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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MICHELE ALLEGRA GOMEZ, M.D.** **Family Care Associates** **1720 El Camino Real, Suite 165** **Burlingame, CA 94010-3200** **Physician's and Surgeon's Certificate No. A 77883,** Respondent.	Case No. 800-2019-054399 **A C C U S A T I O N**

PARTIES

1. William Prasifka (Complainant) brings this Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On February 6, 2002, the Board issued Physician's and Surgeon's Certificate Number A 77883 to Michele Allegra Gomez, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on February 29, 2024, unless renewed.

3. At all times during the allegations herein, Respondent was a family practice physician in a California practice.

JURISDICTION

4. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 2001.1 of the Code provides that the Board's highest priority shall be public protection.

6. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Board deems proper.

7. Section 2234 of the Code, states, in pertinent part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
>
> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
>
> (b) Gross negligence.
>
> (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
>
> (1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.
>
> (2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

8. Section 2266 of the Code states: The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

COST RECOVERY

9. Section 125.3 of the Code states:

(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) In the case of a disciplined licensee that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licensee to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g) (1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licensee who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licensee who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

PERTINENT DRUGS

10. **Opiate** or opioid analgesics are a class of drugs that provide relief for pain. The particular opiate drugs described below are Schedule II controlled substances as defined by section 11055 of the Health and Safety Code and the federal controlled substances schedule. Opiates can produce drug dependence, alter mental function, and cause respiratory depression. They have potential for being abused and can cause injury or death via unintentional overdose. Use of multiple opiates compounds these risks and increases the chance of overdose. Physicians must carefully monitor patients who are prescribed opiates. There are many types of opiate drugs that vary in strength. Some of the opiate drugs include:

- *Morphine*: An opiate for use in patients who require a potent opiate analgesic for relief of moderate to severe pain. When calculating the total daily dosage of opiates a patient is taking, morphine is used as a baseline, and other opiate drugs are calculated at a conversion factor to their morphine equivalency. This is referred to as the Morphine Equivalent Daily Dose (MEDD).

- *Fentanyl*: An extremely powerful opiate that that is much stronger than morphine with a high potential for addiction. Its strength makes it one of the riskiest opiates for unintentional lethal overdose. It is among the most powerful opiates available for prescription to humans. Unlike other commonly prescribed opiates, fentanyl is delivered via a transdermal patch, in an effort to control its delivery.

- *Methadone*: A strong opiate, with a notable property that makes it more likely to cause irregular heart rhythms. Methadone is significantly more powerful than morphine. Methadone is fast acting, but also has a long elimination half-life. This long half-life is one of the reasons methadone is particularly associated with overdose deaths, and should only be used after safer opiates have failed.

- *Hydromorphone* (trade name Dilaudid): An opiate analgesic significantly more powerful than morphine.

- *Oxycodone* (trade name Oxycontin): An opiate analgesic, somewhat more powerful than morphine.

- *Hydrocodone/acetaminophen* (trade name Norco or Vicodin): A drug that combines hydrocodone bitartrate which is an opiate analgesic with acetaminophen (i.e., Tylenol) which is a non-opiate analgesic. It is used to treat symptoms of moderate to severe pain. It is similar in strength to morphine.

11. **Benzodiazepines** are a class of depressant drugs. They are central nervous system depressants often prescribed for the management of anxiety disorders. The particular benzodiazepine drugs described below are Schedule IV controlled substances as defined by section 11057, subdivision (d) of the Health and Safety Code and the federal controlled substances schedule. They can produce psychological and physical dependence and should be prescribed with caution, particularly to addiction-prone individuals because of the predisposition of such patients to habituation and dependence. Combining benzodiazepines with opiates can put a patient at greater risk for overdose. Two of the types of benzodiazepine drugs are:

- Clonazepam (trade name Klonopin): A powerful benzodiazepine.
- Diazepam (trade name Valium): Another benzodiazepine. It is not as strong as clonazepam, but still has the dangerous and addictive features of benzodiazepines.

12. **Zolpidem tartrate** (trade name Ambien) is a non-benzodiazepine sedative hypnotic drug. It is a Schedule IV controlled substance as defined by section 11057, subdivision (d) of the Health and Safety Code and the federal controlled substances schedule. It is indicated for the treatment of insomnia if safer alternatives do not work. Zolpidem increases the risk of respiratory depression, sleep walking, loss of coordination, daytime sleepiness, and addiction. It is a central nervous system depressant and should be used cautiously in combination with other central nervous system depressants. Any central nervous system depressant could potentially enhance the CNS depressive effects of Ambien. Because of the risk of habituation and dependence, individuals with a history of addiction to or abuse of drugs or alcohol should be carefully monitored while receiving this drug.

