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TO: Melanie DeLeon, Executive Director
Medical Quality Assurance Commission
Washington State Department of Health

FROM: Douglas D. Walsh, Senior Assistant Attorney General and Director
Medicaid Fraud Control Unit (MFCU)
Washington State Attorney General's Office

RE: Unprofessional conduct complaint against Dr. Frank D. Li

I. INTRODUCTION

MFCU is investigating various Medicaid false claim allegations involving Dr. Frank Li and his Seattle Pain Center Medical Corporation (SPC). We intend to file a civil complaint in federal court to recover damages and penalties for Medicaid false claims. However, for several reasons, that law suit will not be ready to file for several months and likely will not be resolved for several years. Based in part on the statements of former SPC employee providers to MFCU Investigators indicating significant quality concerns, MFCU believes that the Medical Quality Assurance Commission (MQAC) should investigate possible unprofessional conduct in Dr. Li's practice.

This memorandum identifies the grounds for this complaint, briefly discusses the standard of care for opioid prescribing, and then identifies SPC-wide practices imposed by Dr. Li that appear to violate the standard of care. Finally, the memorandum identifies several examples of patient harm apparently caused in part by that unprofessional conduct, including the unintentional overdose deaths of 15 Medicaid patients. Three of the 15 deaths occurred in 2015.

II. GROUNDS

Per RCW 18.130.080(1)(a):

> an individual ... may submit a written complaint to the disciplining authority charging a license holder .... with unprofessional conduct and specifying the grounds therefore ....

Dr. Li, as SPC's medical director, issued standing orders and established practice conditions that advanced his financial interests as sole shareholder of the corporation at the expense of SPC patients. Dr. Li encouraged general practitioners throughout Washington State to refer their "most difficult pain patients" to his clinics. But, he failed to ensure that SPC had the infrastructure and qualified pain management specialists necessary to serve the large numbers of

complex patients referred to the practice. Instead, Dr. Li's rapid expansion of SPC's clinical practice placed the care of those "most difficult pain patients" in the hands of providers who were not qualified or not able to care for such patients.[1] The combination of Dr. Li's focus on generating company revenue and his tendency to cut regulatory corners resulted in harm to many of the "most difficult pain patients" referred to SPC. The clinical and business practices that caused that harm are ongoing and place many other patients at risk.

As described further in the last section of this memo, our false claims investigation identified several characteristics of SPC's clinical practice that apparently constitute unprofessional conduct according to RCW 18.130.180, including:

- Incompetence, negligence, or malpractice, which results in injury to a patient, or which creates an unreasonable risk that a patient may be harmed.[2]

- Misrepresentation or fraud in any aspect of the conduct of the business or profession.[3]

- Failure to adequately supervise auxiliary staff to the extent that the consumer's health or safety is at risk.[4]

- Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service.[5]

III. LONG TERM OPIOID THERAPY FOR NON-CANCER PAIN PATIENTS

Generally speaking, the medical literature suggests that long term opioid therapy provides little benefit to non-cancer chronic pain patients. However, there are significant risks of serious harm associated with the therapy.[6] The risks are many and varied including hyperalgesia, opioid tolerance, drug addiction or abuse, drug interaction effects, depression, anxiety, diversion for illicit use, increased occurrence of falls, motor vehicle and other accidents, death from unintentional or intentional drug overdose, and suicide, among others.

Chronic pain patients with comorbidities such as some mental illnesses, or drug or alcohol abuse are exceptionally poor candidates for long term opioid therapy because such patients tend not to

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[1] The phrase in quotation marks was taken from Dr. Li's own description of SPC patients on page 2 of his June 20, 2013, letter to Denise Gruchalla (MQAC File #2013-1135MD/LI). According to Dr. Li, it is his "role to evaluate and treat these higher risk patients in order to best serve the medical community."

[2] RCW 18.130.180(4).

[3] RCW 18.130.180(13).

[4] RCW 18.130.180(14).

[5] RCW 18.130.180(16).

[6] *See, e.g., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain* at http://www.painphysicianjournal.com/2012/july/2012;15;S1-S66.pdf and studies cited therein.

adhere to the prescribed dosage and other safety guidelines.[7] Such patients have an elevated risk of accident, such as unintentional overdose, in comparison to patients without the comorbidity.

Prescription opioid misuse is prevalent in our state. A health advisory issued in 2012 noted that:

> Washington is among those states with the highest rate of opioid-related deaths in the U.S. This now exceeds both motor-vehicle accidents and firearms as the leading cause of injury-related death. Prescribers need to be aware of the potential for deaths and life threatening side effects in patients taking methadone, morphine, fentanyl, oxycodone and other opioids. Providers need to be knowledgeable about the specific opioid's indication, dosing, pharmacology, pharmacokinetics and toxicities before prescribing these dangerous drugs.[8]

To address prescription opioid misuse, years ago several Washington state agencies enacted pain management regulations that establish standards of care.[9] The standards include guidance for opioid dosing known as the Interagency Guideline on Opioid Dosing for Non-cancer Pain[10] (Opioid Dosing Guideline), which in turn includes several recommendations to providers based in part on a report by the Centers for Disease Control.[11]

Specifically, the Opioid Dosing Guideline advises providers to,

- Use the lowest effective dose of opioid medications for acute or chronic pain only after determining that alternative therapies do not deliver adequate pain relief.

- In addition to behavioral screening and use of patient agreements, consider random, periodic, targeted urine testing[12] for opioids and other drugs for any patient less than 65 years old with non-cancer pain who has been treated with opioids for more than six weeks.

- The safety and effectiveness of opioid therapy for chronic non-cancer pain should be routinely evaluated by the prescriber.

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[7] *See* WAC 246-919-853(3)(e) regarding risk factors that should be addressed at the initial patient evaluation.

[8] *See Health Advisory: Unintentional Overdose Deaths Associated with Methadone and Other Opioids* attached as Exhibit 1 (Emphasis added).

[9] RCW 18.71.450; WAC 246-919-850 *et seq.*

[10] http://www.agencymeddirectors.wa.gov/files/opioidgdline.pdf. The AMDG, which published the dosing guidelines, consists of the medical directors from the Departments of Corrections, Social and Health Services, and Labor and Industries and the Health Care Authority. Dr. Li has written that his "formal training and practice philosophy regarding opioid prescribing for chronic non-cancer pain patients follows the WA state guidelines ... [and that he] was on the board that came up with the WA state guidelines." *See* June 20, 2013, letter from Dr. Li referenced in footnote 1 *supra.* In fact, our investigation revealed that SPC routinely provide care that contradicted guidelines pertaining to evaluation and monitoring, dosage, and urine drug testing.

