**BEFORE THE STATEWIDE HEALTH COORDINATING COUNCIL AND THE STATE HEALTH PLANNING AND DEVELOPMENT AGENCY**

DR-159

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STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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| **IN RE:** | ) |
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| **2LR HEALTHCARE HOLDINGS, LLC d/b/a HEART AND VACSULAR INSTITUTE OF ALABAMA, LLC and STATE HEALTH PLAN SECTION 410-2-3-.03** | ) |
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## PETITION FOR DECLARATORY RULING

Plaintiff, 2LR Healthcare Holdings, LLC d/b/a Heart and Vascular Institute of Alabama ("HVIA"), files this Petition for Declaratory Ruling (the "Petition") pursuant to ALA. CODE § 41-22-11. This Petition relates to the interpretation by the Statewide Health Coordinating Council ("SHCC") of its intent in drafting Alabama State Health Plan § 410-2-3-.03 entitled "Cardiac Services." Specifically, HVIA requests the SHCC issue a Declaratory Ruling that determines an Ambulatory Surgery Center ("ASC") with a fixed-based cardiac catherization laboratory ("cardiac cath lab") performing elective percutaneous coronary intervention ("PCI") is consistent with § 410-2-3-.03 of the Alabama State Health Plan ("SHP").

### Introduction and Procedural History

1. On September 25, 2020, HVIA filed a Certificate of Need ("CON") Application proposing to establish a free-standing, single-specialty ASC.
2. The proposed ASC would be designed, equipped, and staffed to perform endovascular and cardiac catheterization procedures, including PCI.
    a. The Centers for Medicare and Medicaid Services ("CMS") paid facility fees to ASCs for most procedures to be performed at HVIA by 2012 but only

began paying for cardiac catheterization and PCI specifically in January of 2020.

b. Prior to reimbursement, in 2019, CMS determined the coronary intervention procedures that would be performed at HVIA "can be safely performed in the ASC setting, for certain Medicare patients" and that "expert consensus, clinical guidelines and clinical studies establish that percutaneous coronary interventions can be safely performed in an ASC setting." 84 Fed Reg 61387.

c. The expert consensus, clinical guidelines, and clinical studies referred to by CMS are those of the Society for Cardiovascular Angiography and Interventions ("SCAI"), the American College of Cardiology ("ACC"), and the American Heart Association ("AHA"). These organizations set guidelines for cardiologist in this country, and, because of their importance and expertise, the SHCC requires their opinions to be considered when determining whether a CON Application for cardiac services in Alabama should be granted. *See* § 410-2-3-.03(1)(b)5 ("Planning Policy 5"). These organizations have determined that PCIs are safely performed in an ASC setting on appropriately selected patients. See Dehmer, Gregory et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Journal of the American College of Cardiology (2014) and Box LC, Blankenship JC, Henry TD, et. al., *SCAI Position Statement on the Performance of Percutaneous Coronary Intervention in Ambulatory Surgery Centers.* Catheter Cardiovasc Interv. 2020;1-9. https://doi.org/10.1002/cc'd.28991

3. On November 20, 2020, The Healthcare Authority for Baptist Health ("Baptist") and Jackson Hospital and Clinic, Inc. ("Jackson") (collectively, "Intervenors") filed their Notice of Intervention and Opposition[1].

4. The Administrative Law Judge ("ALJ") assigned to this matter conducted a contested case hearing, which concluded on April 26, 2021.

5. On July 28, 2021, the ALJ issued a Recommended Order to the CON Review Board declining to recommend the project due to the omission of the term "ASC" in the Cardiac Service section of the SHP. The ALJ stated he would defer this issue to the CON Review Board's interpretation of its rules and asked that the matter then be remanded back to him for a later finding on the merits of the case if the CON Review Board disagreed with his interpretation.

6. On September 15, 2021, the CON Review Board held a meeting where the ALJ's findings were reviewed. HVIA presented testimony regarding its project at this time, and the Intervenors presented their opposition to HVIA's project.

    a. After such review and presentation of testimony, the CON Review Board requested HVIA seek a modification of the SHP regarding the performance of PCI in an ASC setting due to the omission of the term "ASC." However, a declaratory ruling from the SHCC finding that ASCs are fixed-based facilities that may perform PCI consistent with the intent of the SHP would negate the need for a modification and would therefore save valuable time, lengthy litigation and financial resources for all parties involved.

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[1] Additional interventions and oppositions were filed by Montgomery Surgery Center and Jackson Surgery Center, although neither performs PCIs or has cardiac cath labs.

b. Therefore, HVIA files this Petition for Declaratory Ruling to obtain SHCC's interpretation of § 410-2-3-.03.

