STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Frank D. Li, MD
Master Case No.: M2016-705
Document: Statement of Charges

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:

> The identity of the complainant if the person is a consumer, health care provider, or employee, pursuant to RCW 43.70.075 (Identity of Whistleblower Protected) and/or the identity of a patient, pursuant to RCW 70.02.020 (Medical Records - Health Care Information Access and Disclosure)

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: **FRANK D. LI, MD** License No. MD00049251 Respondent.	**No. M2016-705** **STATEMENT OF CHARGES**

The Executive Director of the Medical Quality Assurance Commission (Commission) is authorized to make the allegations below, which are supported by the evidence contained in Commission file numbers 2015-4699 and 2015-4708. The patients referred to in this Statement of Charges are identified in the attached Confidential Schedule.

1. ALLEGED FACTS

1.1 On January 31, 2008, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent is board certified in anesthesiology. Respondent's license is currently active.

1.2 Respondent specializes in pain management and is the Medical Director and sole shareholder of the Seattle Pain Center (SPC), which has eight (8) clinic locations in Washington State: Seattle; Renton; Everett; Tacoma; Olympia; Spokane; Poulsbo; and Vancouver. SPC represents itself as a pain management treatment center focused on "finding treatment alternatives to narcotic pain medications" by incorporating "emerging best practices." SPC promotes itself as employing five fellowship-trained physicians, and mid-level practitioners with Advanced Registered Nurse Practitioner (ARNP) and Physician Assistant (PA) licenses. SPC patient records reveal that Respondent and SPC providers repeatedly maintained clinical practices that are extreme departures from the standard of care in chronic pain management and the practice of medicine.

1.3 Respondent established a business model where SPC hired newly licensed mid-level practitioners without training or expertise in pain management, allowed newly hired practitioners to treat patients before establishing insurance accreditation, sought out Medicaid enrolled chronic pain patients, and billed Medicaid the maximum allowable

amounts for excessive quantities of unnecessary urine drug screen (UDS) tests, durable medical equipment and patient office visits.

1.4 As the owner of SPC and employer for all the clinic providers, Respondent established the business model, treatment protocols, and training for treating chronic pain patients. Under Respondent's management and ownership, sixty (60) identified SPC patients died between 2010 and 2015. The Commission investigated Respondent's treatment of eighteen (18) SPC patients (Patients A through R).

1.5 The death certificates of Patients A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, R listed acute drug intoxication as a cause or likely contributing cause of death. Patient P died from a vehicle accident, and Patient Q died from a stroke; however, Patients P and Q had multiple serious health conditions that SPC disregarded during opiate therapy. Patients A through R's medical records reveal an egregious pattern of substandard medical care and disregard by Respondent and SPC providers for patient health and safety.

Patients A through R's deaths

1.6 Patients A through R's deaths occurred over five consecutive years. Respondent represents that he and SPC providers meet "weekly to discuss difficult cases and refine protocol." However, Respondent failed to address how notice of SPC patient deaths altered clinical practices and how practice-wide measures were implemented in mitigating iatrogenic events.

1.7 A unanticipated patient death is a singular, sentinel event requiring immediate critical review for medical and institutional contributions. There is no evidence that SPC established documented investigation or review of Patients A through R's deaths. As SPC Medical Director, Respondent failed to evaluate and investigate patient deaths, and he failed to conduct records review for standard of care concerns attributable to his employed staff and providers.

Substandard Care of Patients A through R

1.8 Patients A through R were Medicaid enrollees who received opioid therapy at SPC and who all died within days or weeks after filling prescriptions for opioid medication

prescribed by a SPC provider. SPC patient records reveal consistent violations of the standard of care. Respondent and SPC providers fail to comprehend legitimate pain management and reference chronic pain as a medical condition that requires higher opioid doses thus demonstrating dangerous, naïve, and unscientific clinical care. Substandard care for Patients A through R includes the following.

1.8.1 Respondent and SPC providers failed to perform independent, thorough medical examinations whereby objective medical diagnosis is made in determining whether the immediate need for opioid therapy is justified. The providers defaulted to opiate-centric treatment plans at the initial patient visit. Patients are acknowledged as "high risk," yet SPC providers legitimized continuing high dose opioid prescriptions by claiming that the patient's non-SPC provider initiated the treatment. SPC providers relied on the patient's subjective complaint and failed to review prior medical histories, imaging studies, and specialty consultations.