[11] The full CDC report is at www.cdc.gov/HomeandRecreationalSafety/Poisoning/brief.htm.

[12] *See Opioid Dosing Guideline* (2010 Update) at pages 31-33 and algorithm at page 34.

- Assessing the effectiveness of opioid therapy should include tracking and documenting both functional improvement and pain relief.

- Patient risk substantially increases at doses at or above 100mg MED, so early attention to the 120mg MED benchmark dose is worthwhile. If a patient's dosage has increased to 120 mg MED (morphine equivalent analgesic dose) per day or more without substantial improvement in function and pain, seek a consult from a pain specialist.

IV. SPC AND ITS PRACTICES THAT RAISE QUALITY CONCERNS

Seattle Pain Center Medical Corporation (SPC) is a Washington corporation established in 2008. The company rapidly expanded from a single clinic located on Sand Point Way in Seattle.[13] It now operates seven pain clinics and one clinical laboratory in Washington. According to former employees, the company planned to open additional clinics in Washington and British Columbia. As of earlier this year, providers employed by SPC billed Washington Medicaid or Medicaid MCOs for about 5000 unique Medicaid clients. SPC has an unknown number of non-Medicaid patients although we know that its Medicare billings are approximately the same dollar amount as its Medicaid billings. SPC treats very few private insurance patients. It is no longer accredited to treat injured workers covered by the workers compensation program, because the Department of Labor and Industries declined to renew SPC's accreditation in 2013. A significant number of SPC patients pay cash.

a. SPC Providers

Dr. Li is an anesthesiologist and board certified pain specialist. He is licensed to practice in Washington and California.[14] Dr. Li is SPC's medical director and its sole shareholder. He is also the company's sole corporate officer, director, and its registered agent. Until recently, Dr. Li was the only medical doctor (MD) on the company payroll, but he personally treated few oral opioid patients. Instead, SPC used a frequently changing roster of inexperienced Advanced Registered Nurse Practitioners (ARNP), Physician Assistants (PA), and Doctors of Osteopathy (DO) at its seven Washington pain clinics.[15] Although Dr. Li is a qualified pain management specialist, most of SPC's treating providers are not.[16]

SPC has approximately 100 total employees in its seven clinics, laboratory, and corporate back office. In recent months, across its seven Washington clinics, SPC has employed approximately 9 ARNPs and 2 PAs at any one time although it experienced extraordinary provider turnover.[17] One former DO worked only six shifts before quitting. Recently, an ARNP at SPC's Spokane clinic quit in the middle of her sixth shift because no other provider or office staff appeared for work. Several ARNPs were employed for only a few weeks or months. Two other key SPC providers were unable to treat patients during much of 2014 for personal reasons.

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[13] The information summarized in this section was derived from several sources, including interviews with numerous former SPC providers, and will be made available to MQAC.

[14] Dr. Li reportedly treats patients at a Beverly Hills clinic in addition to his Washington practice.

[15] http://seattlepaincenters.com/provider/.

[16] WAC 246-919-863. For example, an ARNP requires a "minimum of three years of clinical experience in a chronic pain management care setting," as well as a credential and continuing education. WAC 246-919-863(3)(a).

[17] We can supply a table of SPC provider names and approximate dates of employment.

In order to maximize patient throughput and revenue in the face of frequent provider turnover or unavailability, SPC routinely employed freshly licensed ARNPs to treat patients before the ARNP was accredited by any insurer.[18] SPC required several months to obtain the necessary insurance accreditation for newly licensed providers. SPC providers awaiting accreditation signed into SPC's electronic medical record system using the identity of an accredited provider. Apparently the company imposed this rule to maximize revenue from payers.

In some such instances, the accredited provider indicated in the patient health record was absent from the clinic while the unaccredited provider treated the patient. In other instances, the accredited provider was treating other patients simultaneously in a nearby room. According to multiple witnesses, as of March, 2015, SPC still required newly hired, unaccredited providers to sign into the company electronic health records system using the identification and password of an accredited provider.[19]

Former SPC practitioners tell similar stories about their recruitment to the company. Recently hired ARNPs reveal that as compared to other clinical employers, SPC's hiring process was remarkably superficial; generally consisting of a single page employment application and a short Skype® interview with Dr. Li.

To encourage the provider to join the company, Dr. Li promised to build a facility or buy an expensive machine for the new provider's practice. But, inevitably after the employment contract was executed, the promised facility or machine failed to materialize and the new provider was stuck conducting medication management visits with the numerous addicts and drug seekers drawn to the SPC practice by its reputed willingness to write opioid prescriptions that other providers would not write. To assure anxious providers inexperienced in pain management, Dr. Li also promised to mentor the candidate and to see patients simultaneously with the new provider during a prolonged clinical training period. However, after signing the contract, several former providers report that they received at most a few days of training from Dr. Li before being required to see patients independently.

Most of the former providers interviewed by MFCU say that SPC's practice conditions caused them to quit out of fear for their professional license. They describe pressure from Dr. Li and SPC administrators to work fast and write prescriptions. Provider contracts included financial incentives designed to increase clinic thoughput. The company imposed time limits on patient visits that prohibited providers from conducting adequate patient history or examination or an appropriately thorough review of patient medical records.

Most providers stayed with SPC only as long as their personal economic circumstances or contractual non-compete clauses required. Virtually all of these former employees reported that Dr. Li failed to deliver on his recruitment promises. All reported a lack of infrastructure to support the wide-spread clinical operations. All reported serious concerns about a lack of

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[18] Thus bypassing the payer's provider quality control processes.

[19] An earlier example of SPC's use of new, unaccredited nurses to cover for absent accredited providers is provided in Dr. Li's June 20, 2013, response to the complaint in MQAC file #2013-1135MD/LI. In that instance, the Doctor attempted to explain why patient care was provided by someone whose name appeared nowhere in the medical record. He attributed the problem to a one-off "administrative error" which SPC subsequently corrected according to Dr. Li. In reality, according to recent witness reports, the use of unaccredited providers to treat patients without supervision remains a standard SPC practice. *See* pages 8-9 *infra*.

oversight from Dr. Li and the low quality of patient care at SPC. Many former employees report that their SPC clinic just did not "seem like other medical practices."

