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# FAX COVER SHEET

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| Date: | **October 3, 2016** | File No. | **8082.002** |
| Matter Name: | **Li, Frank MD M2016-705** | **HARD COPY: ☑ TO FOLLOW ☐ RETAINED** | |
| From: | **Tom Fain** | | |
| To: | Company: | FAX No: | Telephone No: |
| **Adjudicative Service Unit** | **DOH** | **360-586-2171** | **360-236-4671** |
| **Kristin G. Brewer** | **Office of the Attorney General** | **360-664-0229** | **360-586-2760** |

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STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

| | |
|---|---|
| In the Matter of the license to Practice as a Physician and Surgeon of<br><br>FRANK D. LI, MD<br>License No. MD00049251<br><br>Respondent. | NO. M2016-705<br><br>ANSWER OF RESPONDENT |

**Section 1: REQUEST FOR ADJUDICATIVE PROCEEDING**

Respondent requests a settlement conference with possibility of formal hearing in this matter. Respondent does not waive his right to a hearing unless a settlement is accepted and approved by Respondent and the Commission.

**Section 2: REPRESENTATION**

Respondent WILL be represented by an attorney. His name and address is:

Thomas H. Fain
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**Section 3: RESPONSE TO ALLEGATIONS**

The Statement of Charges involve approximately 48 broad allegations concerning 18 patients and more than 140 visits, over a period of 5 years. With 8 of the 18 patients, Respondent provided care for only 1 or 2 visits; and provided no care at all for 5 of the patients (patients A, D, I, J and R). It further appears that the State is alleging vicarious liability, contrary to Washington law, against the Respondent for acts or omissions of other providers that were licensed by the Department of Health.

Respondent has not agreed to waive his constitutional due process right to compel the State to prove any and all allegations by clear and convincing evidence, and all matters not expressly admitted herein are DENIED.

In response to paragraph 1.1, it is ADMITTED, but in addition to being board certified in anesthesiology, Respondent has subspecialty certification in Pain Medicine, and completed a fellowship in Pain Management at UCLA.

In response to paragraph 1.2, it is ADMITTED that Respondent specializes in pain management, and that he was the Medical Director of Seattle Pain Center (SPC) until the spring of 2016, when another fellowship-trained physician licensed by the State of Washington took over those responsibilities. It is also ADMITTED that at relevant times Respondent was the sole shareholder of SPC, and that SPC had clinic locations in Seattle, Renton, Everett, Tacoma, Olympia, Poulsbo, Vancouver and Spokane. It is also ADMITTED that Respondent and other SPC providers considered and attempted a variety of treatment methods to help patients deal with chronic pain, including drug and non-drug alternatives to opioids. It is also ADMITTED that SPC employed pain management fellowship-trained physicians, as well as



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Advanced Registered Nurse Practitioners and Physician Assistants qualified and licensed by the State of Washington Department of Health. It is DENIED that Respondent, or the other SPC providers maintained clinical practices that constituted departures from their respective standards of care in the State of Washington at the times in question, and under the circumstances of each case.

In response to paragraph 1.3, it is DENIED that there was a business model of hiring newly licensed mid-level practitioners without training or expertise in the management of pain, and it is pointed out that the Department of Health licensed each of the providers. It is ADMITTED that Respondent acknowledged his willingness to accept and treat Medicaid beneficiaries with chronic pain that many other physicians would not accept as patients. As Respondent is not an expert in billing details (nor are most physicians), he does not claim expertise in that area, but on information and belief it is permissible for providers to treat patients before insurance credentialing is achieved, and different insurance companies may have different policies regarding payment for services received prior to final approval of insurance credentials. Allegations that excessive quantities of urine drug screen (UDS) testing were performed, that durable medical equipment was unnecessary, or that excessive patient visits took place, are DENIED.

In response to paragraph 1.4, It is ADMITTED that the Commission investigated portions of the treatment of patients A-R, but notes that in the Commission's investigative file provided to Respondent's counsel, contains no factual data concerning any purported 60 patient deaths; and the remainder of this paragraph is DENIED.



