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December 20, 2023

VIA EMAIL & HAND DELIVERY

Ms. Ruby Potter
ruby.potter@maryland.gov
Health Facilities Coordination Officer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Shore Health System, Inc. Responses to Completeness Questions dated December 6, 2023 for Replacement and Relocation of University of Maryland Shore Medical Center at Easton

Dear Ms. Potter:

On behalf of the applicant Shore Health System, Inc., we are submitting an electronic version of the Responses to Completeness Questions dated December 6, 2023. By separate email, we will provide a WORD version of the responses.

We hereby certify that a copy of this submission has also been forwarded to the appropriate local health planning agency as noted below.

If you have questions about the information provided above, please contact us at your convenience.

Sincerely yours,

Mallory Regenbogen

Mallory Regenbogen

Alison Lutich

Alison Lutich

cc: Ben Steffen, Executive Director, MHCC
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SHORE HEALTH SYSTEM, INC.
RELOCATION OF UNIVERSITY OF MARYLAND SHORE MEDICAL CENTER AT EASTON
Matter No. 23-20-2463

Responses to Completeness Questions Dated December 6, 2023

STATE HEALTH PLAN

COMAR 10.24.11.
General Surgical Services

1. **Under COMAR 10.24.11.07B(34), the definition for a "special purpose operating room" means a sterile operating room that is dedicated for a specific purpose or surgical specialty such as a cesarean-section operating room and in which space, equipment, or other factors limit its use to a narrow range of surgical procedures.**

   Pursuant to COMAR 10.24.11.05B(2)(a) - (c), Need – Minimum Utilization for a New or Replacement Facility, please provide a response that address each subparagraph of this standard, with particular attention to (b) that references COMAR 10.24.11.06 to support the need for two special purpose operating rooms at UM SMC Easton upon project completion.

Below are the Applicant's responses to each substandard within COMAR 10.24.11.05B(2)(a)-(c).

COMAR 10.24.11.05B(2) - Need - Minimum Utilization for Establishment of a New or Replacement Facility.

An applicant proposing to establish or replace a hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for the number of operating rooms proposed for the facility, consistent with the operating room capacity assumptions and other guidance included in Regulation .06 of this Chapter.

Applicant Response

Regulation .06A(c) provides the applicable capacity assumptions for special purpose ORs, which are as follows:

> Optimal capacity for a special purpose operating room is best determined on a case-by-case basis, using information provided by an applicant regarding:
>
> (i) The population or facility need for each special purpose operating room or both;
>
> (ii) The documented demand for each special purpose operating room; and
>
> (iii) Any unique operational requirements related to the special purpose for which the operating room will be used.

UM SMC at Easton needs two cesarean ORs so that one OR is always available for an emergency cesarean delivery. The American College of Obstetricians and Gynecologists generally recommends that units have the capacity to initiate emergency C-sections with a decision-to-incision time of 30 minutes or less. In certain emergent circumstances, such as uterine rupture, placental abruption, hemorrhage from placenta previa, prolapse of the umbilical cord, and maternal cardiac arrest, however, it is essential to have a C-section OR immediately available to initiate the cesarean section, in order to improve the maternal and fetal outcomes. *See* American Academy of Pediatrics and American College of Obstetricians and Gynecologists, *Guidelines for Perinatal Care*, 267 (8th Ed. 2017).

Table 47 below identifies the number of instances in FY2020, FY2021, and FY2022 when more than one C-section was performed at UM SMC at Easton within the same four-hour period.

Table 47
Frequency of 2 or More C-Sections Performed in the Same 4-Hour Period
FY2020 – FY2022

	Instances of 2+ C-Sections within 4 Hours		
	FY2020	**FY2021**	**FY2022**
Count	24	17	17

Source: Shore internal data

As shown in *Table 47*, in each of the years analyzed, there were between 17 and 24 instances where more than one C-section was performed in the same four-hour period. This highlights the need for more than one C-section OR, as delays in initiating surgery for patients in need of emergency C-sections could result in unfavorable outcomes for both the mother and child.

(b) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the initiation of surgical services at the proposed facility, consistent with Regulation .06 of this Chapter.

Applicant Response

Unlike for general purpose ORs, there is no minimum volume capacity threshold for special purpose ORs. For the reasons discussed in the response to section (a) above, having two C-section ORs at the Replacement Facility will support improved patient safety and outcomes by ensuring that one of the rooms is immediately available for emergency C-sections.