We have, and can provide to you, several memoranda of witness interview that include descriptions of apparent malpractice.[20]

b. SPC Patients

According to Medicaid claims data, SPC primarily treats non-cancer chronic pain patients.[21] From the Medicaid claims data supplied by the company, the patients' underlying diagnosis or original injury varies widely. On its website, SPC advertises that it offers at least seventeen different services designed to treat non-cancer pain and it specializes:

> [i]n interventional pain medicine & medication management. [SPC] takes an individual approach to pain care, from conservative treatment to the most advanced, minimally invasive procedures. [SPC's] strategies are focused on reducing pain and functional restoration of physical capacities. Emphasis is placed on maximizing mobility and reducing opioid reliance [and SPC] draw[s] from a broad base of proven treatment options.[22]

c. Typical Medicaid Patient Encounter at SPC

In reality, and in contrast to the broad based treatment advertised on its website, almost all SPC Medicaid patients receive some form of long term opioid therapy.[23] Patient medical records spanning several years of treatment reveal little or no serious attempt by many SPC providers to document functional improvement in patients on very high opioid dosages. According to Medicaid billing records, more than 85% of all SPC encounters with Medicaid patients involved opioid treatment.[24]

The overwhelming majority of SPC patient encounters are characterized as "medication management" or "prescription refill" visits. Every SPC Medicaid patient on opioid therapy visits an SPC provider at least every 90 days to obtain a 90 day supply of drugs.[25]

In the typical SPC "medication refill" office visit, a medical assistant (often an unpaid extern from a local school) pulled the available medical records and Prescription Monitoring Program data and made notations in the patient medical record. The patient provided a urine sample in a point-of-care test cup (POCT) to the medical assistant. The medical assistant interpreted and recorded the results of the POCT. The medical assistant placed the sample cup and POCT report

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[20] After reviewing one of those memoranda, which described multiple opioid overdoses occurring in SPC's Olympia clinic, HCA MQAT staff asked MFCU Investigator Triplett-Kolerich to file a complaint with DOH regulators regarding the lack of policies for dealing with overdose incidents. *See* email from Maureen Guzman attached as Exhibit 3.

[21] WAC 246-919-852(3).

[22] http://seattlepaincenters.com/.

[23] Many of these same Medicaid patients also receive injections and durable medical equipment from SPC.

[24] De-identified Medicaid claims data showing SPC's remarkably consistent billing patterns is available to MQAC. The percentage of patients on opioid therapy is has increased as SPC transitioned to serving more MCO clients.

[25] SPC providers write three thirty day prescriptions for "stable" opioid patients and post-date two of those prescriptions.

in clear bag on a table in the exam room. Per a standing order issued by Dr. Li (through early March 2015), urine samples from all seven SPC clinics were sent to the SPC lab for a standard panel of drug tests specified by Dr. Li.

Then, the patient was roomed and visited by the SPC provider for five minutes or less, just enough time to prescribe 90 days' worth of opioids. The provider documented the office visit in SPC's electronic medical record (Prognocis®), generally using a "template" descriptor provided by Dr. Li. Some medical assistants scanned incoming patient medical records into SPC's electronic patient medical records but many did not. Some medical assistants put the results of their PMP review and lab tests into the patient electronic medical record but many did not.

d. Cash Flow from Patient Urine Drug Testing Creates a Conflict-of-Interest

To maximize the government reimbursement available, in mid-2013, Dr. Li started a laboratory to conduct urine drug tests on SPC opioid patients. From February, 2014, until early March 2015, Dr. Li had in place a standing order directing that all SPC patients on opioid therapy provide a urine sample at every office visit.[26] His order required that every such urine sample be subjected to a point of care screening test and a panel of 16 laboratory tests conducted at the SPC laboratory.

Consequently, throughout 2014 about 75-80% of the company's Medicaid billings represented charges for laboratory drug testing of opioid patient urine. To illustrate, in 2014 Medicaid reimbursed SPC approximately $72 for the typical outpatient office visit and point of care test cup for each prescription refill visit. In addition, Medicaid reimbursed SPC approximately $340 for all of the laboratory urine drug tests generated by each outpatient office visit.[27] SPC charged cash-paying patients between $400-$500 for the office visit and required urine drug testing. There was a clear financial incentive to maintain high risk patients on opioid therapy to justify the recurrent laboratory urine testing.

In any event, there is little or no indication in patient health records that SPC providers regularly used the results of the urine drug tests in their provision of patient care. Results from the company's laboratory urine testing were not available to the provider until the patient's *subsequent* office visit - usually 90 days after the urine sample date. The limited patient medical records available to us reveal the absence of test requisition forms and lab test results. Generally the records fail to reveal how the laboratory test results were used in patient care.[28] According to past employees, at times SPC patients tested positive for drugs of abuse and displayed other aberrant behavior but were nonetheless allowed to continue on opioid therapy. At other times, Dr. Li arbitrarily directed SPC providers to dismiss any patients after a third aberrant test. The few patient medical records available to us include examples of both types of conduct.

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[26] In our review of the few patient medical records available to MFCU, we have noticed the existence of other standing orders from Dr. Li, including one from 2013 directing that all SPC patients on opioid therapy should be tapered back to the state "limit" of 120 MED. It appears that order was not uniformly followed, however, as many SPC patients remained on opioid dosages that were several times larger than 120 MED. These patient medical records are available for MQAT review.

[27] Medicaid does not separately reimburse physicians for writing prescriptions.

[28] WAC 246-919-857 requires a periodic review of the course of treatment including evidence of misuse, addiction or diversion.

e. A "Pill Mill"

According to Medicaid data, Dr. Li and several other SPC providers were amongst the top 10 prescribers of opioids to Medicaid clients from 2010 until the agency stopped gathering such data in 2012. Reports from multiple former SPC providers (ARNPs, MDs, and DOs from multiple clinics) described SPC as a "pill mill."

These providers report that many SPC providers routinely prescribed opioids to addicts or "drug seekers" without adequate review of the patient's medical history or records and without adequate screening to identify patients seeking drugs for other than therapeutic purposes. According to former employees, in some cases the SPC provider was experienced but negligent. In other instances, the provider was inexperienced, inadequately trained and supervised, and generally ill-equipped to treat the sort of patient recruited to the practice. Former employees report that the inexperienced ARNPs frequently employed by SPC had difficulty withstanding the pleas of determined drug seekers and often wrote prescriptions that should not have been written.

Witness interviews indicate that Seattle Pain Center is well known amongst opioid addicts and other drug seekers as an easy place to get drugs. Medicaid claims data show that many clients travel hundreds of miles to be seen by certain SPC providers known to readily prescribe opioids. One young Medicaid client, already known as drug seeker to MFCU, obtained prescriptions for a smorgasbord of opiates and tranquilizers from SPC without a referral from a general practitioner after being rejected from more reputable pain treatment facilities.

