

May 14, 2021

RV2021-019

RECEIVED

May 14 2021

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

VIA ELECTRONIC FILING:

shpda.online@shpda.alabama.gov

Ms. Emily T. Marsal, Executive Director
State Health Planning & Development Agency
100 North Union St., Suite 870
Montgomery, AL 36104

RE: Non-Reviewability Determination Request – The Heart Center Cardiology
Our File No.: 38685

Dear Ms. Marsal:

Enclosed please find a restructured non-reviewability request submitted by Dr. Mitchell, on behalf of his private physician's practice The Heart Center Cardiology, pursuant to CON Rule 410-1-7-.02. The Heart Center's request is restructured to reflect the narrow scope of services Dr. Mitchell will actually perform in the office-based lab and to demonstrate that the particular procedures are recognized as appropriately performed in the office-setting. The request also reaffirms that the services will be provided within, and on behalf of, his private physician's office at The Heart Center. The Heart Center's request satisfies the Physician's Office Exemption and does not constitute a new institutional health service under Alabama law. Respectfully, the Agency should therefore issue a letter of non-reviewability for the subject request.

The Agency is well-aware of the Physician's Office Exemption under Alabama law. Alabama Code § 22-21-263(a)(1) includes in the definition of new institutional health services subject to CON review: "the construction, development, acquisition through lease or purchase, or other establishment of a new health care facility or health maintenance organization." Under Alabama Code § 22-21-260(6), the definition of a health care facility includes among other things, "facilities for surgical treatment of patients not requiring hospitalization", "laboratories" and "out-patient clinics." Specifically excluded from this definition are "the offices of private physicians or dentists, whether for individual or group practices and regardless of ownership.." *Id.*

The definition of new institutional health services also includes any new health services offered through a health care facility. ALA. CODE 22-21-263(a)(4) (1975 as

{B4025124}

amended). However, a "the lawful practice of any profession or vocation conducted independently of a health care facility and in accordance with applicable licensing laws of this state" is excluded from the health services definition. ALA. CODE 22-21-260(8) (1975 as amended).

In *Ex parte Sacred Heart*, the Alabama Supreme Court clarified the POE to the definition of a "health care facility" by "adopt[ing] a modified four-part test to be used to determine" whether a proposal qualifies for the exemption. 155 So. 3d 980, 987-88. As the Agency is aware, the test is straightforward:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

Id., at 988. The Supreme Court stated its intent that "[t]he POE application test will provide an objective standard that can be used to determine whether the POE applies to any medical practice, whether the practice is solo or group, large or small, specialized or general." *Id.*

As set forth in Dr. Mitchell's letter, The Heart Center's request satisfies each of these criteria. There is no basis to dispute that the proposal satisfies each of the four-criteria outlined in *Ex parte Sacred Heart*. This request qualifies for the POE under Alabama law.

Dr. Mitchell has also outlined that the only procedures he will perform in his office-based lab are low risk peripheral angiography and interventional procedures and fixed-based diagnostic coronary angiography procedures. He is trained and qualified to perform these procedures in his private physician's practice and is credentialed to perform these procedures on an outpatient or inpatient basis at East Alabama Medical Center.

As described in Dr. Mitchell's letter, these are not novel procedures, and they are standard and commonly performed in both inpatient and outpatient settings. Although not directly applicable to The Heart Center's request that satisfies the Physician's Office Exemption, the State Health Plan acknowledges in its content that "[m]any noncardiac

diagnostic and therapeutic vascular procedures are now being offered in the cardiac catheterization laboratory settin[g],” and expressly states that “[c]ertain cardiac catheterization procedures are now offered in physicians’ office outside of the usual hospital environment.” *See generally*, ALA. ADMIN. CODE R. 410-2-3-.03(2). Dr. Mitchell has also outlined general literature recognizing that the proposed procedures are routinely and appropriately performed in the office settings or like settings without cardiovascular surgical backup onsite, due to the low risk nature of the described procedures.

The Heart Center’s request further expressly states that the lab will be operated in accordance with Alabama’s Office-Based Surgery Rules as outlined in Chapter 540-X-10 of the Alabama Administrative Code in conjunction with Dr. Mitchell’s education, training and experience as a board-certified cardiologist. Dr. Mitchell’s certification that the lab will be operated in accordance with Chapter 540-X-10 is an express statement that the lab will operate in accordance with the Alabama Board of Medical Examiner’s Rules regarding anesthesia use, equipment, personnel, and patient safety for office-based surgery.