1.8.2 Respondent and SPC providers failed to conduct risk assessments in order to mitigate patient harm and drug abuse, diversion, and addiction. SPC providers ignored co-morbidities such as mental health problems, prior and current substance abuse, and other physical conditions that may be contraindicated with opiate medication. Failure to consider and address risk factors prior to opioid therapy place patients at serious risks for respiratory depression, overdose, continued addiction, and death. Furthermore, SPC providers ignored the potential for drug diversion and risk to public safety when prescribing high doses or large quantities of opioid medication.

1.8.3 Respondent and SPC providers failed to define a treatment plan for patients where review of alternative therapies was considered for pain management and referrals were made to other specialists. Patients A through R were initiated on opioid therapy and maintained on medications by receiving increasing and continuing opioid doses at subsequent SPC office visits.

1.8.4 Respondent and SPC providers failed to enforce treatment compliance despite repeated evidence of: failed urine drug screens; requests for

early medication refills; inconsistent pill counts; obtaining opioids from other providers; and admitted drug misuse and abuse. SPC providers issued "aberrancy" findings of non-compliance, yet there was no consistent enforcement whereby medications were withheld or the patient discharged from the practice. Compliance was monitored with urine drug screen (UDS) tests, and results were infrequently reviewed with the patients.

1.9 The pattern of substandard care not only demonstrated failure to recognize serious risks of drug-related harm, it also created an unreasonable risk of serious harm or death to Patients A through R, many of whom were vulnerable due to their health conditions.

Patient A

1.10 Patient A, a 33-year-old single mother, was found dead in a hospital restroom on April 2, 2014. She had a catheter in her antecubital fossa which contained a pink granular substance, a likely intravenous drug residue. The death certificate listed the cause of death as pulmonary and systemic angiogranulomatosis due to chronic injection drug abuse. Patient A died 12 days after filling her prescription for oxycodone.

1.11 Prior to care at SPC, Patient A had two years of opioid therapy with no documented improvement in pain relief or quality of life. An opiate centric treatment plan was formulated at SPC without critical consideration of physical co-morbidities including morbid obesity, history of stroke, atrial fibrillation, and hypertension. Respondent failed to review Patient A's prior medical history of multiple mental health risk factors – including somatization disorder, depression, insomnia, panic disorder and adjustment disorder. Patient A was exposed to respiratory depression and death as a result of failure to consider past medical history and critical co-morbid conditions.

1.12 Respondent treated Patient A with an aggressive regimen of oxycodone without conducting an objective physical examination. Respondent prescribed opioid medication even after Patient A's initial UDS tested positive for alcohol. A physical exam would have revealed needle marks on Patient A's arm indicative of intravenous drug abuse. A review of Patient A's prescription monitoring program (PMP) report would have identified drug-seeking behaviors and hospital over-utilization. Respondent documented

that he does not like to prescribe oxycodone because of "high abuse potential," yet he prescribed to Patient A after she displayed angry emotions when denied oxycodone prescriptions. Respondent and SPC providers continued to escalate Patient A's opioid dose despite Patient A's known overuse of Percocet, doctor-shopping for medications, requests for early refills, and repeated presence of alcohol in her UDS.

Patients B

1.13 Patient B, a 35-year-old woman and homemaker, died on January 25, 2010. The death certificate listed the cause of death as acute methadone intoxication. Just three days prior, Respondent prescribed Patient B methadone and Norco. Although Patient B had a history of cocaine overdose and mental health issues, there are no SPC medical records documenting Respondent's examination or discussion with Patient B about the risks of Norco and methadone use.

Patient C

1.14 Patient C, a 50-year-old man, died on January 15, 2012, from a heart attack. However, a toxicology report revealed diazepam, methadone, and tetrahydrocannabinol (THC) in Patient C's blood. Patient C obtained treatment at SPC seven times from March 2011 through January 2012. SPC providers prescribed increasing methadone doses of 30 mg to 40 mg daily even after Patient C admitted to taking more pills than prescribed, had a history of overdose, and continued to smoke marijuana.