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In response to paragraph 1.5, it is DENIED that each of the death certificates for patients A-R listed acute drug intoxication as a cause or likely contributing cause of death. To the contrary, the records supplied by the Commission indicate that Patient A died in a hospital, while under the care of hospital providers, when the patient self-injected herself with a pink granular substance that did not come from Respondent (or SPC). Patient B, from the records supplied by the State, appears to have taken 5 times the prescribed amount of her prescription, suggesting intentional act by the patient. Patient C died from a heart attack, and contrary to the allegations in this paragraph, the death certificate supplied by the state indicates that the contributing factor was diabetes mellitus. Patient D appears to have taken medications obtained from multiple sources other than the Respondent or SPC; and this appears to be the case for all the cases of combined medications. The death of Patient L was determined by the coroner to have been caused by bronchopneumonia with pulmonary abscesses and empyema due to pulmonary emphysema. Patient Q died of a stroke. And Patient R died from mechanical asphyxiation, according to the records supplied by the Commission.

It is DENIED that Respondent disregarded the health conditions of Patients P and Q, as those health conditions were clearly documented in the SPC records, and none were an absolute contraindication for treatment; and it is further noted that Respondent saw Patient P on only one visit of the fifteen office visits to SPC, and that he saw Patient Q on only one of the twelve visits to SPC.

Once again, it appears from these allegations that the State is attempting to assign vicarious liability to the Respondent, contrary to Washington law; and in its zeal to prosecute



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the case the State exaggerates the clear language appearing on the death certificates provided by the state and ignores the clear language found in the medical records of the patients.

In response to paragraph 1.6, It is ADMITTED that SPC providers held regular meetings to discuss difficult cases. But the Statement of Charges alleges that Respondent "failed to address how notice of SPC patient deaths altered clinical practices ...." *Respondent was never asked to address this issue by DOH.* Furthermore, it is inappropriate to assume that Respondent or SPC was advised of the death of these patients. Most of the deaths only became known to Respondent when the Commission sent Respondent's counsel copies of the death certificates earlier this year. Counsel is unaware of any policy or practice for the Department of Health to notify a physician when his or her patient dies, although that would be a good policy to implement so that these events could be brought to the attention of health care providers and discussions commenced to consider means of mitigating such events in the future.

In response to paragraph1.7, it is again pointed out that the State did not advise Respondent of these deaths until earlier this year when the Commission provided death material to Respondent's counsel; and there was no specific request for SPC to investigate or review the deaths. Respondent did, however, provide the Commission with his interpretation on the material provided by the State, pointing out where data was lacking, as well.

In response to paragraph 1.8, It is ADMITTED that patients A through R were Medicaid enrollees who received opioid and/or other therapy at SPC. It is DENIED that all died within days or weeks of filling prescriptions for opioid medication prescribed by an SPC provider – indeed the State included charges for patients that died months after being seen at



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SPC, patients that died from stroke, heart attack, trauma, self-induced IV medication at a hospital while under hospital care, and patients that had been seen at other pain specialists after being discharged from SPC. Furthermore the allegation that Respondent and SPC providers failed to comprehend "legitimate" pain management is vague and ambiguous, and Respondent in fact did follow then-current methods regarding pain management as concepts evolved over the course of years involved in the Statement of Charges.

In response to paragraph 1.8.1, contrary to the allegations, the medical records of these patients DO reflect independent thorough medical examinations and appropriate medical diagnoses, used in determining whether opioid therapy was justified. Furthermore, the records reflect that the SPC providers DID review prior medical histories, imaging and consultations where appropriate, and considered that information, along with the patients' subjective complaints of pain (which is subjective by nature) in determining the course of therapy.

In response to paragraph 1.8.2, risk assessments WERE made by SPC providers and commented upon in the medical records, contrary to the allegations in the Statement of Charges. Furthermore, the State ignores the fact that the comorbidities listed in the Statement of Charges were developed from the comorbidities listed in the medical records at SPC. So, contrary to the allegation that they were ignored by SPC, they were clearly considered and documented; and there were NO absolute contraindications to opioid therapy among the patients – even patients with risk factors or comorbidities deserve treatment to minimize chronic pain, and such is recognized by Washington State guidelines. Furthermore, the records demonstrate that there was no "default" to "opiate-centric" treatment plans at the initial visit.