13. **Carisprodol**, also known by the trade name Soma, is a powerful muscle relaxant. It has been abused for its sedative and relaxant effects. It is a Schedule IV controlled substance as defined by the federal controlled substances schedule. Since the effects of carisoprodol and

alcohol or carisoprodol and other central nervous system depressants or psychotropic drugs may be addictive, appropriate caution should be exercised with patients who take more than one of these drugs simultaneously.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct re: Patient A[1]: Gross Negligence, Repeated Negligent Acts, Inadequate Medical Recordkeeping)

14. Respondent Michele Allegra Gomez, M.D. is subject to disciplinary action for unprofessional conduct through her acts and omissions regarding Patient A under section 2234 subd. (a) [violation of Medical Practice Act]; and/or section 2234 subd. (b) [gross negligence]; and/or section 2234 subd. (c) [repeated negligent acts]; and/or section 2266 [inadequate medical recordkeeping] of the Code. The circumstances are as follows:

15. Paragraphs 10-13 are included in this disciplinary cause as if set forth herein.

16. From June 2015 to August 2019, Respondent treated Patient A, an older adult female patient. Patient A's medical ailments included chronic pain arising from severe degenerative hip joint arthritis and pulmonary issues. She was not a candidate for surgical intervention due to severe obesity. Patient A also had chronic obstructive lung disease, sleep apnea, and a variety of other medical illnesses.

17. At various times during her treatment of Patient A from June 2015 to August 2019, Respondent prescribed opiates—methadone and oxycodone. Both are controlled substances prone to dependence that can result in abuse and accidental overdose.

18. Multiple times in the records, Respondent states that she prescribed both methadone and oxycodone in order to accommodate Patient A's insurance coverage issues. Respondent stated that Patient A said she only had coverage for oxycodone for part of the year, and that she could not afford to self-pay for oxycodone. Respondent stated that when Patient A did not have coverage for oxycodone, Patient A would receive methadone, a cheaper medication for which

[1] The patients in this matter are referred to by pseudonym. Respondent is aware of their identities.

Patient A could self-pay. Respondent instructed Patient A multiple time not to take both methadone and oxycodone together.

19. However, according to CURES[2], between June 2015 and August 2019 there were 13 occasions when Patient A filled prescriptions of oxycodone and methadone within around two weeks of each other—several of those times were within a few days of each other, and one time was on the same day. These are described below.

- In August 2015, Patient A filled within three days of each other a 23-day methadone prescription (August 8, prescription from another provider in Respondent's office) and a 30-day oxycodone prescription (August 11, prescription from Respondent).
- In October 2015, Patient A filled within one day of each other (October 6 and October 7), a 30-day prescription for oxycodone and a 13-day prescription for methadone—both prescribed by Respondent.
- In November 2015, Patient A filled prescriptions for 23-days of methadone and 30-days of oxycodone within one day of each other (November 3 and November 4). Both were prescribed by Respondent.
- On June 30, 2016, Patient A filled a 30-day oxycodone prescription only eight days after she filled a 30-day methadone prescription (June 22, 2016). The oxycodone was prescribed by Respondent and the methadone was prescribed by another provider in Respondent's office.
- On September 9, 2016, Patient A filled a 30-day prescription for methadone. This was approximately two weeks after Patient A had already filled one of Respondent's 30-day oxycodone prescriptions (August 25), and approximately two weeks before Patient A would fill another one of Respondent's 30-day oxycodone prescriptions (September 20). All three prescriptions were from Respondent.
- On November 12, 2016, Patient A filled a 30-day prescription for methadone, five days before Patient A would fill a 30-day oxycodone prescription (November 17).

[2] The Controlled Substance Utilization Review and Evaluation System (CURES) is a database of certain controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement.

Respondent prescribed the oxycodone, and another provider in Respondent's office prescribed the methadone.