V. DEPARTMENT OF LABOR AND INDUSTRIES' MQAC COMPLAINTS

Due to quality concerns expressed by several medical reviewers, the Department of Labor and Industries refused to renew Dr. Li's provider contract for the worker compensation insurance program in 2013. The L&I medical review, which led to the non-renewal, found numerous SPC providers on its top opioid prescriber list, two serious overdoses (one fatal) involving injured workers occurring in one month in late 2012, and a handful of other problems with the care provided by SPC. L&I's reviewers found multiple instances where SPC providers maintained patients on extraordinarily large doses of opioids (> 120 MED per day) for long periods of time without evidence of functional improvement by the patient. As required by RCW 18.130.080(b)(i), L&I medical quality staff from made several reports to MQAC regarding SPC opioid treatment practices.

An illustration of the effects of SPC's use of inexperienced ARNPs to treat drug seeking patients and the widespread existence of that practice can be seen in Dr. Li's response to one of those L&I complaints.[29] Based on patient medical records and prescription data provided to L&I by Seattle Pain Center, it appeared to agency medical reviewers that Dr. Li and/or Physician Assistant Godec had mistreated the injured worker; so the agency directed a complaint to the board overseeing physicians and physician assistants.[30]

[29] MQAC cases 2013-1134 through -1136.

[30] *See* letter dated February 4, 2013, to Jim Smith from Linda Grant, RN in MQAC file #2013-1135MD/LI.

In his response to the complaint, Dr. Li wrote that, due to an "administrative error," SPC's patient medical records were incorrect. According to Dr. Li, a newly licensed ARNP actually treated the patient after PA Godec became "unexpectedly ill."[31] According to Dr. Li, due to the new ARNP's inexperience with SPC's electronic medical record software and the absence of any supervision, the ARNP made an error in the patient's methadone prescription.

More importantly after a single and very short office visit a new ARNP wrote a prescription for a very large amount of methadone to an obviously ill-suited patient.[32] That patient was an L&I client and a documented long time substance abuser. He overdosed almost immediately after filling the prescription and then spent multiple weeks in a hospital.

In a report supplied to DOH long after the incident, Dr. Li attributed the mistakes in the patient's prescription and the patient medical records to a one-off "administrative error." Dr. Li wrote that "we have corrected the process of changing the provider on the EMR." In reality, and in contrast to Dr. Li's 2013 representation to MQAC, SPC's use of newly minted ARNP's as undisclosed substitutes for absent accredited providers was (and continues to be) standard operating procedure for the company.[33]

Curiously, after describing the PA's unexpected absence and the ARNP's administrative error, Dr. Li described for the MQAC an extensive process of medical decision making and weighing of patient risks and benefits that, according to Dr. Li, lay behind the ARNP's decision to prescribe methadone on the initial patient visit. Dr. Li characterized this process as "our diagnostic workup" which resulted in "our initial impression" of the appropriate plan of care for the challenging patient.

MFCU investigators recently interviewed the ARNP involved in the December 5, 2012, overdose incident described in Dr. Li's letter of June 20, 2013. That ARNP reported that when she started working at SPC in October, 2012, Dr. Li promised that she would be able to shadow his practice for a lengthy period to learn the pain management practice. However, in reality, the ARNP spent little time with Dr. Li and a few weeks shadowing PA Godec. Her training time was cut short when PA Godec got sick in December.

On December 5, 2012, due to the unexpected absence of PA Godec, instead of seeing patients with PA Godec or Dr. Li, the ARNP saw patients on her own. Because the PA's absence was unexpected, the ARNP did not have time to prepare a workup before the office visit. Nor did she have time to review much information during the initial 25 minute office visit. The ARNP reported to MFCU that she knew nothing of any "diagnostic workup" or "initial impression" reportedly prepared by other unidentified SPC providers.[34] Nonetheless, less than six weeks

[31] *See* June 20, 2013, letter from Dr. Li in MQAC file #2013-1135MD/LI at page 4.

[32] Please *see* WAC 246-919-853 regarding the regulatory prerequisites for treating chronic non-cancer pain.

[33] *See* page 5 *supra*.

[34] Dr. Li did not examine this patient and was not involved in the ARNP's decision making process. Based on information provided to us by several witnesses, it appears that there were numerous materially misleading statements in Dr. Li's response to Complaint #2013-1135MD/LI. For example, according to multiple former

after starting work, the ARNP wrote an error-filled prescription for methadone to an extraordinarily high risk patient following a single short office visit. Not surprisingly, that patient immediately overdosed on the drug.

VI. MFCU EVIDENCE OF PATIENT INJURY RESULTING FROM UNPROFESSIONAL CONDUCT

As MFCU's false claims investigation progressed, we heard numerous anecdotal reports of drug overdoses of likely Medicaid clients from former SPC providers. About the same time we spoke to Dr. Gary Franklin, the Medical Director for the Department of Labor and Industries, and the agency's pharmacy services manager Jaymie Mai, both of whom were familiar with SPC from the L&I medical review.[35] Dr. Franklin told us that a high number of unintentional overdose deaths of Medicaid clients would be a conservative indicator of opioid prescribing problems in a pain management practice. Dr. Franklin pointed to other forms of significant patient harm, such as hospitalization for non-fatal overdose, harm caused by diversion, harm arising from the creation of new opioid dependent patients, and harm to non-Medicaid patients.[36]

However, from our perspective, the most immediately concerning evidence of widespread patient harm possible caused by SPC is the number of unintentional overdose deaths of SPC patients. Our working hypothesis for the fraud investigation has been that because SPC effectively traded opioid prescriptions for urine samples, one should expect widespread patient harm. We expected to find such evidence because SPC's business model delivered very large amounts of very dangerous drugs to the type of vulnerable Medicaid client most likely to abuse or misuse such drugs.

Because MFCU has not yet obtained many SPC patient medical records, we gathered evidence from health and law enforcement agencies pertaining to SPC patients who died of unintentional opioid overdose. To determine the number of unintentional overdose deaths associated with SPC providers, we reviewed Medicaid fee-for-service claims and managed care organization (MCO) encounter data to identify Medicaid clients who died within twelve months of an SPC service claim. We compared the identity of those clients to the DOH opioid over dose death list.[37] We

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providers, at the time of Dr. Li's statement, SPC providers did not "meet once a month to discuss difficult patients and refine prescribing guidelines" as he represented. Nor did the company "avoid cash paying patients and patients without a provider referral." In reality, all seven SPC clinics accepted cash patients and all accepted patients without referrals.