Patient D

1.15 Patient D, a 56-year-old man, died on November 14, 2014. The death certificate listed the cause of death as combined drug toxicity due to simultaneous use of morphine, cyclobenzaprine, and amantadine. The manner of death is listed as suicide. Patient D died nine days after his filling his last prescription from SPC.

1.16 SPC providers initiated an opiate regimen of morphine, Dilaudid, and Flexeril despite Patient D's history of critical risk opioid risk factors: alcohol abuse/dependency; use of illegal drugs; hepatitis; psychosis; depression; and history of discharge from other providers for drug-seeking behaviors. SPC providers failed to document or further inquire into Patient D's current mental health status despite documenting pharmacologic treatment for depression. Opioid medication worsens depression, insomnia, and panic. SPC

providers failed to recognize that Patient D's hepatitis is associated with alcohol abuse and dependency and that alcohol use with opioid therapy is contraindicated placing Patient D at excessive risk of overdose, respiratory depression, and death.

1.17 Patient D had three SPC office visits over two months, and the medical documentation for each visit is identical. Patient D's UDS results are inconsistent and pill counts are aberrant, yet there were no enforcement measures. There is no meaningful, defined treatment goal, and there is no indication that the prescribed combination of morphine, Dilaudid, and Flexeril, at 92 morphine equivalent dose (MED) is effective. This dose is associated with increased incidences of drug abuse and diversion. SPC failed to document or inquire further into Patient D's mental status except to observe "denies suicidal ideation." Failure to define mental status is a critical oversight and violation of the standard of care because opiates worse depression, cause mood instability, worsen panic and cause insomnia.

Patients E

1.18 Patient E, a 60-year-old man living in a residential care facility, died on August 4, 2011. The death certificate listed the cause of death as acute methadone intoxication. SPC medical records dated April 18, 2011 document that Patient E had an office visit for a "medication refill" and received a letter of discharge for violating his opioid agreement.

1.19 SPC medical records document Patient E's prior drug overdoses and hospitalizations, drug diversion, and illegal buying of prescription drugs. A physician assistant, supervised by Respondent, regularly prescribed to Patient E oxycodone, Ambien, clonazepam, and Fentanyl patches. Two months prior to his last office visit, Patient E's primary care provider informed SPC that oxycodone and Fentanyl patch doses caused breathing difficulties for Patient E. The provider also referenced a written recommendation from the hospitalist to decrease Patient E's opioid dose because of a recent hospitalization for drug overdose.

Patient F

1.20 Patient F, a 42-year-old woman, died on December 28, 2011. The death certificate listed the cause of death as acute combined morphine, diphenhydramine, and

citalopram intoxication. Patient F had eight total SPC visits between November 2010 and December 2011, and medical records document a history of depression and requests for increased opiate doses, early refills, and known use of illegal substances. On December 20, 2011 SPC issued a letter of discharge, as well as prescription refills for Klonopin, MS Contin and morphine.

Patient G

1.21 Patient G, a 46-year-old woman, died on February 20, 2013. The death certificate lists the case of death as acute drug intoxication due to the combined effects of methadone, hydromorphone, nortriptyline and Citalopram. The medical examiner also noted a probable contributory factor of cardiovascular disease. Patient G died 15 days after filling her last prescriptions of morphine and Dilaudid prescribed by SPC.

1.22 Patient G was under the care of a PA supervised by Respondent, and for over two years the PA prescribed multiple opioids without evidence of pain or functional improvement. Patient G had vague complaints of back and leg pain, experienced failed treatment by her primary care provider and the University of Washington pain clinic, and showed little improvement after a series of six spinal injections. Patient G had multiple high risk factors for opiate abuse: repeated complaints of insufficient pain treatment requiring escalating opioid doses; inconsistent UDS; self-treatment with alcohol and marijuana; history of major depression, anxiety, alcohol abuse and dependency; history of incarceration; and psychiatric disorders requiring hospitalization. She also suffered from multiple physical health co-morbidities which contraindicated the on-going use of chronic opiates: hepatitis, cirrhosis (secondary to alcohol abuse), asthma, obesity and seizures.