- Patient A filled a methadone prescription, prescribed by another provider in Respondent's office, on March 14, 2017. But only six days later, on March 20, 2017, Patient A filled a prescription from Respondent for a 30-day supply of oxycodone.
- On June 16, 2017, Patient A filled a 30-day methadone prescription from another provider in Respondent's office. Just two weeks after that (June 30), Patient A filled a 30-day prescription for oxycodone from Respondent.
- Within two days of each other (November 28 and November 30, 2017), Patient A filled 30-day prescriptions for methadone and oxycodone. The methadone was prescribed by another provider in Respondent's office, and the oxycodone was prescribed by Respondent.
- On March 9, 2018, Patient A filled a 30-day methadone prescription prescribed by another provider in Respondent's office. Eleven days later (March 20, 2018), Patient A filled a 30-day oxycodone prescription prescribed by another provider in Respondent's office.
- On September 11, 2018, Patient A filled 30-day prescriptions for both methadone and oxycodone on the same day. Both were prescribed by Respondent.
- On April 14, 2019, Patient A filled a 30-day prescription for methadone only three days after she filled a 30-day prescription for oxycodone (April 11, 2019). The methadone was prescribed by another provider in Respondent's office, and the oxycodone was prescribed by Respondent.
- Respondent treated Patient A on May 16, 2019 and noted that Patient A had recently gotten methadone because Patient A could not get oxycodone at that time. Patient A's most recent filling of a methadone prescription before that May 16, 2019 encounter was April 14, 2019 (a 30-day prescription, prescribed by another provider in Respondent's office). But the CURES report shows that Patient A filled an

oxycodone prescription just three days before she filled the April 14, 2019 methadone prescription. The oxycodone was prescribed by Respondent.

20. For much of this treatment time, both methadone and oxycodone were documented on Patient A's list of current outpatient prescriptions. There is no indication in the record that Respondent engaged with Patient A about why she was frequently filling prescriptions for methadone and oxycodone near in time to each other.

21. Throughout her treatment of Patient A from June 2015 to August 2019, in addition to her oxycodone and methadone prescribing, Respondent consistently prescribed hydrocodone.

22. Respondent prescribed high opiate dosages to Patient A.

23. Respondent did not properly perform an objective risk assessment of the patient's opiate addiction potential during her chronic pain management of Patient A.

24. As described above, there were multiple instances where Patient A was filling prescriptions for both methadone and oxycodone at near the same time. The prescriptions came from both Respondent and other providers in her practice. Methadone and oxycodone are both highly potent and long-acting opiates—both are very susceptible to abuse and accidental overdose, and prescribing both together was not advisable. Methadone, with its long half-life, is particularly dangerous and associated with many overdose deaths. Moreover, Patient A's behavior should have prompted Respondent to discuss strict compliance with Respondent's prescribing instructions, which included not taking methadone and oxycodone at the same time. This behavior also should have compelled Respondent to perform more frequent urine toxicology testing to monitor for diversion behaviors. Respondent also should have done appropriate CURES checks that would have identified Patient A as sometimes filling both methadone and oxycodone prescriptions close in time to each other. Patient A was unnecessarily exposed to the potential overdose toxicities of two highly potent and long-acting opiates. And Patient A in particular—with her comorbidities of obstructive lung disease and sleep apnea—was particularly exposed to the dangers of these two drugs.

25. The dangers of prescribing both oxycodone and methadone was not limited to just the times when Patient A was taking both at the same time. Alternating these two opiates exposed

Patient A exponentially to additional risks of accidental overdose because of their unique pharmacokinetics and rapid loss of opiate tolerance.

26. Because of their potential adverse health side effects of increasing risks of falls, fractures, cognitive impairments, depression, and traffic accidents, long-term opiate therapy is not generally recommended for the elderly population.

27. Respondent's medical record documentation of opiate monitoring was insufficient. There was hardly any detailed musculoskeletal or hip examination, and the physical findings did not justify prescribing the excessive opiate dosage. The medical record often lacked analysis of analgesic effects, adverse side effects, functional benefits, and personal affect. Without this information, it was unclear if Patient A truly benefitted from the opiates prescribed. Instead, it appears that Respondent automatically renewed the opiate prescriptions without any serious consideration of tapering.