[35] In addition to serving as the Medical Director for the Department of Labor and Industries, Dr. Franklin is a neurologist and a Research Professor the University of Washington's Environmental and Occupational Health Sciences Department. Dr. Franklin is the chair of the Washington State Medical Director's Group, which published the guidelines cited in footnote 13 *supra*. He is a recognized expert in the epidemiology of opioid treatment.

[36] *See also* documents referenced in footnotes 6, 8, 10, & 11 *supra*. Dr. Franklin thought that our Medicaid overdose death evidence should concern the HCA's Medicaid quality assurance team. We have provided that HCA team with much of our information and continue to supply updates. We will make all information from the relevant interviews available to MQAC investigators along with de-identified Medicaid claims data showing SPC's billing patterns.

[37] DOH compiled the death certificate information, which was current through 2013.

then ordered autopsy, toxicology, and police reports for each Medicaid client with a recent SPC claim who was included on the opioid overdose death list.

We also ordered reports for several other overdose victims associated with SPC providers and identified by personnel at Medical Examiner's Offices or other witnesses. We reviewed Medicaid claims data and Prescription Management Program (PMP) data to determine the date that the decedent last filled a prescription written by an SPC provider.

We continue to receive information but, thus far, for the period from January, 2010, through the most recent death on 1 - Healthcar... 2015, we have identified 15 Medicaid patients who died of unintentional opioid drug overdoses within 90 days of filling a relevant prescription from an SPC provider. We reviewed the autopsy and/or toxicology reports or interviewed medical examiner's staff to confirm the cause of death for those 15 Medicaid clients. We reviewed Medicaid Provider One claims data as well as Prescription Monitoring Program records to confirm an active prescription from a SPC provider. Three of the 15 deaths occurred in 2015; the most recent death was in 1 - Healthcar... on 1 - Healthca... 2015.

In addition to the 15 unintentional overdose deaths, we identified one Medicaid client who died of a car accident likely caused by opioid intoxication and another whose cause of death was listed as heart attack, although he also had potentially fatal methadone levels in his blood.[38] We identified a third thirty-three year old Medicaid client died from the effects of chronic injection drug abuse, 13 days after filling an opioid prescription from SPC.

Although we intentionally searched only for Medicaid clients who died from unintentional opioid overdoses, we came across evidence proving Dr. Franklin's point that Medicaid client overdoses were a conservative indicator of patient harm caused by the practice. For example, we identified two L&I clients who died of unintentional overdoses within 23 days of filling a prescription from an SPC provider. There is also the hospitalized L&I injured worker who was the subject of MQAC file # 2013-1135MD/Li. In total we have identified about twelve other SPC patient deaths, outside the scope of our Medicaid focus, which may merit medical review.

Many of the medical examiners' reports for the 15 unintentional overdose deaths of Medicaid clients included family member interviews that provided some insight into the decedent's recent health. Few, if any, family members described *active* injuries or other sources of acute or chronic physical pain in their loved ones. On the other hand, almost all of the decedents were described as chronic abusers or addicts of prescription and street drugs, alcoholics, morbidly obese, or depressed people – precisely the sort of patient known to face extreme overdose risk from the long term use of opioids in high dosages.

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[38] *See* table attached as Exhibit 4 for information on these 18 decedents. MFCU can provide the patient names to MQAC. Because SPC providers routinely wrote prescriptions for a 90-day supply of opioids, the 90 day cut-off was used for this analysis. Most died within 30 days of their last prescription. However, note that many of these decedents had prescriptions from other providers too. Several died from the combined effects of opioids and some other substance.

In sum, our false claims investigation has uncovered the following conduct by Dr. Li and SPC that appears to constitute grounds for investigation by MQAC:

- A persistent shortage of qualified staff and an absence of the clinical and business infrastructure required to care for thousands of the state's "most difficult pain patients" spread across seven clinics;
- Extraordinarily frequent turnover of providers and support staff;
- Persistent daily quotas of 18-20 patients per 8 hours per provider and bonuses for additional patients, typically allowing for limited face-time and medical record review with by the provider and resulting in too little time to manage the challenging, complicated patient population recruited by Dr. Li;
- Use of unaccredited, inexperienced, and inadequately trained and supervised ARNPs to care for complex, high risk patients;
- Institutional financial pressure to prescribe opioids in order to obtain patient urine samples for lab testing;
- Prolonged oral opioid therapy at dosages greatly exceeding 120 MED without evidence of functional improvement;
- Ineffective, albeit costly, use of screening tools to identify co-morbidities, that placed patients at especially high risk of harm from long term opioid therapy;
- High opioid dosing rates (frequently *significantly* over 120 MED) based on PMP, Medicaid, L&I prescription data, and a review of several patient medical records; and
- Wide-spread and significant patient harm including the unintentional overdose opioid deaths of many Medicaid patients.

Virtually all of the evidence we have gathered is available to MQAC and staff can make arrangements with MFCU Investigator Kim Triplett-Kolerich (KimT2@atg.wa.gov) to review. Finally, please accept this complaint from the MFCU for investigation and subsequent actions you deem appropriate.

cc: Gail Kreiger, Health Care Authority
Martin Thies, Health Care Authority
MQAC, Intake Coordinator

Enclosures

EXHIBIT 1

Health Advisory: Unintentional Overdose Deaths Associated with Methadone and Other Opioids

Washington is among those states with the highest rate of opioid-related deaths in the U.S. This now exceeds both motor-vehicle accidents and firearms as the leading cause of injury-related death. Prescribers need to be aware of the potential for deaths and life threatening side effects in patients taking methadone, morphine, fentanyl, oxycodone and other opioids. Providers need to be knowledgeable about the specific opioid's indication, dosing, pharmacology, pharmacokinetics and toxicities before prescribing these dangerous drugs.

What should providers do?

- Read and follow the best practices outlined in the Agency Medical Directors' Group (AMDG) Opioid Dosing Guideline (http://www.agencymeddirectors.wa.gov/opioiddosing.asp).
- Read and follow the FDA labeling before prescribing an opioid.
- Carefully weigh the risks with potential benefits before prescribing an opioid.
- Review the new Pain Management Rules on prescribing opioids for chronic non-cancer pain.
- Access the Prescription Monitoring Program (PMP) to review your patient's controlled substances history available as of January 4, 2012.
- Closely monitor patients who receive opioids, especially during treatment initiation and dose adjustments.
- Use extreme caution in prescribing opioids in combination with sedative hypnotics or benzodiazepines.
- "Stop and take a deep breath" by seeking assistance with patients on doses of 120 mg/day or higher and when pain and function are not improving.
- Complete the 4 hours of free Category I CME available (http://www.agencymeddirectors.wa.gov/opioiddosing.asp - Click on the "CME Activities" tab)
- To prevent serious complications from methadone, providers who prescribe methadone should read and carefully follow the methadone (Dolophine) prescribing information.