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In response to paragraph 1.8.3, it is DENIED. The medical records reveal treatment planning and consideration of alternative therapies, contrary to the allegation.

In response to paragraph 1.8.4, the allegations are DENIED. The medical records reflect that treatment compliance was routinely monitored, and appropriate counseling and other measures (sometimes including discharge), pursued based upon the circumstances of the particular case.

In response to paragraph 1.9, the alleged "pattern" is not defined in the Statement of Charges, and imparts no notice to the Respondent of the specifics of the allegation. Therefore Respondent DENIES this allegation.

**Patient A**

In response to paragraphs 1.10 – 1.12, although the treatment for Patient A appears to be reasonable under the circumstances of the case, Respondent never provided treatment to Patient A and Washington law does not support vicarious liability for disciplinary action. It is therefore inappropriate for Respondent to be compelled to respond to these allegations and they should be considered as DENIED for purposes of this pleading.

Note that according to the information supplied by DOH to Respondent, Patient A died of an intentional self- injection of a substance not prescribed by any SPC provider, while hospitalized and under the care of other health care providers.

**Patient B**

In response to paragraph 1.13, it is ADMITTED that the death certificate listed the cause of death as acute methadone overdose (apparently intentional, as 25-30 pills were missing per the Coroner's report), and that the patient had recently been prescribed methadone



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and Norco. The remainder is DENIED, and it should be noted that the history of a cocaine overdose was not provided to Respondent despite a detailed initial visit evaluation. Contrary to the allegation of no SPC records documenting Respondent's exam or discussion about the risks of Norco and methadone, these matters are documented and did occur.

**Patient C**

In response to paragraph 1.14, it should be pointed out that Respondent saw the patient on only one visit seven months before Patient C's death, and that Patient C was seen by other providers on the other six visits. It is ADMITTED that Patient C died of a heart attack, and not from his medications prescribed at SPC. As for the allegations regarding Patient C's use of marijuana, Patient C had a valid medical marijuana card issued by another provider; and the Washington guidelines allowed providers to prescribe opioids to cannabis users. Yet the risks or efficacy of THC were discussed with Patient C, as clearly documented in the chart. It is also ADMITTED that Patient C had experienced a non-fatal reaction at higher doses of methadone prescribed by non-SPC providers, and that this was considered by SPC providers before prescribing methadone (all of which was at doses lower than the prior dose that produced the non-fatal reaction). The remainder is DENIED.

**Patient D**

In response to paragraph 1.15 – 1.17, although the treatment for Patient D appears reasonable under the circumstances of the case, Respondent never provided treatment to Patient D and Washington law does not support vicarious liability for disciplinary action. It is therefore inappropriate for Respondent to be compelled to respond to these allegations and they should be considered as DENIED for purposes of this pleading.



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**Patient E**

In response to paragraph 1.18, it is ADMITTED that Patient E died 4 months after being discharged from SPC (and 8 months after last being see by Respondent), that the toxicology report at the time of the patient's death showed the absence of medications prescribed by SPC, and showed the presence of medications NOT prescribed by SPC. Furthermore, the records indicate that Patient E was being treated at another pain clinic at the time of his death. It is also ADMITTED that months before his discharge, Patient E's egregious aberrant behavior was noted by SPC providers and a plan was put in place to taper down Fentanyl to a low enough dose to safely discharge Patient E from SPC and provide him with other alternatives for care. Patient E was counseled appropriately, and that this plan was carried out successfully, with the patient discharged in April with an appropriate amount of medications to complete his taper and transfer his care.

In response to paragraph 1.19, it is ADMITTED that SPC records indicated prior difficulties managing the patient's chronic pain by other providers, and that the SPC records document the challenges facing SPC providers managing the patient, as well.