Dr. Mitchell will only offer the option of an office-based procedure to appropriately selected, low risk patients. In accordance with the Office-Based Surgery Rules, each patient will be individually evaluated “to determine if the office is an appropriate setting for the anesthesia required and for the ... procedure to be performed,” and each patient will have an “appropriately documented history and physical examination as well as other indicated consultations and studies.” ALA. ADMIN. R. 540-X-10-.01(b) & (c). Based on his education, training and experience as a board-certified cardiologist, Dr. Mitchell is qualified and competent to make clinical judgments and patient selection determinations for the described procedures. These determinations are made on the basis of an individual patient risk and benefit analysis, which would include whether a patient’s risk stratification is such that she or he may be a better candidate for a procedure in the hospital setting or the office setting.

As discussed above, while the practice of medicine is not devoid of risk, the literature recognizes both that complication rates from the proposed procedures are low and that the procedures can be appropriately performed in the office setting. In the event of a complication or change in a patient’s status, Dr. Mitchell has outlined portions of his established care plan to deal with any issues related to changes in a patient’s status. This includes, among other things, oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing as well as a pathway to transfer to a higher level of care, as needed. In the event of a transfer to the hospital, Dr. Mitchell would also personally ride in the ambulance to continue care for the patient as well.

May 14, 2021

Page -4-

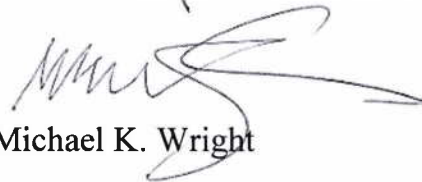
Plainly, The Heart Center's request demonstrates that the performance of the narrowed list of proposed services will constitute the lawful practice of medicine in accordance with applicable licensing laws and in accordance with Alabama's Office-Based Surgery Rules. The request further demonstrates that the requested procedures will be performed in Dr. Mitchell's private physician's office and that the proposed services are recognized as appropriately performed in the office-setting. The Agency has appropriately granted at least eleven LNR requests specifically including peripheral angiography and interventional procedures (or lower extremity diagnostic and interventional procedures).¹ On information, these services are currently being offered in office-based labs in Alabama. The Agency has appropriately granted at least four LNR requests specifically including diagnostic coronary angiography (or left and right diagnostic heart catheterization).² On information, these services are currently offered in at least one of these office-based labs.

The request satisfies the Physician's Office Exemption, and The Heart Center respectfully requests that the Agency grant a determination of non-reviewability for the proposal outlined by Dr. Mitchell.

Should the Agency have any questions or need any further information, please do not hesitate to contact me.

Sincerely,

STARNES DAVIS FLORIE LLP



Michael K. Wright

MKW/

cc: Dr. John W. Mitchell

¹ RV2017-033 – Birmingham Heart Clinic; RV2019-032 – Cardiology Consultants, P.C.; RV2021-002 – Salame Heart & Vascular Clinic; RV2017-022 – Montgomery Vascular Surgery; RV2017-011 – Bama Heart Doc, P.C.; RV2017-022 – Cardiovascular Institute of the Shoals, P.C.; RV2018-006 – Alabama Vascular Solutions; RV2019-004 – Heart South Cardiovascular Group, P.C.; RV2020-004 – Southeastern Cardiology Consultants, P.C.; RV2020-014 – Valley Vascular Access Center, LLC; RV2020-017 – Southern Specialty Physicians, LLC.

² RV2016-007 – River Region Cardiology; RV2018-013 – Bama Heart Doc, P.C.; RV2019-037 – Birmingham Heart Clinic; RV2020-004 – Southeastern Cardiology Consultants, P.C.



RV2021-019
RECEIVED
May 14 2021
STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

The Heart Center Cardiology
2375 Suite 100 Champions Blvd.
Auburn, AL 36830
(334) 321-3700

May 14, 2021

Hon. Emily T. Marsal
Executive Director
State Health Planning and Development Agency
100 North Union Street
RSA Union Building, Suite 870
Montgomery, AL 36130-3025
Shpda.online@shpda.alabama.gov

Re: Non-Reviewability Determination Request for The Heart Center Cardiology

Dear Ms. Marsal:

On behalf of The Heart Center Cardiology, I am writing pursuant to CON Rule 410-1-7-.02 to submit a reviewability determination request in accordance with the Alabama State Health Planning and Development Agency's Certificate of Need program rules and regulation. This request has been reformatted and restructured to: reflect the narrow scope of services I actually intend to offer in the office-based lab; demonstrate that these services are performed in the office setting; and reaffirm that the services will be provided within, and on behalf of, my private physician's office at The Heart Center.