The FDA has issued a public health advisory to alert patients and their caregivers and health care professionals to the following important safety information on methadone:

- **Prescribing methadone is complex.** Methadone should only be prescribed for patients with moderate to severe pain when their pain is not improved with other non-narcotic pain relievers. Pain relief from a dose of methadone lasts about 4 to 8 hours. However methadone stays in the body much longer– from 8 to 59 hours after it is taken. As a result, patients may feel the need for more pain relief before methadone is gone from the body. Methadone may build up in the body to a toxic level if it is taken too often, if the amount taken is too high, or if it is taken with certain other medicines or supplements.

- **Patients should take methadone exactly as prescribed.** Taking more methadone than prescribed can cause breathing to slow or stop and can cause death. A patient who does not experience good pain relief with the prescribed dose of methadone, should talk to his or her doctor.

- **Patients taking methadone should not start or stop taking other medicines or dietary supplements without talking to their health care provider.** Taking other medicines or dietary supplements may cause less pain relief. They may also cause a toxic buildup of methadone in the body leading to dangerous changes in breathing or heart beat that may cause death.

- **Health care professionals and patients should be aware of the signs of methadone overdose.** Signs of methadone overdose include trouble breathing or shallow breathing; extreme tiredness or sleepiness; blurred vision; inability to think, talk or walk normally; and feeling faint, dizzy or confused. If these signs occur, patients should get medical attention right away.

Please use caution when prescribing these potentially dangerous drugs and read the important safety information (attached) on long-acting opioids.

EXHIBIT 1

Important Safety Information on Long-acting Opioids:

FENTANYL

DURAGESIC contains a high concentration of a potent Schedule II opioid agonist, fentanyl. Sehedule II opioid substanees whieh include fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone have the highest potential for abuse and assoeiated risk of fatal overdose due to respiratory depression. Fentanyl can be abused and is subject to criminal diversion. The high content of fentanyl in the patches (DURAGESIC) may be a partieular target for abuse and diversion.

DURAGESIC is indicated for management of persistent, moderate to severe chronie pain that:

- requires continoous, around-the-cloek opioid administration for an extended period of time,
- and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids

DURAGESIC should ONLY be used in patients who are already reeeiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to DURAGESIC 25 meg/h. Patients who are eonsidered opioid-tolerant are those who have been taking, fur a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxyeodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesie dose of another opioid.

Because serious or life-threatening hypoventilation could occur, DURAGESIC (fentanyl transdermal system) is eontraindicated:

- in patients who are not opioid-tolerant
- in the management of acute pain or in patients who require opioid analgesia for a short period of time
- in the management of post-operative pain, including use after out-patient or day surgeries (e.g., tonsillectomies)
- in the management of mild pain
- in the management of intermittent pain (e.g., use on an as needed basis [prn]) **(See CONTRAINDICATIONS for further information.)**

Since the peak fentanyl eoneentrations generally oecur between 20 and 72 hours of treatment; preseribers should be aware that serious or life threatening hypoventilation may oceur, even in opioid-tolerant patients, during the initial application period.

The eoneomitant use of DURAGESIC with all eytoehrome P450 3A4 inhibitors (sueh as ritonavir, ketoeonazole, itraconazole, troleandomyein, clarithromyein, nelfinavir, nefazodone, amiodarone, amprenavir, aprepitant, diltiazem, erythromyein, fluconazole, fosamprenavir, grapefruit juice, and verapamil) may result in an inerease in fentanyl plasma eoneentrations, which could inerease or prolong adverse drug effeets and may eause potentially fatal respiratory depression. Patients reeeiving DURAGESIC and any CYP3A4 inhlhitor should be carefully monitored for an extended period of time and dosage adjustments should be made if warranted (see CLINICAL PHARMACOLOGY – Drug Interaetions, WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION fur further information).

The safety of DURAGESIC has not been established in children under 2 years of age. DURAGESIC should be administered to children only if they are opioid-tolerant and 2 years of age or older (see PRECAUTIONS Pediatric Use).

DURAGESIC is ONLY for use in patients who are already tolerant to opioid therapy of comparable potency. Use in non-opioid tolerant patients may lead to fatal respiratory depression. Overestimating the DURAGESIC dose when converting patients from another opioid medication ean result in fatal overdose with the first dose (see DOSAGE And ADMINISTRATON – Initial DURAGESIC Dose Selection). Due to the mean half-life of approximately 20-27 hours, patients who are thought to have had a serious adverse event, including overdose, will require monitoring and treatment for at least 24 hours.

DURAGESIC can be abused in a manner similar to other opioid agonists, legal or illieit. This risk should be considered when administering, preseribing, or dispensing DURAGESIC in situations where the healtheare professional is concerned about increased risk of misuse, abuse, or diversion.

Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients should be assessed for their clinieal risks for opioid abuse or addiction prior to being prescribed opioids. All patients reeeiving opioids should be routinely monitored for signs of misuse, abuse, and addiction. Patients at increased risk of opioid abuse may still be appropriately treated with modified-release opioid formulations; however, these patients will require intensive monitoring for signs of misuse, abuse, or addiction.

DURAGESIC patches are intended for transdermal use (on intact skin) only. Do not use a DURAGESIC patch if the pouch seal is broken or the patch is cut, damaged, or changed in any way.

Avoid exposing the DURAGESIC application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, saunas, hot tubs, and heated water beds, while wearing the system. Avoid taking hot baths or sunbathing. There is a potential for temperature-dependent increases in fentanyl released from the system resulting in possible overdose and death. Patients wearing DURAGESIC systems who develop fever or increased eore body temperature due to strenuous exertion should be monitored for opioid side effects and the DURAGESIC dose should be adjusted if necessary.

METHADONE

Deaths, cardiac and respiratory, have been reported during initiation and conversion of pain patients to methadone treatment from treatment with other npinid agonists. It is critical to understand the pharmacokinetics of methadone when converting patients from other opioids (see DOSAGE AND ADMINISTRATION). Particular vigilance is necessary during treatment initiation, during conversion from one opioid to another, and during dose titration.

Respiratory depression is the chief hazard associated with methadone hydrochloride administration. Methadone's peak respiratory depressant effects typically occur later, and persist longer than its peak analgesic effects, particularly in the early dosing period. These characteristics can contribute to cases of iatrogenic overdose, particularly during treatment initiation and dose titration.