**Patient F**

In response to paragraph 1.20, Patient F's death occurred more than 1 year after Respondent last treated her; and Respondent ADMITS that Patient F's death certificate listed her cause of death as due to the combined ingestion of the 3 medications listed, 2 of which were not prescribed by SPC. It is also ADMITTED that the SPC records documented a history



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of depression, which is NOT a contraindication for chronic opioid therapy per Washington State guidelines. Furthermore, the records demonstrate that her providers routinely assessed the patient's mental status, and that assessment tools were utilized in conformance with the standard of care. Acting upon a failed UDT, SPC placed calls to local pharmacies and discovered that the patient was obtaining pain medications from other providers without the knowledge of SPC providers. Therefore, Patient F was discharged from SPC on December 20, 2011, and provided with 3 alternative pain providers or clinics, and a bridging supply of medications to deal with her pain until she could get in to her chosen alternative provider.

**Patient G**

In response to paragraph 1.21, it is ADMITTED that Patient G's death certificate indicates that the likely cause of death was due to a combination of medications, including 2 medications(Citalopram and Nortriptyline) prescribed by non-SPC providers. Respondent also notes that he provided care to patient G on only 4 of her 21 SPC visits, the last of which was for a steroid injection that occurred 3 months before her death and had no role in her death.

In response to paragraph 1.22, it is ADMITTED that Patient G was under the care of a Physician's Assistant licensed by the Department of Health, and that opioids were used to treat her chronic pain. It is DENIED that there was "no evidence of pain or functional improvement", as the records reflect otherwise. It is also ADMITTED that Patient G had multiple risk factors and comorbidities, and had failed prior treatment attempts, but that as supported by Washington State guidelines, these are not contraindications to treatment.

In response to paragraph 1.23, it is DENIED that Patient G was not monitored appropriately, as she was followed closely with pill counts, risk assessment questionnaires and



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appropriate histories and physical exams. Furthermore, Patient G appeared compliant with her regimen. The remainder is DENIED.

**Patient H**

In response to paragraph 1.24, Respondent treated this patient only 1 time, several months prior to her death. It is ADMITTED that Patient H's death certificate listed her cause of death as intoxication due to the combined effects of medications, including medications not prescribed by SPC providers. It is also ADMITTED that Patient H had risk factors, comorbidities and a history of hospitalizations that were appropriately documented in the SPC records, and that treatment was not contraindicated by Washington State guidelines. Furthermore, it is ADMITTED that at Patient H's last office visit on May 11, 2011 the LCMS validation testing was not available until May 19, 2011, which is not unreasonable for a complex lab turnaround time. It is also ADMITTED that it was Respondent's opinion, when asked to review the care by DOH, that the regimen prescribed by the other provider appeared reasonable under the circumstances of the case.

**Patient I**

In response to paragraph 1.25, although the treatment for Patient I appears reasonable under the circumstances of the case, Respondent never provided treatment to Patient I and Washington law does not support vicarious liability for disciplinary action. It is therefore inappropriate for Respondent to be compelled to respond to these allegations and they should be considered as DENIED for purposes of this pleading.



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**Patient J**

In response to paragraph 1.26, although the treatment for Patient J appears reasonable under the circumstances of the case, Respondent never provided treatment to Patient J and Washington law does not support vicarious liability for disciplinary action. It is therefore inappropriate for Respondent to be compelled to respond to these allegations and they should be considered as DENIED for purposes of this pleading.

**Patient K**

In response to paragraph 1.27, it is ADMITTED that Patient K's death certificate indicates that her cause of death was ingestion of four medications (Alprazolam, Hydrocodone, Carisoprodol, and Meprobamate) NOT prescribed by Respondent or SPC, and that the medication prescribed by SPC (which was for her pump) was NOT detected in the toxicology report. It is also ADMITTED that Patient K was referred to SPC to manage the intrathecal pain pump originally inserted by the University of Washington. It is also pointed out that contrary to the allegations of this paragraph, the patient was titrated upward with noted improvement, then adjusted downward and maintained on a stable dose. It is also ADMITTED that when it became known that the patient was also getting pain medication from another provider, the other provider was contacted and reduction of her PO medications advised.

**Patient L**

In response to paragraph 1.28, it is ADMITED that the death certificate indicates the cause of death was bronchopneumonia with pulmonary abscesses and emphysema. It is further ADMITTED that prior to being referred to SPC, the patient had been at an MED of 2460 mg/day, and that once the patient came to SPC, his dose was reduced at every visit per



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recommendation by UW TelePain on April 21, 2014. At the time of his death his MED had been reduced to 1500 mg/day, with further reductions planned. Although the State alleges that "acute opiate intoxication" was a contributing cause of death, this conclusion is wrong, as the patient had been on continuous methadone treatment for years, which was being reduced by SPC at every visit, and the witness description of events at the time of death is inconsistent with an opioid overdose.