28. Respondent did not have from Patient A a signed pain care agreement for opiate treatment.

29. Respondent is guilty of unprofessional conduct and Respondent's certificate is subject to discipline pursuant to section 2234 subd. (a) and/or section 2234 subd. (b) and/or section 2234 subd. (c) and/or section 2266 of the Code based upon gross negligence and/or repeated negligent acts and/or failure to maintain adequate records, including but not limited to the following:

a. Failing to have a formal opiate risk stratification for Patient A;

b. Failing to discuss with Patient A about receiving extra refills of methadone and/or oxycodone from other providers in her practice;

c. Failing to discuss with Patient A about receiving methadone and oxycodone refills at nearly the same time, despite the instruction to not consume methadone and oxycodone at the same time;

d. Failing to perform routine urine toxicology testing to monitor for diversions;

e. Failing to perform regular CURES queries in this patient on high dosage opiates or to identify the instances of methadone and oxycodone being filled within a short time from each other;

f. Prescribing high dose oxycodone with intermittent methadone therapy in an elderly patient with severe lung diseases and exposing Patient 1 to adverse side effects of opiate therapy;

g. Inadequately documenting physical examinations and opiate side effects during clinical monitoring.

h. Failing to safely and adequately monitor long-term opiate therapy.

i. Failing to have a signed pain care agreement and informed consent for opiate treatment.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct re: Patient B[3]: Gross Negligence, Repeated Negligent Acts, Inadequate Medical Recordkeeping)

30. Respondent Michele Allegra Gomez, M.D. is subject to disciplinary action for unprofessional conduct through her acts and omissions regarding Patient B under section 2234 subd. (a) [violation of Medical Practice Act]; and/or section 2234 subd. (b) [gross negligence] and/or subd. (c) [repeated negligent acts] and/or under section 2266 [inadequate medical recordkeeping] of the Code. The circumstances are as follows:

31. Paragraphs 10-28 are included in this disciplinary cause as if set forth herein.

32. From February 2016 to October 2018, Respondent treated Patient B, a young adult female patient.

33. Patient B began seeing Respondent on February 8, 2016. At this encounter, Patient B's complaints included chronic low back pain and insomnia. Patient B reported very occasional illicit drug use, and denied regular use or interference with work or relationships. Patient B reported that she had tried other pain relief methods in the past, and that oxycodone worked best.

34. During this initial visit, Respondent did not perform an adequate physical examination of Patient B's spine and its range of motion limitations. Respondent also failed to consider orthopedics for surgical evaluation as part of the diagnostic evaluation. At this encounter, Respondent did not propose a trial of safer non-opiate medication before proceeding

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with opiate medication—oxycodone. Safer and non-addictive medication, such as NSAIDs[4] other than ibuprofen or nabumetone, muscle relaxants other than baclofen, higher dosages of gabapentin than the prescribed 300 mg daily, pregabalin, SSRIs, tricyclic medications, and acetaminophen. Respondent acquiesced to Patient B's claim that oxycodone was the medication that helped the most to relieve her pain. Respondent prescribed a 30-day supply of oxycodone, 5 mg per day at bedtime for pain. She also prescribed nabumetone, an NSAID stronger than ibuprofen.

35. At this initial encounter with Patient B, Respondent also treated the insomnia complaint by prescribing 30 5-mg tablets of zolpidem (i.e., Ambien) for occasional use. Zopidem, a non-benzodiazepine hypnotic sedative, carries potentially dangerous risks, including respiratory depression, sleep walking, loss of coordination, daytime sleepiness, and addiction. Respondent reminded Patient B not to combine zolpidem with the oxycodone. This combination of opiates and zolpidem would clearly expose Patient B to risk of accidental overdose. But Respondent did not first try safer over-the-counter sleeping medications like melatonin or antihistamines before resorting to long-term zolpidem therapy. Respondent failed to perform a thorough assessment of Patient B's insomnia before prescribing zolpidem. Throughout her treatment of Patient B Respondent continued to occasionally prescribe zolpidem.

36. The oxycodone was rapidly escalated. Just two days after the initial prescription (February 10, 2016), Patient B reported that it was not helping, and the medication was increased to 10 mg per day. Twelve days later (February 22, 2016), Patient B reported that she was still not getting any help from the oxycodone at 10 mg per day, and so on her own had increased the prescription to 20 mg per day. Respondent then prescribed 20 mg per day. Just 21 days after the initial encounter with Respondent (February 29, 2016), Patient B filled an oxycodone prescription from Respondent at a 16-times higher dosage. The original February 8, 2016 prescription was for one 5-mg tablet per day, and the February 29, 2016 prescription was for four 20-mg tablets per day. In March 2016, Patient B filled two more oxycodone prescriptions from Respondent at this

[4] NSAIDs, or Non-Steroid Anti-inflammatory Drugs, are lower risk non-opiate pain relief medications.

same rate. A few times in March 2016, Respondent advised Patient B to only take 40 mg per day, but the patient had increased to 60 mg per day on some days.