The proposed lab is to occupy space within the footprint of my existing private practice at the location for The Heart Center Cardiology, located at 2375 Champions Blvd. Suite 100 Auburn, AL 36830. It will be within the same physical space as The Heart Center currently occupies as demonstrated by the attached floorplan for Suite 100. The circled portion of the plan demonstrates an accurate approximation of the space the lab will occupy. This proposal satisfies the Physician's Office Exemption as outlined by Alabama law. The lab will also be operated in accordance with Alabama's Office-Based Surgery Rules as outlined in Chapter 540-X-10 of the Alabama Administrative Code in conjunction with my education, training, and experience as a board-certified cardiologist.

I. PROPOSED SERVICES

I will only perform low risk peripheral angiography and interventional procedures and fixed-based diagnostic coronary angiography procedures within my private physician's practice. I am trained, qualified, and competent to perform these procedures, and I am credentialed to perform these procedures on an outpatient (or inpatient) basis at East Alabama Medical Center. My Alabama Medical License is appropriately registered with the Board to perform "office-based surgery." I will be engaged in the lawful practice of medicine in accordance with applicable licensing laws as a board-certified cardiologist in the proposed office-based lab.

The procedures to be performed are not novel procedures. They are standard and commonly performed in both inpatient and outpatient settings. Indeed, while not directly applicable to my present proposal that is submitted pursuant to the Physician's Office Exemption as defined by Alabama law, the State Health Plan acknowledges in its content that "[m]any noncardiac diagnostic and therapeutic vascular procedures are now being offered in the cardiac catheterization laboratory settin[g]," and expressly states that "[c]ertain cardiac catheterization procedures are now offered in physicians' office outside of the usual hospital environment."¹

It is further well-recognized in the literature and field of cardiology that the proposed procedures are routinely and appropriately performed in the office setting or in settings that may not have cardiovascular surgical backup onsite. For informational purposes and as a general example related to diagnostic coronary angiography, the American College of Cardiology Foundation and Society for Cardiovascular Angiography and Interventions published an "Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update" in the Journal of the American College of Cardiology in 2012. The update highlights "remarkably low risk associated with diagnostic cardiac catheterization;" recognizes "favorable reports regarding both safety and quality;" and recognizes that "diagnostic cardiac catheterization is increasingly being performed in facilities without onsite surgical backup ... [including] ... freestanding laboratories, and mobile cardiac catheterization unites (either parked at a hospital or occasionally at a cardiovascular clinic)."² The update expressly recognizes that "with diagnostic cardiac catheterization now principally becoming an outpatient procedure, these types of laboratories have become more accepted and widespread." *See id.*

As a general example of literature regarding invasive diagnostic and therapeutic vascular procedures, an article published this year in the Journal of Vascular Surgery recognizes that "approximately 80% of peripheral vascular interventions today have been reported to be catheter based and can be performed in [OBL]."³ This transition to the outpatient space has occurred while maintaining patient safety. The article studied 6201 "minimally invasive office based" vascular

¹ *See generally*, ALA. ADMIN. CODE R. 410-2-3-.03(2).

² Bashore TM, et al., "2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update," J. AM. COLL. CARDIOL., 2012; 59:2221-305.

³ *See* Aurshina, Afsha, et al., "Safety of Vascular Interventions Performed in an Office-Based Laboratory in patients with Low/Moderate Procedural Risk," J. VASC. SURG., 2021; 73:1298-303.

procedures and found: “No office-based center mortality, major bleed, acute limb ischemia, myocardial infarction, stroke, or hospital transfer” within 72 hours of the procedure. *Id.*

The Agency has appropriately granted at least eleven LNR requests specifically including peripheral angiography and interventional procedures (or lower extremity diagnostic and interventional procedures).⁴ On information, these services are currently being offered in office-based labs in Alabama. The Agency has appropriately granted at least four LNR requests specifically including diagnostic coronary angiography (or left and right diagnostic heart catheterization).⁵ On information, these services are currently offered in at least one of these office-based labs.

