STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Susan J. Shlifer, MD
Master Case No.: M2012-269
Document: Second Amended 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 **SUSAN J. SHLIFER, MD** License No. MD00035541 Respondent.	**No. M2012-269** **SECOND AMENDED STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER**

The Medical Quality Assurance Commission (Commission), through Larry Berg, Staff Attorney, and Respondent, submit this Second Amended Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Amended Agreed Order) for acceptance.

1. PROCEDURAL STIPULATIONS

1.1 On June 27, 2012, the Commission issued a Statement of Charges against Respondent. The Statement of Charges alleged that Respondent violated RCW 18.130.180(4).

1.2 On February 21, 2013, the Commission entered Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order) signed by Respondent and her attorney resolving all issues.

1.3 Respondent completed a clinical skills evaluation at the Center for Personalized Education for Physicians (CPEP) pursuant to the Agreed Order, Paragraph 4.3. CPEP Report recommendations included: Respondent should establish a relationship with an experienced educational Preceptor in family medicine with experience and knowledge of chronic pain management; Continuing Medical Education (CME) and self-study in courses related to the topics indicated in areas of demonstrated need; and completion of a course on medical record keeping that includes a follow-up component.

1.4 The Agreed Order, Paragraph 4.3.2, also states that Respondent must complete all of the CPEP recommendations to the satisfaction of CPEP and the Commission.

1.5 On November 5, 2015, the Commission entered Amended Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Amended Agreed Order). The Amended

Agreed Order incorporated CPEP recommendations and updated sanctions to reflect Respondent's progress in completing requirements.

1.6 On March 23, 2016, Dr. Donna Moore, Respondent's clinical and educational preceptor, notified the Medical Commission that she had concerns regarding Respondent's progress in completing CPEP recommendations. Dr. Moore concluded that she had not been effective at helping Respondent to improve her practice.

1.7 On March 28, 2016, CPEP notified the Commission that Respondent's Education Plan was suspended for lack of progress and failure to meet requirements.

1.8 On May 13, 2016, Respondent personally appeared before the Commission. Respondent acknowledged that she had been overwhelmed by the effort required to meet CPEP recommendations while delivering health care to her patients. Respondent notified the Commission that she needed to cease practice for an indefinite period of time in order to focus on personal issues, including whether she wanted to continue the practice of medicine. Respondent requested that she be allowed to continue practicing medicine for approximately thirty (30) days in order to facilitate the transfer of her remaining patients to other providers. Respondent also requested that she not be foreclosed from the possibility of practicing medicine in the future.

1.9 This Second Amended Agreed Order supersedes prior orders in this case. The Findings of Fact and Conclusions of Law stated in the Agreed Order and the Amended Agreed Order remain unchanged for the sake of continuity and clarity.

1.10 This Second Amended Agreed Order is not binding unless it is accepted and signed by the Commission.

1.11 If the Commission accepts this Second Amended 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.

1.12 This Second Amended 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.

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

2. FINDINGS OF FACT

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

2.1 On September 30, 1997, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active. Respondent was formerly board-certified in Family Medicine.

2.2 During all pertinent time frames, Respondent provided medical care for patients at her medical office known as Sound Health and Wellness Center, Inc., located in Poulsbo, Washington. The substandard care detailed below was determined from a review of seven patient charts brought to the attention of the Commission through complaints.

GENERAL PATTERN OF SUBSTANDARD CARE

2.3 Respondent's general approach to medical care for patients consistently fell below the standard of care in similar respects. The following patterns of Respondent's practice created unreasonable risks of harm to these patients.

2.3.1 Respondent did not conduct adequate physical examinations.

2.3.2 When Respondent obtained detailed histories and reports of symptoms from patients, she failed to use this information in the development of diagnoses and treatment plans that meet the standard of care. Based on patients' ongoing reported symptoms, the Respondent did not adjust treatment in a manner consistent with standards of care.

2.3.3 Respondent labeled patients with invalid diagnoses, which she determined without sufficient physical examination, analysis of blood tests, or other documented explanation.

2.3.4 Respondent failed to address patients' complaints and symptoms with individualized, evidence based treatment plans. Respondent instead imposed

cookie cutter treatment methods that were unproven and inefficacious to meet the patients' conditions. Respondent failed to document adequate treatment plans.

2.3.5 Respondent failed to list abnormalities detected in diagnostic testing of patients. Respondent failed to acknowledge or record concerns or recommendations articulated by consultants. Respondent failed to develop appropriate action to be taken to respond to abnormal test results or to consultant's reports.

2.3.6 Respondent failed to articulate and balance known risks against potential benefits of her treatment approach, and failed to provide sufficient information to patients about the unproven nature and the risks of treatments provided to ensure their informed consent.

2.3.7 Respondent's record-keeping for these patients is generally insufficient and illegible.

SUBSTANDARD MANAGEMENT OF CHRONIC PAIN WITH OPIOIDS

2.4 Respondent's approach to the management of chronic pain with opioid therapy for patients was repeatedly substandard in the following areas.

2.4.1 Respondent did not sufficiently develop or respond to baseline patient risk assessments for use of opioid therapy. Respondent failed to adequately direct therapies to treating underlying medical problems presented.

