



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
Olympia, Washington 98504

RE: James F. McGuckin, MD  
Master Case No.: M2013-185  
Document: Agreed Order

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center  
P.O. Box 47865  
Olympia, WA 98504-7865  
Phone: (360) 236-4700  
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

**STATE OF WASHINGTON  
MEDICAL QUALITY ASSURANCE COMMISSION**

In the Matter of the License to Practice  
as a Physician and Surgeon of:

**JAMES F. MCGUCKIN, MD**  
License No. MD00047625

Respondent.

**No. M2013-185**

**STIPULATED FINDINGS OF FACT,  
CONCLUSIONS OF LAW AND  
AGREED ORDER**

The Medical Quality Assurance Commission (Commission), through Phi V. Ly, Commission Licensed Legal Intern, Larry Berg, Supervising Attorney, and Respondent, represented by counsel, D.K. Yoshida, stipulate and agree to the following.

**1. PROCEDURAL STIPULATIONS**

1.1 On November 25, 2014, the Commission issued a Statement of Charges against Respondent.

1.2 In the Statement of Charges, the Commission alleges that Respondent violated RCW 18.130.180(4), (7), (13), (16), (22), and 21 CFR § 56.103, 21 CFR § 812.100, and 21 CFR § 812.110(a).

1.3 The Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 The Commission has the authority to impose sanctions pursuant to RCW 18.130.160 if the allegations are proven at a hearing.

1.6 The parties agree to resolve this matter by means of this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.7 Respondent waives the opportunity for a hearing on the Statement of Charges if the Commission accepts this Agreed Order.

1.8 This Agreed Order is not binding unless it is accepted and signed by the Commission.

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1.9 If the Commission accepts this Agreed Order, it will be reported to the National Practitioner Data Bank (45 CFR Part 60), the Federation of State Medical Boards' Physician Data Center and elsewhere as required by law.

1.10 This Agreed Order is a public document. It will be placed on the Department of Health's website, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). It may be disclosed to the public upon request pursuant to the Public Records Act (Chapter 42.56 RCW). It will remain part of Respondent's file according to the state's records retention law and cannot be expunged.

1.11 If the Commission rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Commission members who heard the Agreed Order presentation.

## 2. FINDINGS OF FACT

Respondent and the Commission acknowledge that the evidence is sufficient to justify the following findings, and the Commission makes the following findings of fact.

2.1 On March 13, 2007, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active. Respondent is board certified in radiology.

2.2 Respondent specializes in vascular and interventional radiology. Respondent is the founder and Chief Executive Officer of Vascular Access Centers (VAC) which has multiple facilities in several states. Respondent travels to different facilities, including the Tukwila, Washington, location to perform endovascular procedures. Between 2010 and 2013, Respondent treated chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis (MS) patients at the Tukwila facility.

2.3 The diagnosis and treatment of CCSVI is investigational and experimental. The CCSVI procedure should be performed as a scientific research study under an Institutional Review Board (IRB) to ensure safety of human subjects. Furthermore, an IRB research study must have approval from the Food and Drug Administration (FDA) Investigational Device Exemption program.

2.4 In 2010, the Hubbard Foundation sponsored a multi-center research study, or registry, for CCSVI treatment. The registry is an organized system that uses observational

study methods to collect uniform data about a specific disease or treatment. Bio-Med IRB approved the registry and established a registry protocol outlining the study design and purpose. The protocol also outlined specific patient inclusion and exclusion criteria. Adherence to the protocol is crucial in order to ensure patient safety and for the registry data to have any scientific validity. Bio-Med IRB approved Respondent to be principal investigator for the CCSVI multi-center registry. However, Bio-Med IRB did not obtain the required FDA Investigational Device Exemption (IDE) approval and failed to monitor Respondent's adherence to the registry protocol.

2.5 Respondent performed CCSVI procedures on patients without ensuring Bio-Med IRB obtained an approved IDE from the FDA. Moreover, Respondent represented to the Commission that he adhered to the Bio-Med IRB protocol when in fact he deviated from it. Respondent's participation in CCSVI research lacked the scientific rigor in determining the effectiveness of treating MS patients.

2.5.1 MS is an immune-mediated disease and not a circulatory disorder. MS lesions are caused by inflammatory injury of the nerve fibers in the brain and spinal cord resulting in significant and disabling neurological symptoms such as focal motor and sensory disabilities. The underlying cause of MS is unknown. MS diagnosis is determined by neurologic studies and magnetic resonance imaging (MRI) identifying lesions in nerve fibers. MS is often treated with medication.

