

Karen Shelton, MD State Health Commissioner Department of Health P O BOX 2448 RICHMOND, VA 23218

TTY 7-1-1 OR 1-800-828-1120

October 18, 2023

Thomas J. Stallings McGuireWoods Gateway Plaza 800 East Canal Street Richmond, Virginia 23219

**RE: COPN No. VA-04863** 

Reston Hospital Center, LLC

**Planning District 8** 

Establish a Specialized Center for CT imaging Within a Freestanding Emergency

Department

Dear Mr. Stallings:

In accordance with Chapter 4, Article 1.1 of Title 32.1 of the Code of Virginia of 1950 (the Code), as amended, I reviewed the application and all supporting documents submitted by Reston Hospital Center, LLC to establish a specialized center for computed tomography (CT) imaging, within a freestanding emergency department, Leesburg Emergency and Imaging Center.

As required by Section 32.1-102.3B of the Code, I have considered all factors that must be taken into account in a determination of public need, and I have concluded that **conditional approval** of the request is warranted based on the following findings:

- The proposed project is consistent with COPN law, is in harmony with the SMFP or public policies, interests, and purposes to which the SMFP and COPN law are dedicated;
- 2. There are no less costly or more efficient alternatives to the project;
- 3. The project is feasible. Its capital costs are reasonable and would be covered without financing;
- 4. The applicant has demonstrated an institutional need to expand its CT services; and

Mr. Thomas J. Stallings COPN No. VA-04863 October 18, 2023

5. The proposed project is unlikely to have a negative impact on the utilization, costs, or charges of other service providers in PD 8.

This certificate is valid for the period October 18, 2023 through October 17, 2024. The total authorized capital cost of the project is \$22,234,000.

Please file two copies of the application for a certificate extension with the Department and one copy with the regional health planning agency no later than 30 days before the expiration date of the certificate. Part VIII of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,

Karen Shelton, MD State Health Commissioner

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#### Enclosures

cc: Allyson Tysinger, Senior Assistant Attorney General, Commonwealth of Virginia Erik Bodin, Director, Division of Certificate of Public Need Deborah K. Waite, Operations Manager, Virginia Health Information David Goodfriend, MD, MPH, District Director, Loudoun Health District Dean Montogomery, Executive Director, Health Systems Agency of Northern Virginia

Vanessa MacLeod, Adjudication Officer, Virginia Department of Health



# MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED COMMONWEALTH OF VIRGINIA DEPARTMENT OF HEALTH

THIS CERTIFIES THAT Reston Hospital Center, LLC is authorized to initiate the proposal as described below.

NAME OF FACILITY: Leesburg Emergency and Imaging Center

LOCATION: 1301 Edwards Ferry Road Northeast, Leesburg, Virginia 20176

OWNERSHIP AND CONTROL: Reston Hospital Center, LLC

SCOPE OF PROJECT: Establish a specialized center for computed tomography (CT) imaging with one CT scanner within a \$22,234,060. The project is expected to be completed by November 30, 2025. This certificate is issued with the condition that freestanding emergency department, Leeshurg Emergency and Imaging Center. Capital costs authorized for this project total appears on its reverse.



Pursuant to Chapter 4, Article 1.1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.12 of the Code of Virginia (1950), as amended and the shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report

Certificate Number: VA-04863

Date of Issuance: October 18, 2023

Expiration Date: October

October 17, 2024

Karen Shelton, MD, State Health Commissioner

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charity care provided individuals pursuant to this condition shall be based on the provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under Title XVIII of the Social Security Act, 42 U.S.C. § equal to at least 2.63% of Reston Hospital Center, LLC's gross patient revenue derived from CT services. Compliance with this development and operation of primary medical care services to medically underserved persons in PD 8 in an aggregate amount Reston Hospital Center, LLC will provide CT services to all persons in need of these services, regardless of their ability to pay, appropriately certified financial statements documenting compliance with the preceding requirement. Reston Hospital Center provider reimbursement methodology utilized by the Centers for Medicare and Medicaid Services for reimbursement under will accept a revised percentage based on the regional average after such time regional charity care data valued under the Title XVIII of the Social Security Act; 42 U.S.C. § 1395 et seq. is available from Virginia Health Information. The value of and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise

seq. Reston Hospital Center, LLC will facilitate the development and operation of primary and specially medical care services Reston Hospital Center, LLC will provide CT care to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et in designated medically underserved areas of the applicant's service area. Recommended Case Decision
Certificate of Public Need (COPN)
Request Number VA-8703
Reston Hospital Center, LLC
Fairfax, Virginia
Planning District (PD) 8
Health Planning Region II
Establish a specialized center for CT Imaging

### I. Introduction

This document is a recommended case decision, submitted to the State Health Commissioner (hereinafter, "Commissioner") for consideration. It follows full review of the administrative record pertaining to the above-captioned application, as well as the convening of an informal fact-finding conference (IFFC)<sup>1</sup> conducted in accordance with the Virginia Administrative Process Act<sup>2</sup> and Title 32.1 of the Code of Virginia.

## II. Authority

Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 et seq.) of the Code of Virginia (the "COPN Law") addresses medical care services and provides that "[n]o person shall undertake a project described in [this Article] or regulations of the [State] Board [of Health] at or on behalf of a medical care facility . . . without first obtaining a certificate [of public need] from the Commissioner." The endeavor described and proposed in this application falls within the statutory definition of "project" contained in the COPN law, and thereby, requires a Certificate to be issued before the project may be undertaken.

#### III. Statement of Facts

The factual basis underlying this recommendation consists of evidence in the administrative record, including, but not limited to, the application giving rise to this review, the testimony of witnesses presented, and written documents prepared by the applicant at and following the IFFC, and the and the two governmental analyses, *i.e.*, staff reports on the proposed project – by the Division of Certificate of Public Need ("DCOPN") and by the Health Systems Agency of Northern Virginia ("HSANV").

<sup>&</sup>lt;sup>1</sup> The IFFC was held on August 2, 2023. A certified reporter's transcript ("Tr.") of the IFFC is in the administrative record ("AR").

<sup>&</sup>lt;sup>2</sup> Va. Code § 2.2-4000 et seq.

<sup>&</sup>lt;sup>3</sup> Va. Code § 32.1-102.1:2 (A); (a "Certificate" or COPN).

<sup>4</sup> Va. Code §§ 32.1-102.1 and 32.1-102.3.

Specific findings of fact are as follows:

- 1. Reston Hospital Center ("Reston") is a limited liability company formed in 1999 under the laws of the State of Delaware. Reston is located in Reston, Virgina. Reston's ultimate corporate parent is HCA Healthcare, Inc. ("HCA").
- 2. Reston proposes to establish a specialized center for Computed Tomography (CT) imaging located in a freestanding emergency department, which would be located in Leesburg, Virginia, in PD8, HPR II.
- 3. The total capital cost of the proposed project is \$22,234,000, which would be paid from HCA Healthcare, Inc. funds.<sup>5</sup> The cost of the CT scanner is \$2,700,000.<sup>6</sup>
- 4. DCOPN is comprised of the Virginia Department of Health's professional health facilities planning staff. On July 19, 2023, DCOPN issued its staff report recommending conditional approval of this project.<sup>7</sup>
- 5. Virginia is divided into five Health Planning Regions. Each Health Planning Region may have a "regional health planning agency", as defined in Va. Code § 32.1-102.1. The proposed project would be located in PD 8, coterminous with Health Planning Region II. HSANV operates in PD 8 by reviewing projects and making recommendations on COPN applications. HSANV's Board of Directors voted, seven in favor and two opposed, recommending denial of this project.<sup>8</sup>
- 6. The administrative record on the proposed project closed on September 8, 2023.9

### A. The Proposed Project in Relation to the Eight Statutory Considerations

The COPN law requires that any decision to issue a Certificate must consider the eight statutory factors enumerated in Virginia Code § 32.1-102.3(B) and consistency with the State Health Services Plan. Virginia Code § 32.1-102.2:1 calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan. Because the State Health Services Plan is still in development, I am considering consistency of the proposed project with the current regulatory language provided in the State Medical Facilities Plan (SMFP). The SMFP, found in the Virginia Administrative Code (VAC) at 12 VAC 5-230-10 et seq., is the planning document adopted by the Board of Health, which includes methodologies for projecting need for medical facilities and services, as well as procedures,

<sup>&</sup>lt;sup>5</sup> COPN Application at 34-35 (AR Exhibit ("Ex.") 4).

<sup>&</sup>lt;sup>6</sup> Id. at 31.

<sup>&</sup>lt;sup>7</sup> AR Ex. 23.

<sup>8</sup> AR Ex. 21.

<sup>&</sup>lt;sup>9</sup> Tr. at 78.

<sup>10</sup> Va. Code § 32.1-102.3.

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criteria, and standards of review of applications for projects for medical care facilities and services.

The eight statutory considerations provided by the COPN law appear in bold type below, with statements pertinent to the proposed project.

1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care.

The population of PD 8 as a whole is expected to increase approximately 14% for the period ending in 2030, nearly double that of the statewide average. The population growth projection for the age 65 and older cohort is 38% for the period ending in 2030, greater than the statewide rate. This is significant as this age group uses medical resources, including diagnostic services, at a rate much higher than the rest of the population.

The specialized imaging center would be located less than 0.3 miles off of US Route 15, making it easily accessible for people in the area to be served. The site is accessible by Loudoun County transit buses and from the Ashburn Metrorail.

Currently, there are 70 COPN-authorized CT scanners in PD 8.<sup>15</sup> DCOPN calculated a need for 9 additional CT scanners in PD 8.<sup>16</sup>

The proposed project seeks to establish a specialized center for CT imaging with one CT scanner at Leesburg Emergency and Imaging Center to serve Reston's existing patients.<sup>17</sup> Reston is a 243-bed acute care hospital, which provides a full range of medical and surgical services.

The proposed project addresses both the public need for additional CT capacity in PD 8 under 12 VAC 5-230-100 and Reston's institutional need to expand its busy CT service under 12 VAC 5-230-110. In 2021, Reston's four CT scanners operated at a utilization rate of 109.17%. HCA did not report any underutilized scanners in PD 8. In 2022, these four CT scanners performed 33,225 CT procedures, with a utilization rate of 112%. In June of 2022, Reston began using a CT Scanner at Tysons Corner Emergency Center. VHI data is not yet available for this fifth scanner.

<sup>11</sup> DCOPN Staff Report at 5 (AR Ex. 23)

<sup>12</sup> Id.

<sup>13</sup> Id. at 6.

<sup>&</sup>lt;sup>14</sup> Id.

<sup>15</sup> DCOPN Staff Report at 2-3 (AR Ex. 23).

<sup>&</sup>lt;sup>16</sup> DCOPN Staff Report at 18 (AR Ex. 23); COPN Application at 26 (AR Ex. 4).

<sup>&</sup>lt;sup>17</sup> A Certificate is not required to establish a freestanding emergency department.

<sup>18</sup> DCOPN Staff Report at 18-19 (AR Ex. 23).

<sup>19</sup> Id.

<sup>&</sup>lt;sup>20</sup> COPN Application at 23 (AR Ex. 4).

<sup>&</sup>lt;sup>21</sup> DCOPN Staff Report at 12 (AR Ex. 23).

<sup>&</sup>lt;sup>22</sup> Id.

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Based on the 2021 data, the average amount of charity care provided by HPR facilities was 2.63% of all reported total gross patient revenues.<sup>23</sup> Pursuant to § 32.1-102.4(B) of the Code of Virginia, I believe the applicant should be subject to a charity care condition of 2.63% of HPR II average. The applicant agrees to this condition.<sup>24</sup>

I believe that the approval of the proposed project would increase access to CT services in PD 8.

- 2. The extent to which the proposed project will meet the needs of the people in the area to be served, as demonstrated by each of the following:
  - (i) The level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

Potentially affected service providers have been notified and are aware of the proposal. The administrative record contains at least 7 letters of support, and three physicians spoke on behalf of the proposed project at the IFFC. HSANV opposes the project and recommends denial of this project.<sup>25</sup> Inova Health Care Services also opposes the proposed project.<sup>26</sup>

(ii) The availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

No reasonable alternative to the proposed project exists. The applicant's expansion of CT imaging services through the addition of one CT scanner at Leesburg Emergency and Imaging Center addresses an institution-specific need for additional services and a PD-wide need for additional CT capacity.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

HSANV's Board of Directors voted, seven in favor and two opposed, recommending denial of this project.<sup>27</sup> Among the reasons for recommending denial, HSANV includes the fifth CT scanner at Tysons Corner Emergency Center in its SMFP calculations;<sup>28</sup> argues that if there is a need then the CT scanner should be added to the hospital campus, not a freestanding emergency department "at the periphery of its service area";<sup>29</sup> and highlights a utilization

<sup>&</sup>lt;sup>23</sup> Tr. at 66; August 30, 2023 DCOPN Proposed Findings of Fact at 1-2.

<sup>&</sup>lt;sup>24</sup> Tr. at 48, 61-62, 66-67; Reston Proposed Findings of Fact and Conclusions of Law and Response to HSANV Concluding Comment at 37.

<sup>&</sup>lt;sup>25</sup> AR Ex. 21: HSANV Concluding Comment.

<sup>&</sup>lt;sup>26</sup> DCOPN Staff Report at 19 (AR Ex. 23); Inova Health Care Services Letter of Opposition AR Ex. 13.

<sup>&</sup>lt;sup>27</sup> AR Ex. 21.

<sup>&</sup>lt;sup>28</sup> Тг. at 70.

<sup>&</sup>lt;sup>29</sup> June 6, 2023 HSANV Report at 9 (AR Ex. 21); Tr. at 71.

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distinction between hospitals and freestanding emergency department CT services to argue a lack of need for an additional freestanding emergency department CT scanner.<sup>30</sup>

In response, Reston argues that HSANV's position is inconsistent, and cites to HSANV's recently calculated need for 11 additional CT scanners in PD 8.31

## (iv) Any costs and benefits of the proposed project;

The estimated capital costs of the proposed project are \$22,234,000, which would be funded through HCA's reserves.<sup>32</sup> The total costs for the project are reasonable in comparison to similar projects.

# (v) The financial accessibility of the proposed project to people in the area to be served, including indigent people; and

The Pro Forma Income Statement anticipates a charity care contribution equal to 2.7% of Reston's gross revenues. The applicant expressly agreed to the charity care condition of no less than the 2.63% of HPR II average, as recommended by DCOPN.<sup>33</sup>

I believe that, if the project is approved, the agreed upon charity care condition of 2.63% of HPR II average is appropriate.

# (vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a proposed project.

No additional factors relating to the review of this project are remarkable or appear to call for the exercise of the Commissioner's discretion in identifying or evaluating them in relation to the proposed project.

## 3. The extent to which the proposed project is consistent with the State Health Services Plan.

The proposed project seeks to add a new CT scanner to PD 8. For PD 8, 95% of the population has access to CT services within a 30 minutes driving distance.<sup>34</sup>

Pursuant to 12 VAC 5-230-100(A),

No new fixed site or mobile CT service should be approved unless fixed site CT services and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area

<sup>&</sup>lt;sup>30</sup> June 6, 2023 HSANV Report at 7(AR Ex. 21); Tr. 72-74; HSANV Concluding Comment at 11.

<sup>&</sup>lt;sup>31</sup> June 6, 2023 HSANV Report at 7(AR Ex. 21); IFFC Ex. 6; IFFC Exhibit 17; Reston Proposed Findings of Fact and Conclusions of Law and Response to HSANV Concluding Comment at 40.

<sup>&</sup>lt;sup>32</sup> COPN Application at 34-35 (AR Ex. 4).

<sup>33</sup> Tr. at 48, 61-62, 66-67; August 30, 2023 DCOPN Proposed Findings of Fact.

<sup>&</sup>lt;sup>34</sup> DCOPN Staff Report at 16-17(AR Ex. 23); Pursuant to 12 VAC 5-230-90, CT services should be available within 30 minutes driving time one way under normal conditions of 95% of the PD's population.

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distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.

The applicant proposes to expand an existing CT service, not establish a new one. Current DCOPN inventory accounts for 70 CT scanners.<sup>35</sup> The utilization of existing CT scanners in PD 8 was 130.8% of the SMFP threshold,<sup>36</sup> and DCOPN calculates a need for nine fixed CT scanners in this planning district.<sup>37</sup> None of HCA's CT scanners are underutilized in PD 8.<sup>38</sup> In 2021, Reston's four CT scanners operated at a utilization rate of 109.17%.<sup>39</sup> In 2022, these four CT scanners performed 33,225 CT procedures, with a utilization rate of 112%.<sup>40</sup> The Leesburg Emergency and Imaging Center is within Reston's primary service area.<sup>41</sup>

I believe the applicant satisfies the requirements for consideration under the institutional need for expansion under 12 VAC 5-230-80 and has demonstrated a need for one more CT scanner.

Not only is there a public need for additional CT capacity in PD 8, but Reston also has an institutional need to expand its busy CT services.