Table 48 below presents the Applicant's historical and projected utilization for its C-section ORs. The Annual growth in C-section cases and the number of C-section OR cases presented in this Table are consistent with those presented in the Applicant's obstetrics need narrative in the CON application. C-section OR minutes per case are assumed to remain constant at the FY 2022 level of 82 minutes per case through the projection period. OR minutes for C-section cases increased from 68 minutes per case in FY 2021 to 82 minutes per case in FY 2022 due to practitioner variability and a greater emphasis on patient safety. The 45-minute TAT for C-section

OR cases is consistent with the assumption used by Shore in the surgical services need narrative and is based on internal data from FY 2021.

Table 48
C-Section OR Need Assessment Using General OR Capacity Standard
FY2019 – FY2032

		Historical				Projected									
		2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
	Growth in C-Sections					0.5%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
A	C-Section OR Cases	263	210	205	208	209	211	212	214	216	217	219	221	223	224
B	OR Minutes per Case	68	67	68	82	82	82	82	82	82	82	82	82	82	82
C = A * B	OR Minutes	17,884	14,070	13,940	17,056	17,139	17,274	17,410	17,547	17,685	17,824	17,964	18,105	18,247	18,391
D	Turnaround Time (TAT) per Case (minutes)	35	45	45	45	45	45	45	45	45	45	45	45	45	45
E = A * D	Total TAT Minutes	9,205	9,450	9,225	9,360	9,406	9,480	9,554	9,629	9,705	9,781	9,858	9,936	10,014	10,092
F = C + E	Total OR & TAT Minutes	27,089	23,520	23,165	26,416	26,545	26,754	26,964	27,176	27,390	27,605	27,822	28,041	28,261	28,483
G	C-Section Operating Room Need	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00

Source: HSCRC statewide data tapes and Shore internal data

The Applicant presents a need for two C-section operating rooms in *Table 48* due to the importance of having one C-section OR immediately available for emergency C-sections to support patient safety and standards of care. If the proposed Replacement Facility were to only have one C-section OR, then emergent cases would be at risk for poor outcomes due to the increased time it could take to initiate an emergency C-section after transporting a patient to the facility's main OR suite and securing an available room. Further, the Applicant is the only hospital in the five-county service area that performs C-sections, making it even more essential that it be equipped with immediate availability for an emergency C-section room to serve the population in this region.

Due to operational constraints during the summer of 2023, the Applicant was forced to perform all C-sections in the main OR for a one-month period. The Applicant manually audited charts for all unscheduled C-sections (emergent and non-emergent) to determine the difference in time it takes from provider decision to "in-room" for C-section cases performed in the main OR compared to those performed in the L&D C-section OR. The time from decision to "in-room" starts when the provider decides that the patient requires a C-section and the patient consents, and ends when the patient enters the operating room. This timeframe includes prep and mobilization. Table 49 below presents the results of this analysis.

Table 49
Comparison of Decision Time to In-Room Time for L&D OR vs. Main OR
FY2022

Room	Average Time from Decision to in Room
Main OR	37
L&D OR	15

Source: Shore internal data

As demonstrated in Table 49, the average time from provider decision to "in-room" for C-section cases performed in the main OR was 37 minutes, which is 22 minutes longer than the same measure for C-section cases performed in the L&D C-section OR. This 37 minute average time also exceeds the upper limit recommended by ACOG for initiating emergency C-sections. For

emergent cases, this 22-minute difference could be the difference between favorable and unfavorable outcomes. In these emergent cases, the proximity of the OR and timeliness of starting surgery is highly correlated with better infant and maternal outcomes. If the Replacement Facility were to only have a one C-section OR, it would extend the timeframe to initiate emergency C-sections by requiring these patients be transported to the main OR suite, which could negatively affect patient outcomes.

(c) An applicant proposing to establish or replace a hospital shall submit a needs assessment that includes:

(i) Historic trends in the use of surgical facilities for inpatient and outpatient surgical procedures by the new or replacement hospital's likely service area population;

Applicant Response

See response to (b) above.

(ii) The operating room time required for surgical cases projected at the proposed new or replacement hospital by surgical specialty or operating room category; and

Applicant Response

See response to (b) above.

(iii) In the case of a replacement hospital project involving relocation to a new site, an analysis of how surgical case volume is likely to change as a result of the relocation.

Applicant Response

See response to (b) above.

2. **Similar to your response to support the need for the seven mixed-use general purpose ORs, provide the historic (FY 2019 through 2022) utilization for the one c-section OR and the projected utilization (FY 2023 through 2029) during construction. Also, provide the projected utilization of the two special purpose ORs ("c-section rooms") upon project completion (FY 2030 through 2032).**

   The utilization data should include the annual number of c-section cases, average number of c-section surgery minutes per case, and the average turnaround time (TAT) for the c-section surgical cases for the historic and projected years.