**Patient M**

In response to paragraph 1.29, it is ADMITTED that the death certificate indicates that Patient M died from the combined effect of medications, including medications not prescribed by SPC providers. It is also ADMITTED that the patient was initially started on morphine, and then switched to methadone when the morphine was ineffective at controlling his pain, with the rationale documented in the chart. It is also ADMITTED that the patient had other comorbidities that were appropriately documented and considered in the chart. It is DENIED that there was a failed urine drug test prior to receiving methadone prescriptions, as demonstrated by the definitive confirmation testing with LCMS .

**Patient N**

In response to paragraph 1.30, it is pointed out that Respondent last saw Patient N more than one year before his death. It is ADMITTED that the death certificate indicated combined intoxication from the drugs mentioned, and that Patient N had risk factors as noted in the chart, which were not contraindications for treatment under Washington State guidelines. It is also ADMITTED that efforts were made to identify aberrancies, and, when found, be documented,



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and corrective action considered, such as the aberrancy noted on 5/7/12. As noted, not all aberrancies are egregious enough to warrant discharge from care.

**Patient O**

In response to paragraph 1.31, it is DENIED that the death certificate reads as alleged, and DENY that methadone ingestion was the cause of death.

In response to paragraph 1.32, it is ADMITTED that Patient O had complaints of knee pain, but DENIED that the initial dose of morphine was aggressive, especially at the time in question. It is also ADMITTED that the patient was seen approximately once a month and examined and assessed as noted in the chart. It is also ADMITTED that the patient was prescribed the medications alleged, but not concurrently as suggested by the allegation, in an attempt to determine the most efficacious regimen, as this is reasonable under the circumstances. It is DENIED that Patient O reported no pain benefit from her medication, and to the contrary, point out that she did report benefit, and also note that she reported improvement in function with medication, with no side effects, as indicated in the records. It is further DENIED that Respondent failed to recognize that there may be an association between psychosomatic pain and childhood abuse history. Not only was this recognized, but is one reason that type of history is inquired about, as was done in this case. Furthermore, pain may have many other origins that are not psychosomatic. It is DENIED that definitive testing with LCMS demonstrated the presence of cocaine or THC.

In response to paragraph 1.33, the reason that the patient was switched from oxycodone to methadone and Dilaudid was because there was evidence of inadequate pain control on oxycodone. Furthermore, not all knee pain is musculoskeletal, and Patient O's knee pain was



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complicated and multifactorial with neuropathic and centralized components. Therefore, use of methadone under these circumstances was reasonable.

In response to paragraph 1.34, although there was an aberrancy as documented in the chart, this was addressed and reasonable corrective action was taken, as documented in the chart.

**Patient P**

In response to paragraph 1.35, Respondent saw Patient P on only one occasion, approximately 5 months before the patient died from injuries sustained in a motor vehicle accident. It is ADMITTED that oxycodone was found in his system, as would be expected for this patient. In addition, although alcohol was also present in his blood (at below the DUI limit), the patient had been counseled to avoid alcohol when taking opioids.

In response to paragraph 1.36, it is ADMITTED that the patient was on a stable dose of 180 MED mg/day for over two years, but contrary to the allegations, Patient P had clear functional gains with the medication that were documented in the chart. This would be consistent with Washington State guidelines. In addition, contrary to the allegation, Respondent DID evaluate Patient P's severe post traumatic headaches and documented his impression and offered the patient treatment. Furthermore, contrary to the allegations in this paragraph, prior records were reviewed, objective diagnoses made, and risks assessed. In addition, SPC providers were aware of the patient's history of depression, hypertension and stroke, and these were considered and documented in the chart. None contraindicated the selected treatment course, and because of the history of depression the providers screened for signs of suicidal ideation at all visits and found none. In addition, it is DENIED that Patient P



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requested early refills, or that any were given. Furthermore, the patient was advised to avoid alcohol when taking opioids. Finally, there was no indication for an opioid exit strategy given his stable dose and functional gains over two years.