The option of an office-based procedure will only be provided to appropriately selected, low risk patients. Each patient will be individually evaluated “to determine if the office is an appropriate setting for the anesthesia required and for the ... procedure to be performed,” and each patient will have an “appropriately documented history and physical examination as well as other indicated consultations and studies.”⁶

I am qualified and competent as a properly trained, experienced board-certified cardiologist to make proper clinical judgments with respect to the types of patients that may need certain procedures and the risks and benefits associated therewith, which would include whether a patient’s risk stratification is such that she or he may be a better candidate for a procedure in the hospital setting or office setting. All procedures offered in the office-based setting will be limited to appropriate candidates greater than 18 years of age only.

No percutaneous coronary interventions will be offered or performed in the office-based lab. I also will not be offering or performing any emergency coronary angiography in the office-based lab, as emergent procedures for those patients would be more appropriately performed in the hospital setting.

No general anesthesia will be used for the procedures performed in the office-based lab. Any anesthesia used in connection with the performance of the procedures will not exceed the level of moderate sedation or deep sedation as defined by Alabama Administrative Rule 540-X-10.02(3) & (4) and will be administered, monitored, and reported appropriately in accordance with the rules outlined in Chapter 540-X-10 of the Alabama Administrative Code for “Office-Based Surgery.” All personnel involved with any portion of the procedure, including the administration,

⁴ RV2017-033 – Birmingham Heart Clinic; RV2019-032 – Cardiology Consultants, P.C.; RV2021-002 – Salame Heart & Vascular Clinic; RV2017-022 – Montgomery Vascular Surgery; RV2017-011 – Bama Heart Doc, P.C.; RV2017-022 – Cardiovascular Institute of the Shoals, P.C.; RV2018-006 – Alabama Vascular Solutions; RV2019-004 – Heart South Cardiovascular Group, P.C.; RV2020-004 – Southeastern Cardiology Consultants, P.C.; RV2020-014 – Valley Vascular Access Center, LLC; RV2020-017 – Southern Specialty Physicians, LLC.

⁵ RV2016-007 – River Region Cardiology; RV2018-013 – Bama Heart Doc, P.C.; RV2019-037 – Birmingham Heart Clinic; RV2020-004 – Southeastern Cardiology Consultants, P.C.

⁶ See ALA. ADMIN. R. 540-X-10-.01(b) & ALA. ADMIN. R. 540-X-10-.01(c).

monitoring, and reporting of any anesthesia will be employees of The Heart Center. Likewise, any equipment, and supplies used in connection with any portion of the procedure will only be billed on behalf of The Heart Center.

With respect to anesthesia, the Alabama Office-Based Surgery rules require the following “equipment and supplies”:

Emergency resuscitation equipment, emergency life-saving equipment medications, suction, and a reliable source of oxygen with a backup tank must be readily available. Monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Patient vital signs, oxygen saturation, and level of consciousness should be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. Facility, in terms of general preparation, should have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.⁷

The office-based lab will satisfy all of these requirements. Further, the administration and monitoring of any anesthesia used (again, not to exceed moderate or deep sedation) will be administered by an employee of The Heart Center who is appropriately, licensed, qualified and competent.

All post-procedure monitoring and reporting will also be performed in accordance with Alabama’s Office-Based Surgery Rules.⁸ For example, post-procedure monitoring will be performed by a qualified, competent, and trained employee of The Heart Center who, among other things, will monitor pulse oximetry and non-invasive blood pressure. Each patient will be “assessed periodically for level of consciousness, pain relief, or any untoward complication.” *See id.* Each patient must also satisfy the discharge criteria appropriately established by The Heart Center prior to leaving the facility, and the patient, or a responsible adult, will have follow-up care arranged and explained. *See id.*

Should patient selection for a particular procedure require the use of general anesthesia, the patient would not have the option of an office-based procedure, and the procedure would be scheduled and performed in the hospital setting.

While the practice of medicine is not devoid of risk, complication rates from the proposed procedures are low and, again, the literature recognizes that the procedures can be appropriately and properly performed in the office setting. In accordance with Alabama’s Office-Based Surgery Rules, the office-based lab will be “set up with patient safety as a primary consideration.”⁹ In the event of a complication or change in a patient’s status, I have an established care plan—including

⁷ See ALA. ADMIN. R. 540-X-10-.07.

⁸ See ALA. ADMIN. R. 540-X-10-.09 & 540-X-10-.11.

