks
# of babies cared for at hospital	1	2	6

6/12/21-1/31/23	BW <1500g but GA >32 weeks	BW >1500g but GA <32 weeks	Both BW <1500g and GA <32 weeks
# of babies cared for at hospital	4	3	22

11/1/20-6/11/21	BW <1500g but GA >32 weeks	BW >1500g but GA <32 weeks	Both BW <1500g and GA <32 weeks
# of babies delivered at hospital and transferred to another hospital for NICU services	0	2	5

6/12/21-1/31/23	BW <1500g but GA >32 weeks	BW >1500g but GA <32 weeks	Both BW <1500g and GA <32 weeks
# of babies delivered at hospital and transferred to another hospital for NICU services	4	3	21

(DI #21, pp.2-5)

Regarding the above chart for the time period of 11/1/20-6/11/21 no babies needing NICU care were transferred to Prince George's Hospital Center for Level III NICU care immediately after delivery from another hospital however those that were already at the hospital stayed until discharge per joint agreement with MIEMSS. For the time period of 6/12/21-1/31/23 infants born at other area hospitals originally needing NICU care were secondarily transferred to UMCRMC when they reached an appropriate weight/age and could be cared for in the Level II Special Care Nursery. (DI #21, pp.2-5 and p.10).

APPENDIX E: HSCRC MEMO

maryland
health services
cost review commission

MEMORANDUM

To: Wynee Hawk, Chief CON
Jeanne Marie Gawel, Analyst, CON

From: Katie Wunderlich, Executive Director
Jerry Schmith, Director
Bob Gallion, Associate Director
March 6, 2023

Re: University of Maryland Capital Regional Health (UMCRH) Capital Regional Medical Center (CRMC) – Certificate of Need (CON) for Recommencement of Level III Neonatal Intensive Care Unit (NICU) Services

This memo is in response to your memo directed to us dated February 9, 2023, regarding a request for our review, comment and analysis pertaining to the feasibility of the proposed project and its impact on the hospital's global budget revenue (GBR).

BACKGROUND

As stated in the above noted memo, on January 17, 2023, UMCRH submitted a CON request for the recommencement of Level IIINICU services at CRMC. Level III NICU services were previously provided at Prince George's Hospital Center (PGHC), subsequently PGHC relocated to Largo, Maryland and resumed operations as CRMH in 2021.

THE PROJECT

The proposed project involves a Level III NICU. There are no other Level III NICU programs in Prince George's County, which is the second most populous county in Maryland. CRMC expects that the unit will treat a minimum average daily census (ADC) of 6.4 patients. There is no construction or renovation needed for the proposed project because CRMC was designed to operate Level III NICU services. There are no incremental capital related costs associated with this project. Also, there will be no changes required to staffing levels. The applicant states that it can open the program immediately after receiving regulatory approvals.

HSCRC STAFF REVIEW, DISCUSSION, AND OPINION

Staff reviewed the rate file for CRMC/PGHC and noted that in October 2020, UMCRH voluntarily downgraded the nursery services from Level III NICU services to Level II Special Care Nursery services following a patient complaint and subsequent internal process review. Subsequently, CRMC has operated with Level II services since its opening in 2021. The NICU rate was not removed from the rate order, nor was the GBR reduced for service change. UMCRH simply charged at the lesser nursery rate rather than the higher NICU rate. Staff intends to make no change to the rate order or to the GBR upon recommencement of the NICU services at CRMC.

Staff reviewed the Table G (P&L Uninflated Entire Facility) as submitted by UMCRH management which is to represent all of Capital Region Health inclusive of Capital Region Medical Center, Laurel Medical Center, and Bowie Health Center. As per review of Responses dated March 1, 2023, the Table G historical and projected P&L for periods FY2021 through FY2028 are modeled after a similar Table G historical and projected P&L for periods FY2020 through FY2027 which was submitted with the related Laurel CON submission dated January 13, 2023, save for changes due to incremental revenues and expenses associated with the Level III NICU. Additionally, such responses also indicated that FY2022 P&L was sourced from FY2022 budgeted values for CRH, not actual audited financials.

CRH Operating Loss measures (in 000s) as presented in the audit report are as follows:

	2020	2021	2022
By Division:	($18,092)	($30,266)	($64,522)
By Hospital:	($19,344)	($32,667)	($59,550)

CRH Operating Loss measures (in 000s) as presented in the submissions are as follows:

	2020	2021	2022
As submitted:	($18,100)	($30,267)	($20,730)

Given that the audited measures by division closely tie to the submissions for FY2020 and FY2021, staff took note of the variance apparent as reflected in the submission for FY2022. Such an understated loss in Table G for 2022 sets up the presentation for the planned performance improvements to overcome the losses within the projected period. Our initial impression of this presentation is that it may represent a negative cushion of $44M in the projections.

Staff reviewed the Table G assumptions included in the submission and the Responses dated March 1, 2023, as they relate to the observed contractions in Gross Patient Service Revenues for FY2026, FY2027, and FY2028 relative to the respective prior years' projected revenues. The contractions were attributed to "shared savings adjustments" as per the responses. The contraction over the three projected years ending FY2028 is $1,650,000. Staff researched the planned reduction in GBR attributed to "All Payer Rate Reduction for TCOC Performance" to get back to HSCRC/federal contract compliance and noted such contraction over the two years ending FY2024 is to be $885,200. Although the timing of the proposed adjustments is considerably different, the contraction as measured by the CRH submission represents a potential cushion of $765K in the projections.

Measured cumulative planned performance improvements of $45.3M are reflected in the assumptions to Table G for the five years ended FY2028, of which nearly 30% are as undefined. This is consistent with the planned performance improvements of $40.2M for the first four years ended FY2027 as reflected in Table G for the Laurel CON submission, of which just over 20% are undefined. Staff took note of the difference in presentations of planned performance adjustments between the two CONs for CRH submitted just days apart. As per the responses dated March 1, 2023, the planned performance improvements are components of both the annual operating plan and the five-year plan for CRH. Here again, the starting point (FY2022) measures are important to the concluding point (FY2028) when considering the results of planned performance improvements between the two points.

Focusing on the last year (FY2028) of the six years projected in Table G, the Operating Income is projected to be $6,876,000 with the benefit of yet to be realized performance improvements of $45,300,000, which by implication could be an Operating Loss of -$38,424,000 without the benefit of planned performance improvements. Cash flow from operations inclusive of performance improvements in FY2028 is projected to be a positive $41,307,000, which could be a negative -$3,993,000 if such improvements are not fully realized. Again, such concluding projections may be optimistic given that the starting point of Operating Income (FY2022) may be $44M overstated.

The Table H projections (P&L Inflated Entire Facility) for CRH are modeled after those of Table G and incorporate assumptions for annual inflation. Staff researched the rate files for the three hospital facilities in CRH and concluded that the 2.58% annual inflation assumption is reasonable.
Also, the assumptions for inflation on operating expenses range from 2% to 4%, which staff concludes to be reasonable.

In conclusion, the projected operating results for CRH may have been presented optimistically. It is quite possible the CRH may not reach profitability within the six years ended FY2028. However, if the consolidated UMMS is willing to absorb any resulting losses incurred by CRH, while honoring its consolidated debt covenants, then the NICU service recommencement (which is projected to have relatively immaterial and near breakeven operating results) may be deemed to be feasible.