2.5.2 CCSVI is a theoretical condition based upon the hypothesis that blockage of the major veins in the neck and chest causes and contributes to the progression of MS. The CCSVI procedure purports to provide symptom relief to MS patients by treating these blocked veins to increase blood drainage from the brain and spinal cord. The CCSVI procedure poses risks and complications inherent to endovascular treatment.

2.6 The CCSVI procedure uses balloon angioplasty and sometimes stent placement to treat blocked veins. Significant venous blockage, or stenosis, is usually defined as vein reduction of at least 50% compared with normal adjacent veins. Stenosis may cause venous hypertension symptoms such as swelling, pain, warmth, skin discoloration, superficial varicosities, or interference with dialysis. In contrast, MS symptoms are neurological and cause visual, motor, sensory, balance, cognitive, and autonomic dysfunction.

2.7 In the CCSVI procedure, the skin is punctured, and a catheter is placed through the femoral vein and then guided to other veins in the body. Contrast is injected into these veins to identify vein abnormalities. If an abnormality is noted, a balloon is inserted and used to dilate the affected vein. In some cases, a stent may be placed to maintain widening of the veins. Though the invasive procedure is done on an outpatient basis without deep sedation, complications and risks exist.

2.8 Angioplasty and stenting of veins are long-standing and well-accepted therapies for venous blockages. Causes of these blockages include catheters, dialysis access, pacemaker leads, tumors, abnormal blood clotting, and bony compression. Complications and risks for CCSVI treatment and of angioplasty and stenting in general include: vein rupture; blood clotting and dissection within treated veins; need to surgically remove ruptured balloons; stent migration requiring surgical removal; stroke; nerve injury; paralysis; and death from bleeding. Both angioplasty and stent placement may also incite further narrowing of the treated vein or restenosis. These therapies are not recognized as standard or approved treatments for MS.

2.9 To date, there are no randomized, controlled, blinded studies proving the existence of CCSVI or the efficacy of treating it with angioplasty or stenting. On May 10, 2012, the FDA released a Safety Communication stating balloon angioplasty and stents are inefficacious in treating MS symptoms and pose risks to patients. Additionally, the FDA found no clear evidence that CCSVI exists or is linked to MS. Accordingly, CCSVI procedures performed after the release of the FDA Safety Study Communication are considered not effective.

2.10 Respondent's reply letter to the Commission dated August 29, 2014, stated that as of May 2012, the scope of CCSVI practice is no longer listed on the VAC website and that VAC is not treating CCSVI patients. However, review of VAC's website reveals that CCSVI is still listed as a scope of venous practice. Respondent claims he had directed his staff to remove all CCSVI content from the website on two occasions.

2.11 Between calendar years 2010 and 2013, Respondent performed CCSVI treatment on 233 patients, including Patients A through G, at the Tukwila facility. None of the patients had a neurologist referral. Respondent failed to meet the standard of care in performing an experimental treatment on MS patients. In doing so, Respondent created an

unreasonable risk of harm by conducting angioplasty and stent placement to treat a non-vascular disease. Respondent failed to adhere to the Bio-Med IRB protocol, and Respondent's diagnosis and treatment documentation contained multiple discrepancies raising concerns about proper patient assessment and accurate procedure notes.

2.12 Respondent failed to adhere to the registry protocol in the following ways:

2.12.1 Only patients diagnosed with MS through proper neurologic examination are to be included in the registry. Respondent represented to the Commission that CCSVI patients are admitted after a comprehensive intake process. However, patient records indicate Respondent's did not obtain or review MS examination records from the patients' neurologist. None of the patients have a recorded neurologic exam before or after the CCSVI procedure. There is no documentation that patients obtained a required Expanded Disability Status Scale rating before and after the procedure.

2.12.2 Respondent did not obtain required magnetic resonance imaging or Doppler testing post-procedure as required for Patients A through G.

2.12.3 Respondent did not conduct adequate physical evaluations, and he relied on patients' self-reporting of MS diagnosis and symptoms in determining whether or not patients met the inclusion criteria.

2.12.4 Respondent did not include Patient D in the registry and performed CCSVI treatment on her before the Bio-Med IRB protocol was approved.