2.4.2 Respondent did not conduct adequate ongoing assessments of patient risk, including urine drug testing, although toxicology screens are recommended on a more regular basis for such patients who are on high doses of prescribed opioids.

2.4.3 Respondent escalated opioid dosing without diagnosing and treating underlying psychiatric co-morbidities. Respondent overused opioids in treating non-malignant pain.

2.4.4 Respondent did not modify pain treatment plans when improvement in function and pain or other goals of therapy were not met.

2.4.5 Respondent did not avoid dose escalation of opioids when pain and functional outcomes failed to improve.

2.4.6 Respondent failed to demonstrate awareness of or assess the impact of opioids on obstructive sleep apnea, endocrine function, fatigue, sleepiness, and depression and failed to manage such problems when noted in patients.

2.4.7 Respondent failed to demonstrate awareness of the syndrome of Opioid Hyperalgesia, where increasing opioid doses leads to increased pain.

2.4.8 Respondent failed to follow recommendations of independent pain consultants to reduce opioid use in therapy.

SUBSTANDARD FIBROMYALGIA DIAGNOSES AND TREATMENT

2.5 Respondent's diagnoses and purported treatment of fibromyalgia was substandard in the following areas.

2.5.1 Respondent diagnosed fibromyalgia without documentation of appropriate evidence or criteria. Respondent's physical exam failed to document commonly described features of fibromyalgia in these patients. Respondent did not document discussion of the symptom complex of fibromyalgia for these patients.

2.5.2 Respondent purported to treat fibromyalgia with an experimental therapy program called the "Marshall Protocol" which focuses on use of antibiotics and vitamin D modulation. There are no clinical trials to support such therapeutic program in the treatment of fibromyalgia. One component of the Marshall Protocol, to continue medications even if known side effects of a medication develop, creates an unreasonable risk for patients.

2.5.3 Respondent labeled a patient with fibromyalgia and implemented the Marshall Protocol without appropriately exploring diagnoses of medical conditions consistent with the presenting complaints, such as inflammatory arthritis and inflammatory bowel disease. Respondent did not meet the standard of care for evaluation of chronic diarrhea and chronic back pain.

SUBSTANDARD CHRONIC FATIGUE SYNDROME DIAGNOSES AND TREATMENT

2.6 Respondent's identification and purported treatment of Chronic Fatigue Syndrome was substandard and placed these patients at unreasonable risk. Chronic Fatigue Syndrome (CFS) is not a diagnosis, but is a constellation of symptoms and signs

that meet certain criteria when no other condition is found to explain the symptoms. The criteria are that:

1. Patients must have clinically evaluated, unexplained, persistent or relapsing fatigue that is:

    a. of new or definite onset,

    b. is not alleviated by rest, and

    c. results in substantial reduction in previous activity levels; plus

2. Four or more specifically defined subsequent persistent or recurring associated symptoms.

Respondent diagnosed patients with CFS based upon complaints of fatigue without discussion in the records establishing that these patients met the criteria for CFS. Respondent failed to consider associated symptoms, time course, and exclusions of other causes including rheumatologic disorders such as Sjogren's syndrome that can present with similar symptoms. Respondent treated the fatigue reported by patients with the "Marshall Protocol" without evidence of its appropriateness. Respondent failed to timely follow-through to determine if sleep apnea contributed to fatigue. Respondent attributed "active human herpes virus – 6 viremia" to a patient without basis and failed to rule out other factors that may have contributed to patients' fatigue.

SUBSTANDARD APPROACH TO VITAMIN D DEFICIENCY

2.7 Respondent failed to diagnose or treat patients with prolonged low levels of vitamin D, which may have contributed to their ongoing symptoms of pain, weakness, fatigue, and increased risk for infectious, neoplastic, allergic and immune disorders. Respondent failed to obtain parathyroid hormone levels, bone density measurements, or other assessments of bone and muscle function for these patients. Respondent failed to discuss orthodox medical literature's conclusions that low vitamin D can be associated with and weaken the immune system, and cause fatigue, pain and weakness disorders.

SUBSTANDARD DIAGNOSIS OF VITAMIN D ELEVATION

2.8 Respondent mis-diagnosed a vitamin D abnormality when laboratory test results showed normal vitamin D levels, both of the 25-hydroxy and the 1,25-dihydroxy vitamin D. Respondent diagnosed elevated vitamin D levels before any clinical evaluation was obtained and without reference to standard diagnostic criteria.

SUBSTANDARD USE OF ANGIOTENSIN RECEPTOR BLOCKING THERAPY

2.9 Respondent treated with the angiotensin receptor blocking medication Benicar (used to treat high blood pressure), the trade name for olmesartan medoxomil, at doses beyond commonly accepted standards. Respondent did not discuss the basis for this off-label use. Respondent failed to document awareness of potential complications or rare adverse reactions or documentation of informed consent by the patients. Respondent failed to make appropriate recommendations to these patients to reduce this medication dosage during times potential toxicity was indicated by the patient's symptoms of dizziness, or laboratory evidence of renal insufficiency. Respondent continued to advance Benicar therapies for patients despite their failure to improve with that treatment.