1.23 Despite Patient G's risk factors and known medication misuse, the PA prescribed methadone, Norco, Dilaudid, and morphine, often at more than 400 MED. Respondent represented that SPC was "successful" in stabilizing Patient G's pain and that increasing prescribed opioids is "a last resort." Yet, SPC medical records contradict Respondent's representation because Patient G obtained escalating doses without clinical justification. The PA and SPC providers failed to exercise more stringent monitoring of Patient G's medication compliance. There is no documented attempt to establish an opioid exit strategy despite Patient G's repeated drug-seeking behaviors and exhibits of

severe over-sedation. This is no documentation revealing Respondent's concerns about the PA's prescribing and management of Patient G.

Patient H

1.24 Patient H, a 55-year-old paraplegic woman, died on May 15, 2011. The death certificate lists the case of death as acute drug intoxication due to the combined effects of morphine, oxycodone, diazepam, trazodone, and gabapentin. Patient H suffered from multiple conditions including chronic obstructive pulmonary disorder (COPD), opioid dependence, and chronic pain. She also had a history of hospitalizations for respiratory failure. Patient H had four SPC office visits where Respondent and a PA he supervised prescribed increasing doses of MS Contin and oxycodone at each visit despite awareness of Patient H's high risk factors for opioid misuse. At Patient H's last office visit on May 13, 2011 the UDS showed benzodiazepines not prescribed by SPC. However, under SPC's model the results of the UDS were not available until 5-19-11. The PA prescribed MS Contin 30 mg tid and oxycodone 30 mg tid (225 MED). This increase was thought to be reasonable according to Respondent because "the long-acting component was raised to 90 MED and we know that she was able tolerate MED of 105 from 3-17-11 to 5-13-11. The strategy was to increase her short-acting component so that she could have more control over how much she needed above the baseline amount, and refrain from taking them if not need or tolerated. Because most of the increase was in the short acting, as-needed component, it was thought to be tolerable."

Patient I

1.25 Patient I, a 45-year-old married man, died on March 10, 2015. The death certificate lists the first cause of death as combined drug toxicity due to the simultaneous use of methadone and hydrocodone. Patient I began treatment at SPC in September 2014, and had five office visits where he obtained prescriptions for methadone, hydrocodone, and Dilaudid for 90 to 140 MED. Patient I had a history of drug and alcohol abuse, post-traumatic stress disorder, agoraphobia, hypertension and sleep apnea, yet SPC providers continued opioid therapy with no tapering plan or referral to alternative therapies such as physical therapy, which Patient I indicated being useful in the past.

According to his wife, Patient I crushed and snorted his medications. Patient I filled his last prescriptions three days prior to overdosing.

Patient J

1.26 Patient J, a 58-year-old woman, was found dead on April 7, 2013. The death certificate lists the cause of death as acute drug intoxication due to the combined effects of methadone, hydromorphone, tramadol, and trazodone. Between September 2012 and January 2013, Patient J had four SPC office visits where she obtained opioid therapy. SPC providers failed to consider Patient J's risk factors (history of depression and seizures, prior suicide attempt, and drug-seeking) and continued prescribing hydromorphone at escalating doses. Respondent states that Patient J received prescriptions for doses below 120 MED suggesting that this is an acceptable, safe dosage despite awareness of depression and prior suicide ideation.

Patient K

1.27 Patient K, a 54-year-old woman, died at home on March 11, 2013. The death certificate list the case of death as acute drug intoxication (alprazolam) and additive drug effects (carisprodol, hydrocodone and meprobamate). Patient K had mental health risk factors and prior hospitalizations for overdose. She received pain infusion at SPC. Respondent failed to recognize that increasing Patient K's intrathecal pump (ITP) infusion dosage was ineffective pain relief because Patient J developed high opioid tolerance from misusing drugs. Respondent was also aware that Patient K had obtained opioid prescriptions from another provider.

Patient L

1.28 Patient L, a 62-year-old man, died at home on January 30, 2015. The death certificate lists the cause of death as bronchopneumonia with pulmonary abscesses and emphysema. Acute opiate intoxication was listed as a contributing condition. Patient L died 15 days after filling his last prescription for methadone, oxycodone, and morphine at more than 1,500 MED. Respondent states that Patient L began a "2 year wean of one pill per day reduction per month" at SPC in April 2014. Respondent further states that Patient L's death was "NOT [sic] the direct result" of the opioid medications because SPC had decreased the doses consistently and gradually.