⁹ See ALA. ADMIN. R. 540-X-10-01(e).

the identification of involved personnel and equipment—to deal with any issues related to unexpected changes in a patient’s status. This includes, among other things, oxygen and masks for ventilation, medications for arrhythmias and reversal of sedation, defibrillation and pacing, a “crash cart,” as well as a pathway to transfer to a higher level of care, as needed.

II. THE PHYSICIAN’S OFFICE EXEMPTION

This proposal does not constitute a new institutional health care service or facility. The services and procedures outlined in this request are to be performed in my private physician’s office, The Heart Center Cardiology, and the performance of the procedures will constitute the lawful practice of medicine and cardiology in accordance with applicable licensing laws, as outlined above.

I am aware of the criteria adopted by the Alabama Supreme Court for whether a proposal qualifies for the POE. I understand that criteria to be as follows:

1. The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.
2. The proposed services are to be provided, and related equipment used, at any office of such physicians.
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice.
4. The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

The Heart Center’s proposal satisfies the following criteria and therefore qualifies for the POE:

1. I am the only physician owner and only physician employee of The Heart Center Cardiology, and I am certified to perform office-based surgery. The proposed services will be provided, and related equipment used, exclusively by me or employees of The Heart Center.
2. All procedures will be performed, and related equipment used, in my private physician’s office of The Heart Center Cardiology and only by employees of The Heart Center.
3. The patient billing related to such services are through, or expressly on behalf of my private physician’s practice of The Heart Center Cardiology.

4. At no time will the equipment identified for the performance of the office-based procedures provided in this letter be used for inpatient care, nor by, through or on behalf of a health-care facility.

Further, while the practice of medicine is not devoid of risk, the field of cardiology and published literature regarding the narrow list of proposed procedures expressly recognize that the procedures carry low risk and are increasingly being performed in the office-based setting. This is outlined in more detail, above. Again, I am trained, qualified, and competent to perform the proposed services, and the performance of the narrowed list of proposed services will constitute the lawful practice of medicine in accordance with applicable licensing laws and in accordance with Alabama's Office-Based Surgery Rules.

This proposal otherwise does not constitute a new institutional health service because:

- a) No new health care facility or health maintenance organization will be constructed, developed or acquired;
- b) No major medical equipment will be acquired by or on behalf of a health care facility that exceeds the statutory purchase price or operating expense thresholds;
- c) No new health care facility beds or stations will be added;
- d) No new health service that is currently offered by The Heart Center Cardiology will be provided with the implementation of the procedures described in the document; and
- e) No other event reviewable under the CON law or Rules will occur as a result of our implementation of the procedures described in this document.

The private physician office location for The Heart Center Cardiology is 2375 Suite 100 Champions Blvd. Auburn, AL 36830. The service area for this request is Auburn, Alabama and surrounding counties. I am licensed in the State of Alabama and certified to perform the procedures listed above. No other healthcare facilities have any financial interests in The Heart Center Cardiology. I am the sole owner and the only participating physician for The Heart Center Cardiology.

III. APPROXIMATED PROJECT COSTS AND DISCLOSURE OF FINANCIAL INTERESTS

The total Major Medical Equipment estimated cost for the office-based procedures is \$350,000.00. This estimation includes a diagnostic x-ray system, patient monitoring equipment, patient recovery equipment, defibrillator and IVUS for arterial and venous procedures and ancillary equipment required for the listed procedures. The estimated annual first year operating cost \$618,000. This estimation includes:

1. Building Lease \$48,000.00/annual
2. Equipment Lease \$120,000.00/annual
3. Supplies – \$200,000.00
4. Employee Wages – 250,000.00
5. Land Cost – None
6. Renovation/Construction Cost- None

The office-based surgery services within The Heart Center Cardiology will not exceed any of the certificate of need expenditure thresholds.

An electronic payment of \$1,000.00 for the filing fee with respect to a request for a reviewability determination will be sent today via the SHPDA online payment portal.

With the support of this document and in consideration of the narrowed list of proposed services, The Heart Center respectfully requests that the Alabama State Health Planning and Development Agency grant a determination of non-reviewability to The Heart Center Cardiology for the proposal described herein. Please do not hesitate to call or contact me with any questions.

Should the Agency have any questions or need any further information, please do not hesitate to contact me. I appreciate your time and consideration in this matter.