   If the TAT is not consistent with COMAR 10.24.11.06A(2)(a) for a 25-minute turnaround time, please provide the assumptions that document and support the need for the alternative TAT.

Applicant Response

See response to (b) above.

3. **Also, in accordance with COMAR 10. 24.11.05B(6), Patient Safety, please address how UM SMC Easton addressed patient safety in the design for the two -c-section ORs.**

Applicant Response

As indicated on page 146 of the CON application, the obstetric unit's two cesarean ORs are standardized designs that were planned with input from the Chair of the OB/GYN Department, Manager of the Labor and Delivery Unit, Chief Nursing Officer, and Director of Surgical Services and Anesthesia.

The two cesarean ORs are designed to meet standards as outlined in American College of Obstetricians and Gynecologists ("ACOG") and American Academy of Pediatrics ("AAP") Guidelines for Perinatal Care, 8th Edition, as well as Guidelines for Design and Construction of Hospitals by The Facility Guidelines Institute ("FGI"). The operating suite is located within the Women's wing, allowing for immediate access for emergency cesarean deliveries from the labor & delivery rooms, as well as immediately adjacent to a trauma elevator with direct connection to the Emergency Department ("ED") for patients presenting at the ED. Within the suite, the two ORs are supported with dedicated prep/recovery bays and support spaces to create a self-sufficient suite fully supportive of anesthesia, nursing, and physicians. Prep/recovery bays are located with nursing support space for direct observation of patients preparing for planned surgeries and recoveries of both planned and emergent surgeries. Support alcoves in the controlled zone of the suite allow for quick access to hemorrhage medications, sterile supplies, and specialty equipment such as a difficult airway cart. Provisions for family support in both prep/recovery and the OR allow for direct communication between the care team, patient, and birthing partner as well as provide safe and dedicated location(s) for the birthing partner in the OR.

Within the OR, appropriate medical gas, electrical power, and data connections will be provided near the table to enable the medical team to act quickly, as time is critical in cesarean sections. Infant resuscitation provisions will be provided in a dedicated zone within the OR as well as additional infrastructure in an adjacent space for additional infant resuscitation bay(s) to support births of multiples.

The cesarean ORs' location within the Women's wing also allows for safe and quick transfer from recovery bays to a postpartum room. This location, adjacent to postpartum rooms, also supports immediate access to necessary OR space, equipment, and personnel for patients experiencing postpartum hemorrhage, a frequent cause of severe morbidity and preventable maternal mortality. Other key adjacencies include nearby on-call room(s) for quick physician or midwife response at all times and the nursery, which is embedded within the Women's department.

Table of Tables

Table	Description

I hereby declare and affirm under the penalties of perjury that the facts stated in the Responses to Additional Information Questions dated December 6, 2023 and its attachments are true and correct to the best of my knowledge, information, and belief.

December 20, 2023
Date

DocuSigned by:
paul nicholson
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Paul Nicholson
Senior Vice President and Chief Financial Officer
University of Maryland St. Joseph Medical Center

I hereby declare and affirm under the penalties of perjury that the facts stated in the Responses to Additional Information Questions dated December 6, 2023 and its attachments are true and correct to the best of my knowledge, information, and belief.

December 20, 2023
Date

DocuSigned by:
William Huffner, MD
81797A00C422456...

William Huffner, MD, MBA, FACEP, FACHE, CMO and Senior Vice President of Medical Affairs
University of Maryland Shore Regional Health

I hereby declare and affirm under the penalties of perjury that the facts stated in the Responses to Additional Information Questions dated December 6, 2023 and its attachments are true and correct to the best of my knowledge, information, and belief.

December 20, 2023
Date

DocuSigned by:
Jennie Bowie
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Jennifer Bowie, MBA, BSN, RN
Senior VP Patient Care Services and
Chief Nursing Officer
University of Maryland Shore
Regional Health

I hereby declare and affirm under the penalties of perjury that the facts stated in the Responses to Additional Information Questions dated December 6, 2023 and its attachments are true and correct to the best of my knowledge, information, and belief.

December 20, 2023
Date

DocuSigned by:
Jessica Genrich
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Jessica Genrich, MBA, RNC-OB
C-EFM, Interim Nurse Manager,
Woman & Children's Service.
University of Maryland Medical
System, Shore Regional Health.

I hereby declare and affirm under the penalties of perjury that the facts stated in the Responses to Additional Information Questions dated December 6, 2023 and its attachments are true and correct to the best of my knowledge, information, and belief.

December 20, 2023
Date

DocuSigned by:
Emily Dickinson
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Emily Dickinson
Vice President
HKS, Inc.