Patient M

1.29 Patient M, a 36-year-old man, died at the hospital on July 26, 2011. The certificate of death lists the cause of death as acute intoxication of the combined effects of methadone, citalopram, trazodone and valproic acid. Other conditions contributing to death were listed as chronic pain syndrome, schizoaffective disorder and fatty liver disease. Patient M began opioid therapy at SPC in February when he obtained morphine prescriptions. Patient M had schizoaffective disorder, a history of physical and emotional abuse, hyperlipidemia, and chronic pain. Respondent and SPC providers failed to recognize high risk factors for opioid abuse and misuse and in less than six months Patient M was switched from morphine to an escalated dose of prescribed methadone. Patient M also had a documented failed UDS prior to receiving methadone prescriptions.

Patient N

1.30 Patient N, a 51-year-old man, died on July 1, 2012, from acute combined hydrocodone, hydromorphone, and methadone intoxication, and four days after filling his last prescriptions for these medications. Patient N had multiple high risk factors for medication abuse and misuse: prior substance abuse; bipolar disorder; attention deficit hyperactivity disorder; taking non-prescribed opioids; and history of sexual/physical abuse. SPC providers documented multiple aberrant behaviors of drug-seeking, but deemed the conduct as not egregious and maintained Patient N on escalating opioid doses.

Patient O

1.31 Patient O, a 28-year-old woman, died on January 12, 2011. The death certificate lists the cause of death as acute combined hydrocodone, hydromorphone, and methadone intoxication. The toxicology report shows a peripheral blood draw was obtained for the testing. Patient O filled her final methadone prescription from SPC just five days prior to her death. After reviewing the toxicology report, Respondent suggests that the coroner wrongfully attributed Patient O's cause of death from acute methadone toxicity because blood sampling was likely not taken from Patient O's heart.

1.32 Patient O had complaints of knee pain, and Respondent initiated an aggressive dose of morphine at 75 MED daily. Patient O had 11 SPC office visits over a one-year period, and she also obtained prescriptions for oxycodone, Norco, and

methadone. Patient O was morbidly obese, ambulated with crutches, and continued to rate her pain level as high even while using opioids. She had a history of significant mental health risk factors (depression, history of abuse) thus she was prone to suffer from chronic pain as a somatic manifestation of emotional suffering. Respondent failed to recognize that psychosomatic chronic pain occurs in patients with significant histories of childhood abuse. Patient O's multiple UDS's were also positive for THC and cocaine and negative for prescribed opioids. Respondent's continued opioid prescribing in light of Patient O's comorbidities and illicit drug use unnecessarily posed serious risks of medication abuse.

1.33 Respondent documented Patient O's request for early medication refills as "evidence of inadequate pain control," and does not provide an early refill of requested oxycodone; instead, Respondent prescribed additional opioids, methadone and Dilaudid. Treating musculoskeletal knee pain with methadone is below the standard of care especially when high risk factors are indicated.

1.34 Patient O's multiple aberrancies were also indicative of drug misuse and likely diversion, yet Respondent failed to cease opiate therapy because he was concerned that discharging Patient O from SPC would "impose more risk to the patient and the community."

Patient P

1.35 Patient P, a 58-year-old man, died on May 3, 2013, from injuries sustained when his vehicle veered over a highway median and collided head-on with a logging truck. A scene investigation revealed a malt liquor can wedged between Patient P's leg and the gearshift. State toxicology report indicates the presence of ethanol, oxycodone, and tricyclic antidepressants in Patient P's blood. Patient P's death occurred 19 days after filling his final prescription from SPC for oxycodone.

1.36 SPC treated Patient P's chronic pain by prescribing oxycodone at 180 MED for greater than two years without evidence of improvement. Patient P's referring provider requested a detailed independent medical evaluation of Patient P's severe post traumatic headaches, but SPC failed to perform this. Patient P was maintained on an oxycodone regimen on his request, and there was no documented objective diagnosis, review of prior

medical records, or risk assessments. Patient P had depression, hypertension, and history of stroke. There was also a language barrier requiring English translation. He took more medication than prescribed, requested early refills, and failed to comprehend the need to avoid alcohol during opiate therapy. The two UDS's performed were positive for the presence of alcohol. Respondent and SPC providers failed to implement an opioid exit strategy knowing that concurrent alcohol use potentiates opioid side effects. Furthermore, SPC providers failed to ensure that medication risks and directions for proper use was properly translated given Patient P's cultural and language barriers.