In addition, cases of QT interval prolongation and serious arrhythmia (torsades de pointes) have been observed during treatment with methadone. Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction.

Methadone treatment for analgesic therapy in patients with acute or chronic pain should only be initiated if the potential analgesic or palliative care benefit of treatment with methadone is considered and outweighs the risks.

MORPHINE LONG-ACTING PRODUCTS

MS CONTIN contains morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Morphine can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing MS CONTIN in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

MS CONTIN Tablets are a controlled-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the clock opioid analgesic is needed for an extended period of time.

MS CONTIN Tablets are NOT intended for use as a prn analgesic.

MS CONTIN 100 and 200 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

MS CONTIN TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, DISSOLVED, OR CRUSHED. TAKING BROKEN, CHEWED, DISSOLVED, OR CRUSHED MS CONTIN TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

KADIAN contains morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. KADIAN can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing KADIAN in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

KADIAN capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

KADIAN capsules are NOT for use as a prn analgesic.

KADIAN 100 mg and 200 mg Capsules ARE FOR USE IN OPIOID PATIENTS ONLY. Ingestion of these capsules or of the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids. KADIAN CAPSULES ARE TO BE SWALLOWED WHOLE OR THE CONTENTS OF THE CAPSULES SPRINKLED ON APPLE SAUCE. THE PELLETS IN THE CAPSULES ARE NOT TO BE CHEWED, CRUSHED, OR DISSOLVED DUE TO THE RISK OF RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

AVINZA capsules are a modified-release formulation of morphine sulfate indicated for once daily administration for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time.

AVINZA CAPSULESARE TO BE SWALLOWED WHOLE OR THE CONTENTS OF THE CAPSULES SPRINKLED ON APPLESAUCE. THE CAPSULE BEADS ARE NOT TO BE CHEWED, CRUSHED, OR DISSOLVED DUE TO THE RISK OF RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

PATIENTS MUST NOT CONSUME ALCOHOLIC BEVERAGES WHILE ONAVINZA THERAPY. ADDITIONALLY, PATIENTS MUST NOT USEPRESCRIPTION OR NON-PRESCRIPTION MEDICATIONS CONTAININGALCOHOL WHILE ON AVINZA THERAPY. CONSUMPTION OF ALCOHOLWHILE TAKING AVINZA MAY RESULT IN THE RAPID RELEASE ANDABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

Oramorph SR (morphine sulfate) Sustained Release Tablets are indicated for the relief of pain in adult patients who require opioid analgesics for more than a few days.

Oramorph SR is a sustained release dosage form. Patients must be instructed to swallow the tablet whole; the tablet should not be broken in half, nor should it be crushed or chewed.

The sustained release of morphine from Oramorph SR should he taken into consideration in the event of adverse reactions or overdosage. Serious adverse reactions caused by morphine, which can be fatal, include **respiratory depression, circulatory depression, apnea, shock, and cardiac arrest.**

Oramorph SR should be used with extreme caution in any patient who may have decreased respiratory reserve. Respiratory depression is the chief hazard of all morphine preparations. Oramorph SR is contraindicated in patients with respiratory depression in the absence of resuscitative equipment, in patients with acute or severe bronchial asthma and in patients with known hypersensitivity to morphine.

Oramorph SR is also contraindicated in any patient who has or is suspected of having a paralytic ileus.

Morphine sulfate is a Schedule II controlled substance. Morphine is the most commonly cited prototype for narcotic substances that possess an addiction-forming or addiction-sustaining liability. A patient may be at risk for developing dependence to morphine if used improperly or for overly long periods of time. Oramorph SR should be used with caution in individuals with a prior history of substance abuse or dependence.

Oramorph SR should be used with extreme caution in patients with increased intracranial pressure or those with a head injury.
The clearance of morphine or its metabolites may be reduced in patients with hepatic or renal dysfunction. Pharmacodynamic changes in these patients should be considered when adjusting the dose and dosing intervals.

The depressant effects of morphine are potentiated by the presence of other CNS depressants such as alcohol, sedatives, antihistamines, or psychotropic drugs. Opioid receptor agonist/antagonist analgesics should NOT be administered to patients who have received or are receiving a course of therapy with a pure opioid agonist analgesic.

There has been no systematic evaluation of Oramorph SR as an initial opioid analgesic in the management of pain. Because it may be more difficult to titrate a patient using a sustained-release morphine, it is ordinarily advisable to begin treatment using an immediate release formulation.

OXYCODONE

IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE
See full prescribing information for complete boxed warning.

OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

OxyContin is NOT intended for use on an as-needed basis.

OxyContin 60 mg and 80 mg Tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in opioid-tolerant patients to avoid fatal respiratory depression.

Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids.

OxyContin tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved which can lead to rapid release and absorption of a potentially fatal dose of oxycodone.

The concomitant use with cytochrome P450 3A4 inhibitors such as macrolide antibiotics and protease inhibitors may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression.

OTHER LONG-ACTING OPIOID PRODUCTS

POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT SELECTION AND LIMITATIONS OF USE
See full prescribing information for complete boxed warning.

OPANA ER contains oxymorphone which is an opioid agonist and a schedule II controlled substance with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA ER is NOT intended for use as an as needed analgesic.

OPANA ER tablets are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed as this leads to rapid release absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, prescription or nonprescription medications containing alcohol. Co-ingestion of alcohol with OPANA ER may result in a potentially fatal overdose of oxymorphone.

POTENTIAL FOR ABUSE and IMPORTANCE OF PROPER PATIENT SELECTION
See full prescribing information for complete boxed warning.

BUTRANS is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.

BUTRANS contains buprenorphine which is a mu opioid partial agonist and a Schedule III controlled substance.

Assess patients for their clinical risks for opioid abuse or addiction prior to prescribing opioids.

Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation.

Avoid exposing the BUTRANS application site and surrounding area to direct external heat sources. Temperature-dependent increases in buprenorphine release from the system may result in overdose and death.