4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served.

Reston is not a new competitor in PD 8. Rather, it is an established provider. Reston's service area overlaps significantly with that of Inova Health Care Services, another established provider in PD 8. Leesburg is among each of these systems' primary service areas. The proposed project would introduce beneficial competition to this area because 50% of the existing CT scanners in PD 8 are owned by or in partnership with Inova Health Care Services, and all but one of the existing CT scanners in Leesburg are owned by or in partnership with Inova Health Care Services. 42

No evidence suggests that the project would adversely affect competition in PD 8. The proposed project is not likely to impact any single provider significantly because the utilization of nearby facilities is high, in some cases well above the SMFP standard for expansion.

5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

<sup>35</sup> DCOPN Staff Report at 18-19 (AR Ex. 23).

<sup>&</sup>lt;sup>36</sup> 12 VAC 5-230-110.

<sup>&</sup>lt;sup>37</sup> DCOPN Staff Report at 18-19 (AR Ex. 23); Existing CT scanners used solely for simulation with radiation therapy treatment were exempt from this utilization analysis in conformity with 12 VAC 5-230-100(B).

<sup>&</sup>lt;sup>38</sup> DCOPN Staff Report at 23 (AR Ex. 23).

<sup>39</sup> Id. at 18-19.

<sup>&</sup>lt;sup>40</sup> COPN Application at 23 (AR Ex. 4).

<sup>&</sup>lt;sup>41</sup> COPN Application at 21, Attachment IV(B)(1), Reston Service Area Map (AR Ex. 4).

<sup>&</sup>lt;sup>42</sup> DCOPN Staff Report at 23 (AR Ex. 23); Tr. at 76-77.

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The proposed project does not entail a substantial change in the regional health care delivery system. The addition of one CT scanner is not likely to negatively affect demand or caseloads at other service providers. Reston has an institutional need for the requested CT scanner. Reston has seen increased demand for emergency and outpatient imaging services. Relocation of an existing CT scanner or maintaining the status quo are not reasonable alternatives to the proposed project.

6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.

The estimated capital costs of the proposed project are \$22,234,000, which would be funded through HCA's reserves.<sup>43</sup> The total costs for the project are reasonable in comparison to similar projects.

With regard to staffing, the applicant anticipates the need to hire 4.2 radiologic technologists. It is unlikely that the applicant would have any difficulty recruiting additional staff. It is also unlikely that the applicant's staffing needs would adversely impact other service providers.

7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of health care services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; and (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

The proposed project does not provide any improvements or innovations in the financing or delivery of healthcare services through the introduction of new technology that would promote quality, cost effectiveness, or both in the delivery of healthcare services.

As an alternative to hospital-based services, the proposed project would offer outpatient CT services for patients who do not require diagnostic imaging services in a hospital setting. Also, the proposed project would improve access to emergency and CT services for Reston's patients who live closer to the proposed site than the hospital.

No additional factors relating to the review of this project are clearly remarkable or appear to call for the exercise of the Commissioner's discretion in identifying or evaluating them in relation to the proposed projects as gauged under this item under the seventh statutory consideration.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served (i) the unique research, training, and clinical mission of the

<sup>&</sup>lt;sup>43</sup> COPN Application at 34-35 (AR Ex. 4).

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teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. This facility is not associated with a teaching hospital or medical school.

#### **B.** Conclusion

Based on the administrative record and in light of the discussion above, I conclude that Reston has demonstrated a public need for the proposed project.

#### IV. Recommendation

Based on review of the evidence contained in the administrative record, the proposed project merits conditional approval under the COPN law. Reston should receive a Certificate authorizing the project, issued with the stated charity care condition of 2.63% of HPR II average.

In addition to the conclusions drawn throughout this document, specific reasons for my recommendation include:

- (1) The proposed project is consistent with the COPN law, is in harmony with the SMFP or public policies, interests, and purposes to which the SMFP and COPN law are dedicated;
- (2) There are no less costly or more efficient alternatives to the project;
- (3) The project is feasible. Its capital costs are reasonable and would be covered without financing;
- (4) The applicant has demonstrated an institutional need to expand its CT services; and
- (5) The proposed project is unlikely to have a negative impact on the utilization, costs, or charges of other service providers in PD 8.

Respectfully submitted,

Vanessa MacLeod, JD Adjudication Officer

October 10, 2023