Patient Q

1.37 Patient Q, a 54-year-old man, died on May 24, 2014, from hemorrhagic cerebral infarct (stroke). Between March 2012 and May 2014, Respondent and SPC providers prescribed escalating monthly doses of oxycodone HCL and OxyContin despite Respondent's representation that SPC avoids prescribing oxycodone because of "abuse potential." Patient Q displayed repeated aberrant behaviors, yet SPC providers maintained an oxycodone therapy regimen without addressing Patient Q's two-years of non-compliant medication use. SPC providers failed to adjust Patient Q's opiate therapy given his serious health conditions including the need for open heart surgery just six months prior to death.

Patient R

1.38 Patient R, a 35-year-old man, died on April 3, 2015. The death certificate lists the cause of death as mechanical asphyxia with a contributing condition of acute intoxication by the combined effects of opiates not otherwise specified, diazepam, cyclobenzaprine and sertraline. Patient R had a history of illicit drug use, bipolar disorder, depression and suicidal ideation, obesity, hypertension, and numerous psychiatric hospitalizations. He also had a history of post-traumatic stress disorder due to childhood sexual abuse and had been dependent on methamphetamine and alcohol. He sought pain treatment at SPC beginning June 2014. SPC providers initiated opiate therapy despite documenting Patient R as having risks for medication abuse. Patient R obtained escalating doses of Percocet and Nucynta despite a failed UDS and admitted over-use of prescribed medication.

Seattle Pain Center Clinical and Business Practices

1.39 Respondent had a practice of hiring ARNP's and PA's with little to no experience or training in treating chronic noncancer pain. In fact, these mid-level providers joined SPC by relying on Respondent's agreement to provide training in chronic pain treatment. SPC hired mid-level providers recently graduated from clinical school and allowed these providers to treat patients and bill for services before obtaining an established National Provider Identifier (NPI) number or insurance credential. Respondent blamed an electronic medical record system flaw for the inaccurate provider billing.

1.40 In 2013, Respondent hired an experienced pain management PA for the Spokane clinic. Respondent allowed the PA to treat patients and bill for services for several months prior to submission of a delegation agreement to the Commission. The PA was unaware that her agreement was not executed and relied on Respondent's representations. Once notified she ceased treating patients until the delegation agreement was in place.

1.41 Respondent represented to the Commission that SPC treats "the most difficult and challenging" pain patients. Most SPC patients are Medicaid enrollees and Respondent attempts to be "an accessible pain care resource" for these patients. In 2013 Respondent furthered his own financial interest by establishing a SPC-owned UDS laboratory (Northwest Analytics) that screened a 16-panel test on every urine sample taken from a Medicaid patient. Medicaid patients were required to submit a UDS at every office visit beginning February 2014, and SPC billed Medicaid the maximum allowable amount for these UDS tests. In February 2015, Health Care Authority (HCA), the state agency that administers Medicaid, suspended Medicaid payment for lab services that included 16 panel drug screening. The payment suspension is in place until a HCA complaint on Respondent and SPC is fully investigated. Furthermore, HCA reports reveal that Medicaid payments were made out to SPC and mailed to Respondent's post office box. Forensic testing of SPC patient urine drug screen using the 16 panel drug screening

was unnecessary to monitor opioid therapy and was performed at that level for Respondent's personal gain.

1.42 In 2013, the Washington State Department of Labor and Industries (L&I) denied Respondent's application to renew his provider contract. L&I's decision was based on complaints of noncompliant opioid prescribing practices and an SPC PA's substandard care of an injured worker who eventually died from drug overdose. Respondent withdrew his application before L&I could report the application denial. SPC's website continues to list L&I and worker's compensation as a service provided although it is unclear which SPC provider has an L&I contract.

2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, Respondent has committed unprofessional conduct in violation of RCW 18.130.180(1), (4), (7), (13), (14), (22), and WAC 246-919-853, -855, -857, and -860.