MORE INFORMATION IS ON THE INTERNET:

HCA Pharmacy Website -- *http://hrsa.dshs.wa.gov/pharmacy/*

AMDG Opioid Dosing Guidelines -- *http://www.agencymeddirectors.wa.gov/opioiddosing.asp*

FDA Website: Methadone --
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142841.htm

FDA Website: Oxycontin --
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm

FDA Website: Fentanyl --
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessianals/ucm084307.htm

FDA Website: Kadian (Morphine) --
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails

FDA Website: MS Contin (Morphine) --
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails

Physician Clinical Support System for Methadone -- *http://www.pcssprimarycare.org/*

Washington's Prescription Monitoring Program -- *http://www.wapmp.org/*

Patient education materials -- *http://here.doh.wa.gov/materials/safe-use-of-prescription-pain-medication*

EXHIBIT 2

EXHIBIT 2

NOT USED – INTENTIONALLY LEFT BLANK

EXHIBIT 3

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: "Guzman, Maureen (HCA)" <maureen.guzman@hca.wa.gov>
Date: April 23, 2015 at 2:42:53 PM PDT
To: "Triplett-Kolerich, Kim (ATG)" <KimT2@ATG.WA.GOV>
Cc: "Kreiger, Gail (HCA)" <gail.kreiger@hca.wa.gov>
Subject: RE: Interviews of Seattle Pain Center employees

4/15/15 for failure to supply records. Then she did not respond to hearing order.

Can I get a copy of her deposition?
Thanks, Maureen

PS After reviewing the deposition you previously sent me I see reasonable cause for you to report to DOH. The fact that SPS is giving intrathecal pain meds in the office and has no policy to handle overdoses is a patient safety issue; the fact that [redacted] describes 2 patient overdoses for meds administered in the office is certainly reportable.

I do not have first hand knowledge of this information but you have this in your deposition. Please report to DOH.

[redacted]

EXHIBIT 3

21A

[redacted]

EXHIBIT 4

Unintentional Overdose Deaths
Seattle Pain Center Mediciad Clients

5/7/2015

Patient Last Name	Gender	Age	County	DOB (Clnt)	DOD (Clnt)	Last Write Date	Last Fill Date	Days Between Last Fill & DOD*	5PC Prescriber Indicated on Last	Drug(s) Filled	Received Death File	Cause of Death	Synopsis
Case #1	F	33						15	TURNER	OXYCODONE HCL 10MG, MELOXICAM 15MG	Y	CHRONIC INJECTION DRUG ABUSE	FDUND IN THE BATHROOM AT VIRGINA MASON HOSPITAL WITH NEEDLE IN HER IV LINE
Case #2	F	34						3	LI		Y	ACUTE METHADONE INTOXICATION	PD CALLED LI AND HE INDICATED SHE WAS A NEW PATIENT
Case #3	M	50						5	DAWSON (CANADAY)		Y	HEART ATTACK (LARGE AMOUNT OF OPIATES FOUND IN SYSTEM PER TOXICOLOGY REPORT)	LARGE NUMBER OF DRUGS IN HIS SYSTEM - SEE TOX REPORT
Case #4	M	56						9	ITVELDT	MORPHINE SULF ER 30MG, HYDROMORPHONE 4 MG	Y	COMBINED DRUG TOXICITY (SIMULTANEOUS USE OF MORPHINE, CYCLOBENZAPRINE AND AMANTADINE	FOUND DEAD ON KITCHEN FLOOR
Case #5	M	60						79	GODEC		Y	ACUTE METHADONE INTOXICATION	VOMITING DURING THE DAY; FOUND DEAD IN RECLINER
Case #6	F	42						52	DAWSON (CANADAY)		Y	ACUTE COMBINED OPIATE MORPHINE, DIPHENDYDRAMINE, CITALOPRAM INTOXICATION	FOUND AT HOME IN BED
Case #7	F	46						21	GODEC		Y	EFFECTS OF METHADONE, HYDROMORPHONE, NORTRITYLINE AND CITALOPRAM	FOUND DEAD IN RECLINER IN LIVING ROOM BY BROTHER
Case #8	F	59						1	GODEC			EFFECTS OF MORPHINE, OXYCODONE, DIAZEPAM, TRAZODONE AND GABAPENTIN	FOUND IN BED BY HUSBAND
Case #9	M	45	1 - Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70....					1	ITVELDT	HYDROCODONE ACETAMINOPHEN 10-325	Y	ACUTE DRUG TOXICITY DUE TO SIMULTANEOUS USE OF METHADONE AND HYDROCODONE	FOUND UNRESPONSIVE IN HIS BED BY WIFE
Case #10	F	58						0	WEINBERG		Y	EFFECTS OF METHADONE, HYDROCODONE, TRAMADOL AND TRAZADONE	WELFARE CHECK BY DAUGHTER - DEAD ON BATHROOM FLOOR
Case #11	F	54						32	LI	SULFENTANIL CITRATE POWDER	Y	ADDITIVE DRUG EFFECTS (CARISOPRODOL AND HYDROCODONE)	CAREGIVER COULDN'T REACH HER AND CALLED 911; LIVING RM FLR; PAIN PUMP (SPC); MJ AND SELLING RX'S
Case #12	M	62						15	MCGHEE	MORPHINE SULF ER 30MG, METHADONE HCL 10MG	Y	BRONCHOPNEUMONIA & ACUTE OPIATE INTOXICATION	WIFE FOUND HIS BODY IN THE BATHROOM OF THEIR HOME
Case #13	M	36						2	LI		Y	METHADONE, CITALOPRAM, TRAZODONE AND VALPROIC	LI WROTE LAST RX; FOUND HIM UNRESPONSIVE IN BED; INJECTION BY LI 07/08/2011
Case #14	M	51						4	WISE		Y	HYDROMORPHONE, METHADONE INTOXICATION AND BRONCHOPNEUMONIA	FOUND DEAD IN HIS HOME (NOT UNCOMMON FOR HIM TO PASSOUT AROUND THE HOUSE)
Case #15	F	27						34	LI		Y	ACUTE METHADONE INTOXICATION	SLEEPING WITH BOYFRIEND; 4A DIDN'T HEAR SNORING, DEAD
Case #16	M	55						27	CANADAY			CAR ACCIDENT CAUSED BY INTOXICATION	NEED TOX REPORT
Case #17	M	55						10	ITVELDT		Y	STROKE AND ACUTE DRUG INTOXICATION	DIED AT FRIEND'S HOUSE
Case #18	M	35						42	MCGHEE		PARTIAL	**LIKELY MULTI-DRUG TOXICITY**	FOUND DEAD IN HIS BEDROOM BY HIS GIRLFRIEND

<=31 DAYS BETWEEN LAST FILL & DOD
31-60 DAYS BETWEEN LAST FILL & DOD
61-90 DAYS BETWEEN LAST FILL & DOD
>90 DAYS BETWEEN LAST FILL AND DOD

Exhibit 4

Open Case MD_2015-4708_PDF-r.pdf redacted on: 7/15/2016 14:09

Redaction Summary (4 redactions)

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1 Privilege / Exemption reason used:

1 -- "Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1)" (4 instances)

Redacted pages:

Page 11, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 3 instances
Page 25, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 1 instance