**Authority of the SHCC**

7. The Alabama Administrative Procedure Act ("AAPA"), ALA. CODE §§ 41-22-1, et seq., is the statutory procedural code for the operation of all state agencies when they take action affecting the rights and duties of the public. In *Ex parte Traylor Nursing Home, Inc.*, 543 So. 2d 1179, 1186 (Ala. 1988), the Alabama Supreme Court found that the SHCC is a state agency within the meaning of the AAPA, and therefore "is required to follow the requirements set forth in the AAPA."

8. Based on ALA. CODE § 41-22-11, the SHCC has the authority to issue a Declaratory Ruling interpreting the applicability of § 410-2-3-.03 to the current CON Application at issue.

   a. Section 41-22-11 states, "On the petition of any person substantially affected by a rule, an agency may issue a declaratory ruling with respect to the validity of the rule or with respect to the applicability to any person, property or state of facts of any rule or statute enforceable by it or with respect to the meaning and scope of any order of the agency."

   b. The SHCC is a state agency that is the advisory council to the State Health Planning and Development Agency (SHPDA) and to the State CON Review Board. ALA. CODE § 22-4-8 (b) (9) (11). The SHCC's interpretation of its own regulations and policy provisions are enforceable by the SHCC pursuant to these and other roles of the SHCC provided in ALA. CODE §§ 22-4-8 (a) and (b).

9. HVIA is substantially affected by § 410-2-3-.03 and SHCC's interpretation of it. The future of HVIA's CON Application and project depends on the interpretation of § 410-2-3-.03 because the CON Review Board will use the interpretation to decide whether to grant HVIA's CON Application.

10. In addition, a declaratory ruling is appropriate in this matter because it will address policy questions that not only affect HVIA immediately but will also affect potential future applicants for cardiac cath labs in ASCs. In the absence of an interpretation by the SHCC, these answers will likely be provided by multiple ALJs, who may make varying determinations.

**Argument**

11. HVIA's CON Application is consistent with § 410-2-3-.03 of the SHP because its application is for "fixed-based" cardiac catherization services, and the omission of the term "ASC" from this provision does not imply the SHCC intended PCIs to be prohibited in the ASC setting.

12. Section 410-2-3-.03(1)(a)(3) states, "Fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama." This is the only limitation in § 410-2-3-.03 regarding the location of certain cardiac catheterization procedures.

    a. While "fixed-based" cardiac catheterization services is not defined for this rule, an ASC is "fixed-based" within the common meaning of the term[2]. Therefore, HVIA's Application for a fixed-based cath lab fulfills the only limitation of this section.

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[2] Even the health planning expert witness hired by the Intervenor/Opponents agreed that an ASC is a fixed-base facility.

13. The Intervenors' argument that HVIA's project is inconsistent with the Cardiac Services section of the SHP is largely based on a portion of Planning Policy 5 of § 410-2-3-.03(1)(b), which provides multiple restrictions and requirements for acute care hospitals without open-heart surgical capability ("OSS") to perform elective PCI. Specifically, the Intervenors argued, and ALJ Waggoner agreed, that because this Planning Policy only refers to acute care hospitals, and not ASCs, this means that ASCs are prohibited. However, this is a faulty interpretation based on a misinterpretation of the omission of the term "ASC" and a lack of acknowledgement regarding the historical context of the provision.

14. The omission of a term in the SHP does not imply prohibition.

    a. In *Affinity Hospital, LLC v. Brookwood Health Services, Inc.*, 143 So. 3d 208 (Ala. Civ. App. 2013), the Court found a CON application could be found consistent with the SHP even if it proposed a service or facility not mentioned in the SHP. As in *Affinity*, HVIA proposes to establish a facility not directly referenced within the SHP but not prohibited. Therefore, as in that case, HVIA's project may still be found consistent with the SHP.

    b. Although the SHCC could have easily inserted plain language into the cardiac services section requiring that cardiac catheterization services could only be performed in a hospital setting, they did not. For any entity other than the SHCC to insert that requirement into the section would be improper.

15. The historical context of Planning Policy 5 explains why only acute care hospitals are referenced.

a. As discussed in the Introduction above, CMS only as recently as 2019 began reimbursing ASCs for the performance of PCIs. Up until that time, and at the time this Planning Policy 5 was written, the only facilities performing PCIs were hospitals.

b. Therefore, Planning Policy 5 could only possibly refer to acute care hospitals because there were no other facilities on which to impose such restrictions. The omission of other such facilities does not imply a prohibition but instead implies the nonexistence of now qualified facilities such as ASCs at the time of the enactment of the Policy.

16. The discussion section of § 410-2-3-.03(1)(a) contains this specific language: "As newer cardiac diagnostic and treatment modalities are developed, it is highly likely that the role of cardiac catheterization will continue to evolve. Certain cardiac catheterization procedures are now offered in physicians' offices outside of the usual hospital environment."