> **RCW 18.130.180 Unprofessional conduct.** The following conduct, acts, or conditions constitute unprofessional conduct for any license holder under the jurisdiction of this chapter:
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> (1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon such a conviction, however, the judgment and sentence is conclusive evidence at the ensuing disciplinary hearing of the guilt of the license holder of the crime described in the indictment or information, and of the person's violation of the statute on which it is based. For the purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter **9.96A** RCW;
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> ...
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> (4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;
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> ...
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> (7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;
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> ...

(13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;
(14) Failure to adequately supervise auxiliary staff to the extent that the consumer's health or safety is at risk;
...

(22) Interference with an investigation or disciplinary proceeding by willful misrepresentation of facts before the disciplining authority or its authorized representative, or by the use of threats or harassment against any patient or witness to prevent them from providing evidence in a disciplinary proceeding or any other legal action, or by the use of financial inducements to any patient or witness to prevent or attempt to prevent him or her from providing evidence in a disciplinary proceeding;
... .

WAC 246-919-853

Patient Evaluation.

The physician shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

(1) The patient's health history shall include:
- (a) Current and past treatments for pain;
- (b) Comorbidities; and
- (c) Any substance abuse.

(2) The patient's health history should include:
- (a) A review of any available prescription monitoring program or emergency department-based information exchange; and
- (b) Any relevant information from a pharmacist provided to a physician.

(3) The initial patient evaluation shall include:
- (a) Physical examination;
- (b) The nature and intensity of the pain;
- (c) The effect of the pain on physical and psychological function;
- (d) Medications including indication(s), date, type, dosage, and quantity prescribed;
- (e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:
  - (i) History of addiction;
  - (ii) Abuse or aberrant behavior regarding opioid use;
  - (iii) Psychiatric conditions;
  - (iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;
  - (v) Poorly controlled depression or anxiety;
  - (vi) Evidence or risk of significant adverse events, including falls or fractures;

(vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;
(viii) Repeated visits to emergency departments seeking opioids;
(ix) History of sleep apnea or other respiratory risk factors;
(x) Possible or current pregnancy; and
(xi) History of allergies or intolerances.

(4) The initial patient evaluation should include:
(a) Any available diagnostic, therapeutic, and laboratory results; and
(b) Any available consultations.

(5) The health record shall be maintained in an accessible manner, readily available for review, and should include:
(a) The diagnosis, treatment plan, and objectives;
(b) Documentation of the presence of one or more recognized indications for the use of pain medication;
(c) Documentation of any medication prescribed;
(d) Results of periodic reviews;
(e) Any written agreements for treatment between the patient and the physician; and
(f) The physician's instructions to the patient.

...

WAC 246-919-855

Informed consent.

The physician shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

...

WAC 246-919-857

Periodic review.

The physician shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the physician shall determine:
(a) Patient's compliance with any medication treatment plan;
(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and
(c) If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards treatment objectives.

(2) The physician shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The physician shall consider tapering, changing, or discontinuing treatment when:

(a) Function or pain does not improve after a trial period;

(b) There is evidence of significant adverse effects;

(c) Other treatment modalities are indicated; or

(d) There is evidence of misuse, addiction, or diversion.

(3) The physician should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The physician should periodically review any relevant information from a pharmacist provided to the physician.

...

WAC 246-919-860

Consultation—Recommendations and requirements.

(1) The physician shall consider, and document the consideration, referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED)(oral). In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in WAC **246-919-863** is required, unless the consultation is exempted under WAC **246-919-861** or **246-919-862**. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the physician;

(iii) An electronic consultation between the pain management specialist and the physician; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present

with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist.

(b) A physician shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the physician, the physician shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist at any time. For the purposes of WAC **246-919-850** through **246-919-863**, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

. . . .

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

3. NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Executive Director of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline and the imposition of sanctions under Chapter 18.130 RCW.

DATED: July 13, 2016.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

Melanie de Leon

MELANIE DE LEON
EXECUTIVE DIRECTOR

KRISTIN G. BREWER, WSBA # 38494
ASSISTANT ATTORNEY GENERAL

CONFIDENTIAL SCHEDULE

This information is confidential and is NOT to be released without the consent of the individual or individuals named below. RCW 42.56.240(1)

Patient A
Patient B
Patient C
Patient D
Patient E
Patient F
Patient G
Patient H
Patient I
Patient J
Patient K
Patient L
Patient M
Patient N
Patient O
Patient P
Patient Q
Patient R