2.12.5 The registry excludes patients with "abnormal kidney function." There is no documentation showing Patients A, C, and G underwent laboratory testing to assess kidney function prior to CCSVI treatment.

2.12.6 The registry lists Pregnancy as an exclusion. There is no documentation that Patients A, B, F, and G underwent laboratory testing to exclude pregnancy prior to the procedure.

2.12.7 Follow-up protocol states patients will be seen in the office and evaluated for complications and will undergo review of the procedure results. Respondent states that patients are typically seen the following day after the CCSVI procedure. However, Patients A through G's records do not indicate any office visit or physical evaluation by Respondent following treatment. Patient follow-up calls are

noted as brief notations on a form by VAC staff. Respondent failed to conduct any physical evaluation of Patients A through G post-procedure.

2.13 Respondent diagnosed Patients A through G with CCSVI by listing chronic venous hypertension with complications, without corroborating reports or exams. Respondent failed to obtain Patients A, B, C, D, F, and G's MRI or magnetic resonance venography (MRV) reports identifying blood flow abnormalities. Respondent's reported vascular findings for Patients A through G are disputable.

2.14 In his procedure reports, Respondent reported stenoses to be more severe than those seen on the radiologic spot images. Review of patients' spot images demonstrated abnormalities that would not be considered significant or justified in requiring endovascular treatment. Respondent claims that the findings seen at angiography are not fully demonstrated in the spot images.

2.15 It is not evident that Respondent forwarded his procedure notes to Patients A through G's neurologist or primary care provider, or if Respondent ever established any post-procedure medical evaluation of patients to determine the efficacy or benefits of CCSVI treatment.

### 3. CONCLUSIONS OF LAW

The Commission and Respondent agree to the entry of the following Conclusions of Law.

3.1 The Commission has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(4) and (16).

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

### 4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order.

4.1 **Agreement to not perform CCSVI procedure.** Respondent shall not perform angioplasty and stenting procedures of the venous system for CCSVI or MS patients in Washington State.

4.2 **Ethics Course.** Within six (6) months of the effective date of this Order Respondent shall attend and successfully complete the Professional/Problem Based Ethics (ProBE) Course, offered by the Center for Personalized Education for Physicians (CPEP). To satisfy this provision, the Respondent must obtain an "unconditional pass" at the conclusion of the course. Respondent will permit CPEP to communicate with the Commission regarding his participation in this course and will provide the Commission a copy of the essay the Respondent writes as part of the course. A failure by the Respondent to obtain an "unconditional pass" upon completion of the coursework may result in the Commission requiring the Respondent to re-take the course, or may result in additional charges for noncompliance under RCW 18.130.180(9). Respondent will submit proof of the successful completion of the course to the Commission within thirty (30) days.

4.3 **Renewal of License.** Respondent's license is set to expire November 7, 2015. Respondent must file an application for reactivation in lieu of renewal if he seeks to continue practicing in the state of Washington subsequent to the expiration of his license.

4.4 **Fine.** Respondent shall pay a fine to the Commission in the amount of seventeen thousand five hundred dollars (\$17,500) which must be received by the Commission within three (3) months of the effective date of this Order. The fine will be paid by certified or cashier's check or money order, made payable to Department of Health and mailed to:

Department of Health  
Medical Quality Assurance Commission  
P.O. Box 1099  
Olympia, Washington 98507-1099

4.5 **Refund to patients.** Within twelve (12) months of the effective date of this Order, Respondent must refund the cash fees to patients who received the CCSVI procedure at the Tukwila facility after May 10, 2012, and who did not have insurance or third-party payors. Failure to fully refund fees to patients shall be a violation of this Order

4.5.1 Respondent shall provide to the Commission documented proof of completed patients' refunds. Proof of payment will list: patient's name and address, check number, amount paid, and date of payment, and will be mailed to:

Department of Health  
Compliance Manager, Medical Quality Assurance Commission  
P.O. Box 47866



Olympia, Washington 98504-7866

4.6 **Reporting.** Respondent will provide to the Commission a semi-annual report that states how he is in compliance with all terms and conditions of this Order. Respondent will submit the report at six (6) months and twelve (12) months after the effective date of this Order. The reports must be sent to:

Department of Health  
Compliance Manager, Medical Quality Assurance Commission  
P.O. Box 47866  
Olympia, Washington 98504-7866

4.7 **Modification.** Respondent may petition the Commission in writing to modify the terms and conditions of this Agreed Order no sooner than twelve (12) months from the effective date of this Agreed Order. If Respondent files a written petition to modify then the Commission may require personal appearance where Respondent must present evidence and respond to questions. The Commission has sole discretion whether to grant or deny Respondent's petition to modify this Agreed Order.

4.8 **Obey all laws.** Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.9 **Costs.** Respondent is responsible for all costs of complying with this Agreed Order.

4.10 **Violation of Order.** If Respondent violates any provision of this Agreed Order in any respect, the Commission may initiate further action against Respondent's license.

4.11 **Change of Address.** Respondent shall inform the Commission and the Adjudicative Clerk Office, in writing, of changes in Respondent's residential and/or business address within thirty (30) days of the change.

4.12 **Effective Date of Order.** The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

## 5. COMPLIANCE WITH SANCTION RULES

5.1 The Commission applies WAC 246-16-800, *et seq.*, to determine appropriate sanctions. Tier B of the "Practice Below Standard of Care" schedule, WAC 246-16-810,

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applies to cases where substandard practices caused moderate patient harm or risk of moderate to severe patient harm. Respondent performed invasive vascular interventional treatment on patients. This posed an unreasonable risk of moderate to severe patient harm because known complications from angioplasty and stenting are life threatening and can range from vein rupture to death. Tier C of the "Practice Below Standard of Care" schedule applies when a patient suffers severe harm or death. There is no evidence Respondent's substandard practices actually caused severe injury or death to a patient. Tier B applies to this matter.

5.2 WAC 246-16-800(3)(c) directs the Commission to identify aggravating or mitigating factors to determine appropriate sanctions. There are mitigating and aggravating factors present in this case. It is mitigating that Respondent has no prior discipline on his license. It is also mitigating that Respondent had closed his Tukwila, Washington, facility in 2013, and he no longer participates in the Hubbard Study or BioMed IRB. It is aggravating that Respondent's substandard care involved multiple MS patients who were highly vulnerable to the false hope provided by Respondent's CCSVI treatment. Respondent failed to ensure that the Hubbard Foundation and BioMed IRB obtained an IDE before engaging the in research study as a Principal Investigator. Respondent's failure to strictly adhere to the study's registry protocol without written approval for any deviations raised patient safety concerns as well as concerns about the study's scientific validity. It is also aggravating that Respondent's reported vascular findings for Patients A through G are disputable.

5.3 Tier B requires the imposition of sanctions ranging from two years of oversight to five years of oversight, unless revocation. However, WAC 246-16-800(2)(d) states that the Commission may deviate if the sanction schedule does not adequately address the facts of the case. This Order is a deviation from the sanctions schedule because Respondent maintains his regular practice in another state and infrequently travels to Washington State. Furthermore, Respondent has ceased performing CCSVI treatment in Washington. This case qualifies for a deviation under WAC 246-16-800(2)(c).

5.4 Respondent's agreement to not perform angioplasty and stenting procedures of the venous system for CCSVI or MS patients in Washington State, attend an ethics course, pay a fine, and refund fees to patients as outlined in this Agreed Order, is adequate in protecting the public.

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**6. FAILURE TO COMPLY**


Protection of the public requires practice under the terms and conditions imposed in this order. Failure to comply with the terms and conditions of this order may result in suspension of the license after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Commission may hold a hearing to require Respondent to show cause why the license should not be suspended. Alternatively, the Commission may bring additional charges of unprofessional conduct under RCW 18.130.180(9). In either case, Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

**7. RESPONDENT'S ACCEPTANCE**

I, James F. McGuckin, Respondent, have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

  
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JAMES F. MCGUCKIN, MD  
RESPONDENT

9/3/15  
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DATE

  
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D.K. YOSHIDA, WSBA# 17365  
ATTORNEY FOR RESPONDENT

09/03/2015  
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DATE

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**8. COMMISSION'S ACCEPTANCE AND ORDER**

The Commission accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: 1 Oct, 2015.

STATE OF WASHINGTON  
MEDICAL QUALITY ASSURANCE COMMISSION

WE Gotthold  
PANEL CHAIR

PRESENTED BY:

PHI V. LY

PHI V. LY, WSBA# 9451564  
COMMISSION RULE 9 LEGAL INTERN

LJ Berg

LAWRENCE J. BERG, WSBA# 22334  
COMMISSION STAFF ATTORNEY