SUBSTANDARD DIAGNOSES AND TREATMENT OF ANTI-PHOSPHOLIPID ANTIBODY SYNDROME

2.10 Respondent diagnosed patients with a "variant" anti-phospholipid antibody syndrome (an autoimmune disease with abnormal antibodies in the blood), although there is no such diagnosis currently accepted by mainstream medicine. Respondent placed patients at risk with heparin anticoagulation without justification based on history or laboratory evidence of clotting risks. Anti-phospholipid antibodies were not performed. Minor abnormalities of fibrinogen and two other experimental coagulation tests relied upon by Respondent do not provide a basis for an anti-phospholipid antibody syndrome diagnosis.

USE OF HIGH RISK AND INEFFICACIOUS MARSHALL PROTOCOL

2.11 The "Marshall Protocol" implemented by Respondent in her treatment of patients is not supported by placebo controlled clinical trials or animal experiments. Developed by a non-physician, this protocol is contrary to the standard of care for treatment of anti-inflammatory and autoimmune diseases in the following aspects.

2.11.1 Vitamin D is restricted, which is potentially harmful from the effects of vitamin D deficiency.

2.11.2 Patients are not allowed to take doses of corticosteroids.

2.11.3 Light is to be avoided.

2.11.4 There is no clear timeline or symptom response that can be evaluated in a reasonable time frame.

2.11.5 In emergency or critical care situation, oral olmesartan must be continued, even in the presence of hypotension.

2.11.6 The protocol says to continue medications even if side-effects are occurring, which is an unreasonable risk to patients.

SUBSTANDARD TREATMENT WITH SYNTHROID

2.12 Respondent persistently treated patients with Synthroid despite recurrently elevated free T-3 and T-4 levels. Thyroid supplementation can lead to osteoporosis. While supplemental thyroid can be responsibly recommended in patients with resistant depression without reference to thyroid levels, the elevated levels should be charted. Heart rate, weight, bowel symptoms and bone density results should be recorded. Respondent did not chart these items.

SUBSTANDARD DIAGNOSES OF IRRITABLE BOWEL SYNDROME

2.13 Respondent charted diagnoses of Irritable Bowel without documented supporting symptoms.

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).

3.3 The above violation provides 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 **Indefinite Suspension.** Respondent's license is INDEFINTELY SUSPENDED effective thirty (30) days from the effective date of this Second Amended Agreed Order.

Respondent must facilitate the transfer of all patient care and cease the practice of medicine on or before that date.

4.2 **Reinstatement.** Respondent may petition to reinstate her license no sooner than one (1) year from the effective date of this Second Amended Agreed Order. Respondent must demonstrate that she is clinically competent and able to practice medicine with reasonable skill and safety as part of her petition for reinstatement. The Commission will issue a notice scheduling a date and time for Respondent to personally appear at a hearing on her petition.

4.3 **Effective Date.** The effective date of this Second Amended Agreed Order is the date the Adjudicative Clerk Office places the signed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this 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 applies to cases where substandard practice causes moderate harm or risked moderate to severe harm. Respondent's care for several patients falls within Tier B of this schedule by causing moderate harm or risking moderate to severe harm by failing to provide adequate treatment in wide ranging aspects of medicine, from inadequate work-ups through invalid diagnoses, inefficacious treatment methods, failure to respond to abnormalities, poor record keeping, and failure to ensure informed patient consent.

5.2 Tier B recommends the imposition of sanctions ranging from two to five years of oversight, unless revocation is imposed.

5.3 Under WAC 246-16-800(3)(d), the starting point for the duration of the sanctions is the middle of the range. There is no specific midrange in tier B, which ranges from two to five years of oversight unless revocation of license. The Commission uses aggravating and mitigating factors to move towards the maximum or minimum ends of the range.

5.4 The aggravating and mitigating factors in this case justify a term of indefinite suspension. This Second Amended Agreed Order deviates from the sanction schedule to the extent that an indefinite suspension may extend beyond a five year term.

5.5 These sanctions are appropriate within the Tier B ranges, given the facts of the case and the following aggravating and mitigating factors. The Commission finds the breadth and depth of the aggravating factors significantly outweigh the mitigating factors.

A. As aggravating factors, Respondent's substandard practices extended through a wide range of treatment modalities and affected numerous patients.

B. As a mitigating factor, Respondent acknowledges that she has been overwhelmed by the requirements imposed on her current practice of medicine and she independently recognizes that she needs some time away from the practice of medicine in order to focus on personal issues and to decide her future goals.

7. RESPONDENT'S ACCEPTANCE

I, Susan J. Shlifer, MD, Respondent, have read, understand and agree to this Second Amended Agreed Order. This Second Amended 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 Second Amended Agreed Order.

SUSAN J. SHLIFER, MD
RESPONDENT

6/17/2016
DATE

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8. COMMISSION'S ACCEPTANCE AND ORDER

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

DATED: 6/23, 2016.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

PANEL CHAIR

PRESENTED BY:

LAWRENCE J. BERG, WSBA#22334
COMMISSION STAFF ATTORNEY