Sincerely,



John Mitchell M.D., Medical Director/Owner
The Heart Center Cardiology

Affirmation of Requesting Party:

The undersigned, John Mitchell M.D., being first duly sworn, hereby make oath or affirm that he, an **Owner and Medical Director of The Heart Center Cardiology**, has knowledge of the facts in the request, and to the best of his information, knowledge and belief, such facts are true and correct.

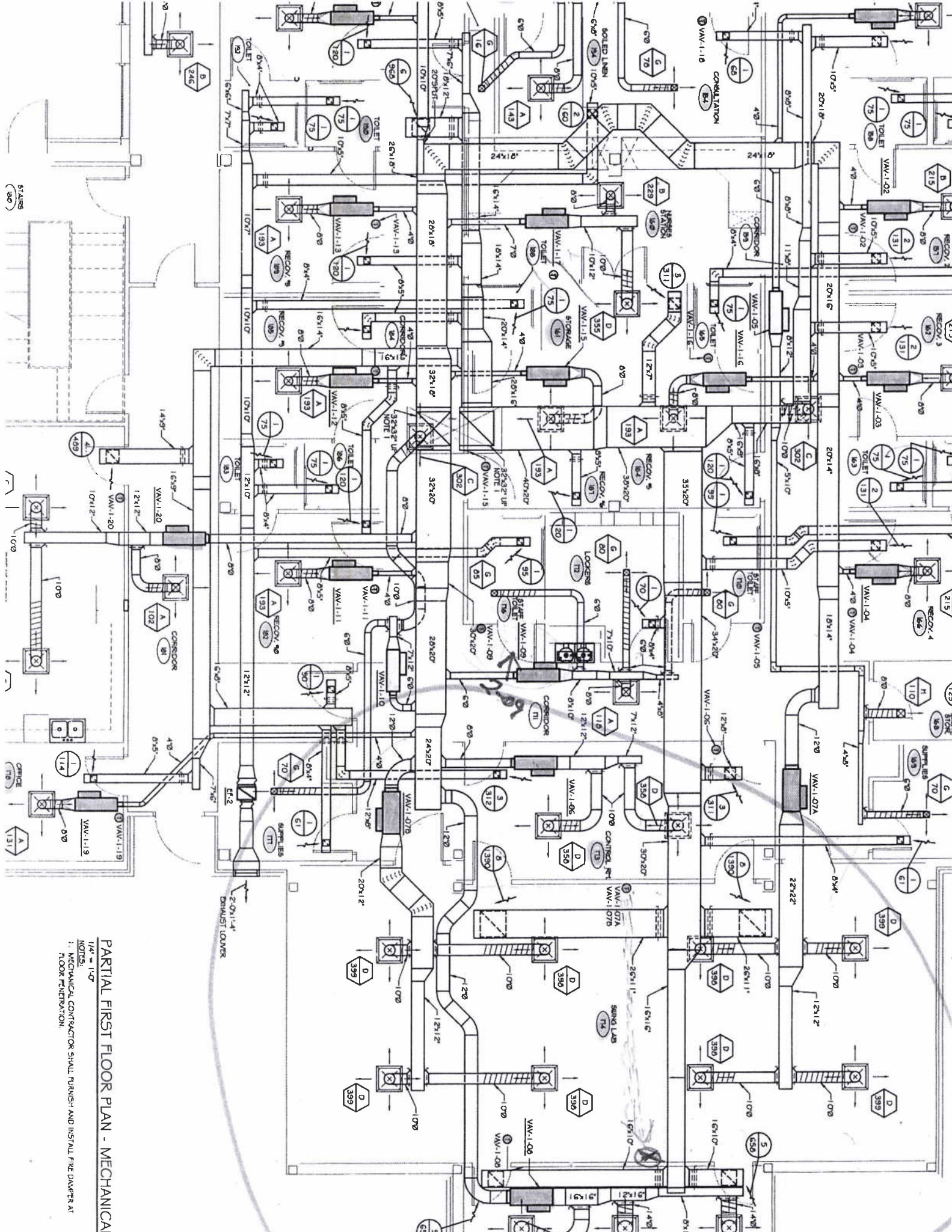
Affiant John W. Mitchell (SEAL)

Subscribed and Sworn to me before this 14th day of May, 2021.

Notary Public Samantha Lowery

My commission expires 4/7/2022





PARTIAL FIRST FLOOR PLAN - MECHANICAL

1/16" = 1'-0"
 NOTES:
 1. MECHANICAL CONTRACTOR SHALL FINISH AND INSTALL FIRE DAMPERS AT FLOOR PENETRATION.