37. On April 14, 2016, Patient B had an encounter with another provider in Respondent's office. Patient B reported that her medication had been stolen and sought an early refill. Patient B also reported that she took some of another person's pain medication—Patient B said the tablets were "blue" and she was not sure what they were. The other provider ordered a urine toxicology screen, which was positive for illicit drug use.

38. On April 21, 2016, Respondent had an encounter with Patient B. Respondent extensively discussed the importance of following the rules with opiate prescribing and had a long conversation regarding following the rules in order to keep receiving opiate medication. Patient B agreed to follow the rules, and Respondent prescribed a 30-day supply of four 20-mg oxycodone tablets per day—at this point, 80 mg of oxycodone per day. Patient B's next three urine toxicology screens (April 21, 2016 , May 19, 2016, and November 11, 2018) were negative for illicit drug use.

39. Seventeen days later, on May 8, 2016, and just over halfway through the 30-day prescription filled on April 21, 2016, Patient B filled a much stronger prescription from Respondent for a 12-day supply of 30 mg of oxycodone, five times a day. This was another quick escalation. This new prescription was 150 mg of oxycodone per day—nearly double the amount in just over two weeks. Respondent issued more oxycodone prescriptions at this level, until July 28, 2016, when Patient B complained about pain. Respondent again increased the prescription, now at 30 mg of oxycodone, seven times a day. This totaled 210 mg of oxycodone per day, another strong increase. Patient B continued to fill prescription at this strength.

40. On November 3, 2016, Patient B had another encounter with Respondent. Patient B said her pain control was more functional on pain medication, but could be better, so she asked for another tablet per day. Respondent agreed and prescribed eight 30 mg tablets per day, or 240 mg of oxycodone per day. Patient B continued to fill prescription at this strength.

41. Respondent had an encounter with Patient B on June 26, 2017. Respondent noted that Patient B was waiting far too long in between appointments. Patient B reported that the pain

was very bad on some days and she wanted some more pain medication. Respondent agreed and prescribed nine tablets per day, or 270 mg of oxycodone per day. The medical record for this encounter states that Patient B was a self-pay patient now without insurance. Respondent told Patient B she needed to take a urine toxicology screen this day, and Patient B said that urine toxicology screens had cost her more than $100 in the past. Patient B said nothing but her pain medication would show up. She also said that she used something from a family member and could not remember what it was called, but it was for back pain and thought it would be the same. Respondent collected a urine sample and tried to process it through a private lab, but the lab would not process results for the patient because the patient was in arrears on her account. Respondent decided to forego urine toxicology because of the excessive cost to the patient and discarded the sample. Patient B continued to fill the oxycodone prescription at 270 mg per day.

42. Respondent had an encounter with Patient B was September 18, 2017. Patient B was agreeable to a urine toxicology screen, but it was deferred, with Respondent stating that she did not have strong concerns about the patient, and cost was an issue. Patient B continued to fill the oxycodone prescription at 270 mg per day.

43. On July 16, 2018, Patient B had an encounter with another practitioner at Respondent's office. That practitioner ordered a urine toxicology screen, which came back positive for illicit drug use. This was the second urine toxicology screen positive for illicit drug use, with some negative tests in between. Attempts to taper Patient B off oxycodone began after this positive test.

44. Patient B's social factors, including young age and illicit drug use, pointed toward a high risk of opiate addiction. But in less than one month, Patient B's filled prescriptions from Respondent went from 5 mg oxycodone per day to 80 mg oxycodone per day. Four months after the initial encounter, the dosage was up to 150 mg per day, and by the end of the year it was up to 240 mg a day. It eventually got up to 270 mg a day. This fast escalation of opiate dosage was clearly a sign of opiate addiction. Patient B exhibited a pattern of addictive behaviors, including using another person's pain medication, using illicit drugs, and reporting lost medication.

Respondent should have recognized Patient B's addiction pattern, tapered the medication far earlier than she did, and referred her for drug detoxification.

45. Respondent's medical record documentation of opiate monitoring was insufficient. There was no focused spine examination of her back, including a range of motion examination. The records often lacked analysis of pain management, including adverse side effects, functional benefits, and personal affect.