**Patient Q**

In response to paragraph 1.37, Respondent saw the patient on one occasion. It is ADMITTED that Patient Q died of a stroke as alleged, and that he had significant risk factors for a stroke including ongoing issues with DVT and recent open heart surgery with questionable anticoagulation status. It is DENIED that from March 2012 through May 2014 Patient Q was prescribed escalating monthly doses by SPC providers, and obviously not by Respondent, who saw him only once. Furthermore, when SPC providers were aware of aberrancies they were dealt with, and known serious health conditions, including his open heart surgery were considered in his treatment plan.

**Patient R**

In response to paragraph 1.38, although the treatment for Patient R appears reasonable under the circumstances of the case, Respondent never provided treatment to Patient R and Washington law does not support vicarious liability for disciplinary action. It is therefore inappropriate for Respondent to be compelled to respond to these allegations and they should be considered as DENIED for purposes of this pleading.

Furthermore, it should be noted that among the medications identified on toxicology of Patient R by the Coroner, none were prescribed by SPC providers.



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**Seattle Pain Center**

In response to paragraph 1.39, it is DENIED that Respondent had a practice of hiring ARNP's and PA's with little to no experience. To the contrary, experienced mid-levels were hired whenever possible. Licensed providers were allowed to see patients, as permitted by Washington law. As stated earlier in this Answer, Respondent is not an expert in billing details (nor are most physicians), and does not claim expertise in that area. However, it is believed that it is permissible for providers to treat patients before insurance credentialing is achieved, and different insurance companies may have different policies regarding payment for services received prior to final approval of insurance credentials.

In response to paragraph 1.40, it is ADMITED that Respondent did not initially know that a Physician's Assistant required a Delegation Agreement, and that once notified of this remedial action was taken to provide the Delegation Agreement.

In response to paragraph 1.41, it is ADMITTED that the chronic pain patients treated at SPC were among the most difficult and challenging of patients. It is also ADMITTED that SPC attempted to be an accessible pain care resource for patients, including Medicaid patients. It is also ADMITTED that HCA suspended payments for lab services pending investigation, and that HCA payments that were made prior to that were sent to the post office box for SPC. The remainder is DENIED.

In response to paragraph 1.42, it is ADMITTED that Respondent withdrew his application for renewal with the Department of Labor & Industries, yet some other SPC providers were allowed to continue seeing Labor & Industries patients.



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In response to paragraphs 2.1 and 2.2, it is DENIED that Respondent violated the laws or regulations cited, or that sanctions are warranted.

**Section 4: INTERPRETER**

Respondent DOES NOT demand an interpreter.

**Section 5: PROCEDURAL RIGHTS**

No response is required.

DATED October 3, 2016.

FAIN ANDERSON VANDERHOEF ROSENDAHL O'HALLORAN SPILLANE, PLLC

By _____
Thomas H. Fain, WSBA #07117
Attorneys for Respondent



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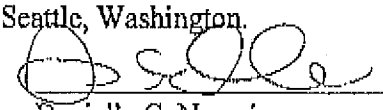
## CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury under the laws of the State of Washington that on the date below I caused the foregoing *Answer of Respondent* to be served upon the following in the manner indicated:

| | |
|---|---|
| Adjudicative Clerks Office:<br>Adjudicative Service Unit<br>Department of Health<br>PO Box 47879<br>Olympia, WA 98504-7879 | ☑ Fax<br>☐ ABC Legal Services<br>☐ Express Mail<br>☑ Regular U.S. Mail<br>☐ E-file / E-mail |
| Assistant Attorney General:<br>Kristin Brewer<br>Office of the Attorney General<br>1125 Washington Street SE<br>P.O. Box 40100<br>Olympia, WA 98504-0100 | ☑ Fax<br>☐ ABC Legal Services<br>☐ Express Mail<br>☑ Regular U.S. Mail<br>☐ E-file / E-mail |

Dated this 3rd day of October, 2016 at Seattle, Washington.



Danielle C. Nouné



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Redaction Summary ( 0 redactions )

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0 Privilege / Exemption reason used:

Redacted pages: