BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF ANDOCHICK SURGICAL CENTER LLC d/b/a PHYSICIANS SURGERY CENTER OF FREDERICK CON APPLICATION TO ADD OUTPATIENT OPERATING ROOMS IN FREDERICK COUNTY	Docket No. 21-10-2451

INTERESTED PARTY FREDERICK HEALTH HOSPITAL, INC.'S RESPONSE TO ANDOCHICK SURGICAL CENTER LLC'S SECOND RESPONSE TO COMPLETENESS QUESTIONS

Frederick Health Hospital, Inc. ("FHH" or the "Frederick Hospital") hereby submits comments to the Response to the MHCC's Second Request for Information dated August 17, 2022 (the "PSCF Final Comments") of Andochick Surgical Center LLC d/b/a Physicians Surgery Center of Frederick (collectively, "Applicant" or "PSCF").[1] As noted previously, the Applicant carries the burden of proof that its proposed project meets the criteria for review by a preponderance of the evidence. COMAR 10.24.01.08G(1). Despite having another opportunity to satisfy its burden, PSCF falls short of its regulatory obligations.

Frederick Hospital incorporates by reference its prior comments of December 30, 2021, and July 7, 2022. Frederick Hospital reiterates its concern that PSCF failed to include reliable facts and objective information upon which the Commission may grant a certificate of need.

[1] The Commission granted Frederick Hospital a chance to respond within seven business days of the PSCF Final Comments.

Rather than repeat its continuing concerns, which PSCF has not fully addressed to date, Frederick Hospital highlights below just some of the more significant inconsistencies and errors contained in the PSCF Final Comments.

1. PSCF's "Individual Physician's Submissions" (PSCF Final Comments, Tab 3, Exhibit 7) signed by each PSCF surgeon[2] purport to project the anticipated surgical cases and minutes into calendar year 2026. *See* COMAR 10.24.11.05B(3).[3] These forms, similar to the previous forms, are simply newer, more recent, guesses of how many surgeries each surgeon would like to perform if PSCF has four operating rooms and additional procedure rooms in its facility.[4] The PSCF Final Comments offered little justification or explanation to support these numbers, including whether these physicians have sufficient man-hours in their schedules to support an increase in overall procedures performed each year. PSCF also did not sufficiently tie these numbers to any actual need for additional operating rooms in Frederick County and surrounding communities.

2. The physicians include in their "Individual Physician's Submissions" surgical procedures that would be clinically appropriate to be performed, on a case-by-case basis, in a procedure room- but may also be performed in an operating room when there is more complexity, also on a case-by-case basis. Procedures of lower complexity that require a lower level of sedation are clinically appropriate for a procedure room, assuming that one is equally available to the physician.

---

[2] Many surgeons refused to sign the Individual Physician's Submission, because of "perjury concerns." (PSCF Submission, Tab 2, Ex. 5b). This required Dr. Andochick to sign, and affirm, these submissions on their behalf.

[3] Consistent with the Commission's guidance concerning this application, citations are to the State Health Plan for Facilities and Services: General Surgical Services COMAR 10.24.11, effective January 15, 2018.

[4] The Applicant must demonstrate need for each proposed additional operating room consistent with COMAR 10.24.11.07. Operating room capacity, in part, should be based upon confirmed volume data, and upon observed trends in demand that take into account population changes for the demographic group expected to be served by the Applicant's facility. COMAR 10.24.11.07B.

There are several surgical procedures identified in each surgeon's "top five" most frequently performed surgeries in the "Individual Physician Submissions" that are clinically appropriate to be performed in a procedure room, on a case-by-case basis, and assuming a procedure room is available for use.[5] The Commission should consider that the Applicant has an available procedure room, and that the Applicant reported a volume of less than 100 procedures per year in its procedure room in 2022, and a projection of less 200 procedures in its anticipated 2 procedure rooms by 2026. (PSCF Submission, Tab 2, Ex.3, Table 1).[6] The use of the most cost-effective, clinically appropriate setting possible is entirely consistent with State Health Plan Policy #2, COMAR 10.24.11.03, pg. 7.

This also means that the surgical minutes "projected to be contributed" by these ophthalmologists and orthopedists may include projections of an historical volume of minutes that may not be limited to operating room need projections. Potentially lower complexity procedures scheduled in a higher complexity setting may result in inflating the number of operating room minutes needed – and procedure room minutes by themselves would be a poor justification for the need for additional operating rooms. These errors, carried forward, means that the Applicant's anticipated surgical minutes to justify two additional operating rooms would be, simply put, overstated- and does not demonstrate the need for two additional operating rooms as required by COMAR 10.24.11.05.B.(2)

[5] PSCF's surgeons identified the following among their top five surgical procedures- each of which would be clinically appropriate to be performed in an available procedure room or operating room, on a case by case basis and depending on complexity: cataract extractions, knee manipulation, pteraviuem excision, endothelial keratoplasty, corneal biopsy, corneal lobellar goniectom, carpal tunnel release, open carpal tunnel release, trigger finger release, cubital tunnel release, lesion excision head & trunk, endoscopic carpal tunnel release, excisions wrist ganglion cyst, Dequervians release, and lesion excision & biopsy.

[6] The addition of a procedure room to an existing Physician Outpatient Surgery Center (using the terminology of January 15, 2018 State Health Plan for General Surgical Services), is subject to the requirements of the Commission's form titled, "Requesting and Obtaining a Determination of Coverage to Establish a Freestanding Ambulatory Surgical Facility in Maryland."

3. Unless most of the surgeons on PSCF's medical staff are currently working part time, it remains unclear how many of the surgeons anticipate finding the time to double or triple their surgical volumes over the course of three years.

4. It remains unclear whether the CY2022 projections in the "Individual Physician Submissions" are based upon partial year actual data.

5. PSCF's Tab 3, Exhibit 6 does not correctly project optimal capacity because the surgical minutes reported by the physicians may include surgical time that may be provided in procedure rooms. The total estimated surgical time including cases that could be performed in procedure rooms is 248,270 minutes by CY2026. Exhibit 6 adds in an additional 7,000 minutes of unexplained procedure room time. PSCF then appears to use the total surgical minutes for procedure room and operating room cases to justify the addition of operating rooms.

6. PSCF's budget projection is based on Tab 2, Exhibit 3, which provides total procedure projections (4165 cases by CY26) that are different from its procedure projections under Tab 3, Exhibit 6 (3955 cases by CY26). PSCF does not explain this discrepancy, which requires the Commission to decide whether either set of facts is accurate.

7. PSCF's Tab 2, Exhibit 3 also includes a row called "Total Surgical Minutes in ORs" with one number inside parenthesis and another number outside of the parenthesis. That row does not explain why there are two sets of numbers, or which set of numbers that the Commission should rely upon.

8. PSCF's Tab 2, Exhibit 3 includes a row representing "Total OR and PR Minutes" and another row representing "Total Surgical Minutes in ORs". While one row purports to include procedure room minutes and the other row does not, the total for both is identical (256,320).

9. PSCF's Tab 2, Exhibit 5 (Table 4) includes projected "Salaries, Wages, and Professional Fees, (including fringe benefits)" in the amount of $**666,210** for CY2026. In PSCF's June 23, 2022 submission, at Tab 5, Exhibit 20, Table L (Workforce Projection), PSCF calculated the total cost for regular employees through the last year of projection (presumably also CY2026) as $**2,515,024**. While it may be appropriate for PSCF to rely on reasonable estimates of retained experts in its application, a discrepancy of almost $2,000,000 would normally stretch the boundary of reasonableness. This discrepancy impacts both the budget and PSCF's regulatory requirement of financial feasibility, particularly when PSCF's calculations demonstrate that the facility will operate at a loss until CY2026 even using the lower figure of $666,210 (and, per Exhibit 5b, even applying the third unexplained "Salaries, Wages…" amount of $872,790, there is still a discrepancy of $1.6M).

10. PSCF's response to the request for additional information on the impact to Frederick Hospital includes two tables with the same data, (*see* Tab 5, table embedded in text, and Ex. 18 with additional detail). Curiously, PSCF declined the Commission's invitation to begin its analysis with the information that was provided by Staff. Assuming PSCF's new information is acceptable over the information already provided, the tables are incorrect in at least two ways.

First, the tables simply surmise, incorrectly, that the <u>only</u> impact Frederick Hospital will experience is that the additional volume anticipated at PSCF each year will not be performed at Frederick Hospital. As explained in Frederick Hospital's July 2022 submission, FHH will experience a far greater impact than demonstrated in PSCF's table. PSCF should, but refuses to, determine impact by looking retroactively at historical data and then prospectively projecting the impact of the decrease in the historical volume at Frederick Hospital after the opening of the proposed surgical capacity.

Second, PSCF's response on the impact to other providers (Tab 5, Ex. 18) states incorrectly that the loss in new volume is limited to that year (e.g., 2024, 364 patients; 2025, 128 patients; 2026, 123 patients). The actual impact to Frederick Hospital should be added year-over-year because PSCF is adding the year-over-year increase in cases each year in its projection - and therefore the positive impact to PSCF is cumulative. As a result, the true volume impact, relying solely on PSCF's information and ignoring the information (for the moment) provided by Staff in its August 3 letter and the table provided by Frederick Hospital in its July 7, 2022 comments, is the following: 2021 – 504 cases; 2022 – 866 cases; 2023 – 1169 cases; 2024 – 1,533 cases; 2025 – 1,661 cases; and 2026 – 1,784 cases. Using solely PSCF's approach, FHH would experience a much larger drop in operating room cases in CY2026, and not the suggested, small 0.81% impact in 2026, or the average impact of 1.9% purported by that table. Should the Commission consider the information provided by Staff in its August 3 letter, and the information provided by Frederick Hospital in its July 7 comments, the actual impact on Frederick Hospital is significantly greater.

In the interest of process integrity, the Applicant must satisfy the CON baseline requirements with reliable and accurate information. The Applicant has not met its burden. The PSCF Final Comments includes potentially inaccurate information, errors, and inconsistencies, which are in addition to the errors and inconsistencies in the Applicant's previous responses.

The Applicant also must address directly both the issues raised in the State Health Plan and those questions raised by the Commission and Staff. Applicant has, on numerous occasions, ignored or avoided these issues. Frederick Hospital respectfully requests that the Commission take Frederick Hospital's response, as well as each of Frederick Hospital's previously filed Interested Party Comments into consideration and **deny** PSCF's CON Application.

Respectfully submitted,

Christopher Dean
Jennifer J. Coyne
MILES & STOCKBRIDGE P.C.
100 Light Street
Baltimore, Maryland 21202
(410) 385-3490 (telephone)
(410) 385-3700 (fax)
cdean@milesstockbridge.com
jcoyne@milesstockbridge.com

Frederick Health Hospital, Inc.

AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in this Interested Party Response are true and correct to the best of my knowledge, information, and belief.

James B. Sherwood
Signature

James B. Sherwood
Printed Name

VP, Business Development & Strategy
Title
Frederick Health