17. Also in Planning Policy 5, the SHCC recognized the possibility that after the enactment of certain provisions governing elective PCI, the field of cardiac services may evolve in such a way that the CON Review Board would be required to consider other authorities outside of the SHP.

a. Planning Policy 5 states the CON Review Board "shall consider" the most recent recommendations/guidelines for cardiac catheterizations adopted by Society for Cardiovascular Angiography and Intervention (SCAI), the American College of Cardiology (ACC), and the American Heart Association (AHA) as informational resources when considering any CON Application for

elective PCI services. As discussed above, these organizations now agree that PCIs may safely be performed in an ASC on appropriately selected patients.

18. HVIA's CON Application is consistent with § 410-2-3-.03 because it meets all the criteria for fixed based facilities performing cardiac catherization services without OSS provided in Planning Policy 5. Although HVIA acknowledges there is no clear statement that PCI may be performed in an ASC setting, it contends there is similarly no clear statement that they cannot, and that the framework for an acute care hospital performing elective PCIs without OSS should also be followed by proposed ASCs without OSS where applicable.

**PRAYER FOR RELIEF**

WHEREFORE, the premises considered, HVIA respectfully requests SHCC make the following determinations:

(1) Locating a cardiac catherization laboratory in an ambulatory surgery center is consistent with the current State Health Plan;

(2) The State Health Plan does not prohibit elective percutaneous coronary intervention from being performed in a cardiac catherization laboratory of an ambulatory surgery center; and

(3) The relevant conditions imposed by the current State Health Plan on a hospital performing elective same day discharge percutaneous coronary intervention procedures apply to the same procedures being performed in an ambulatory surgery center.

Respectfully submitted this 9th day of November 2021.

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**CERTIFICATE OF SERVICE**

I hereby certify that I have served a copy of the foregoing document on each of the following by sending each a copy of same by U.S Mail or electronic mail, properly addressed, on November 9th, 2021:

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| **INSTITUTE OF ALABAMA, LLC** | ) | |
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## ORDER ON DECLARATORY RULING REQUEST

This matter came before the Statewide Health Coordinating Council (SHCC) on a Petition for Declaratory Ruling filed by 2LR Healthcare Holdings, LLC d/b/a Heart and Vascular Institute of Alabama, LLC. The petition seeks a determination from the SHCC whether the cardiac services section of the current Alabama State Health Plan (SHP) allows the performance of percutaneous coronary artery interventions (PCI) in an ambulatory surgery center (ASC).

The SHCC finds it significant that the current SHP mandates that the Certificate of Need Review Board (CONRB) shall consider the recommendations of the Society for Cardiovascular Angiography and Intervention (SCAI), the American College of Cardiology (ACC), and the American Heart Association (AHA) regarding cardiac services, including the performance of PCI in fixed based catheterization labs in ASC's. All these organization have published findings that scheduled PCIs on selected patients can be performed safely in cardiac catheterization labs located in ASCs.

In 2019, with written recommendation and support from the ACC and SCAI, Medicare approved the performance of PCIs in cardiac catheterization labs located in ASCs. Some of the language in section 410-2-3-.03 of the SHP only mentions hospitals since when this section was written only hospitals were approved by Medicare to perform PCI in fixed based cardiac catheterization labs. Now that Medicare has approved PCIs to be performed in fixed based cardiac catheterization labs in ASCs, it is the position of the SHCC that the omission of the words "ambulatory surgery center" or "ASC" in these sections of the current SHP does not prohibit PCI from being performed in cardiac catheterization labs located in ASCs within the state of Alabama.

The SHCC finds and determines that the 2020-2023 Alabama SHP and more particularly section 410-2-3-.03(1) authorizes the performance of PCIs in approved Alabama health care facilities with fixed-based cardiac catheterization labs.

The SHCC defines a fixed-based cardiac catheterization lab as a nonmobile procedural room designed and equipped for the performance of minimally invasive cardiovascular interventional procedures. These procedures include, but are not limited to, PCI, diagnostic coronary artery angiography, implantation of cardiac rhythm devices and monitors, peripheral vascular interventions, maintenance of dialysis access, etc.

The SHCC declares that it is inherent in the language of the current Alabama SHP that the above-mentioned procedures may be performed in Medicare approved health facilities in Alabama with a fixed based cardiac catheterization lab(s). Currently these Medicare approved health facilities include Alabama hospitals and Alabama ambulatory surgery centers only.

In summary, for the reasons described above, the SHCC declares that the current language of the Alabama SHP permits scheduled PCIs to be performed in licensed ambulatory surgical centers with fixed based cardiac catheterization labs in the State of Alabama that meet the applicable conditions in section 410-2-3-.03 of the SHP.

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Elaine H. Beech
Chairman