46. The combination of zolpidem with high-dosage oxycodone exposed Patient B to real risk of accidental overdose.

47. Respondent did not have a signed pain agreement with Patient B.

48. Respondent is guilty of unprofessional conduct and Respondent's certificate is subject to discipline pursuant to section 2234 subd. (b) and/or section 2234 subd. (c) and/or section 2266 of the Code based upon gross negligence and/or repeated negligent acts and/or inadequate medical recordkeeping, including but not limited to the following:

a. At the initial visit with Patient B, failing to perform an adequate physical examination of Patient B's spine and range of motion limitations.

b. At the initial visit with Patient B, failing to consider orthopedics for surgical evaluation as part of the diagnostic evaluation.

c. Failing to trial safer non-opiate medication.

d. Respondent failed to perform proper opiate risk stratification.

e. Respondent chose oxycodone as an initial opiate medication.

f. Respondent rapidly escalated daily oxycodone dosage within the first 30 days of opiate therapy, and continued to escalate the daily dosage over the course of treatment.

g. Respondent failed to recognize Patient B's addictive behaviors.

h. Respondent failed to timely taper down Patient B's oxycodone usage and refer Patient B to detoxification.

i. Respondent inadequately documented relevant findings from physical examinations of Patient B.

j. Failing to safely and adequately initiate and monitor long-term opiate therapy.

k. Failing to perform a thorough assessment of Patient B's insomnia before prescribing zolpidem.

l. Failing to try safer over-the-counter sleeping medications before resorting to long-term zolpidem medication.

m. Causing potentially unnecessary exposure to the risks associated with combining oxycodone and zolpidem.

n. Failing to have a signed pain care agreement for opiate treatment.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct re: Patient C: Gross Negligence, Repeated Negligent Acts, Inadequate Medical Recordkeeping)

49. Respondent Michele Allegra Gomez, M.D. is subject to disciplinary action for unprofessional conduct through her acts and omissions regarding Patient C under section 2234 subd. (a) [violation of Medical Practice Act]; and/or section 2234 subd. (b) [gross negligence] and/or subd. (c) [repeated negligent acts] and/or under section 2266 [inadequate medical recordkeeping] of the Code. The circumstances are as follows:

50. Paragraphs 10-48 are included in this disciplinary cause as if set forth herein.

51. Respondent treated Patient C, a middle-aged female patient, for many years, including from May 2015 to June 2018. On May 14, 2015, Respondent was prescribing opiate pain medication for a diagnosis of chronic pain syndrome. The opiate prescription included 600 mg per day of extended release morphine and 180 mg per day of immediate release morphine. The medical record stated that Patient C had a history of illicit drug abuse and opiate dependence. Patient C also had an anxiety diagnosis, and Respondent was prescribing the benzodiazepine clonazepam at 4 mg per day. Aside from chronic pain syndrome and anxiety, Patient C also had a chronic obstructive pulmonary disease (COPD) diagnosis that Respondent was treating.

52. Respondent continued prescribing these medications for multiple years. This was a large amount of opiates prescribed by Respondent. Moreover, the opiates were contemporaneously prescribed with a strong benzodiazepine. Both opiates and benzodiazepines

are central nervous depressants that can cause accidental overdose. Prescribing both at the same time makes the risk even higher.

53. On December 7, 2017, Respondent noted that Patient C had received opiate medications (hydrocodone) from her podiatrist that was treating Patient C's foot issue. Patient C reported taking a few extra pain pills when she was not supposed to. Patient C reported that back pain made tasks difficult. At this appointment, Patient C reported that she was out of medication for a couple of days, and did not think she could provide a urine toxicology sample because she had already urinated. Respondent deferred the urine toxicology screen and refilled the pain medication two days early, reminding Patient C that she needed to call if there were pain increases and not take more pills than prescribed. Respondent noted that pain control was less effective now, and noted that she would consider adding a fentanyl patch after doing calculations and calling Patient C to discuss. Fentanyl is a powerful opiate.

54. Respondent decided to add the fentanyl patch to Patient C's medication, and on December 27, 2017, Patient C filled a fentanyl patch prescription (a 25 mcg/hour patch lasting three days). Respondent's records state that now with fentanyl in use, the goal was for Patient C to start using half as much immediate-release morphine as she was before, but Patient C reported she was back up to the full amount of immediate-release morphine and still had no change in pain. Respondent continued to prescribe the full amount of immediate-release morphine (180 mg/day), along with the extended-release morphine and the fentanyl patch.

55. On January 4, 2018, Patient C had an encounter with Respondent. Patient C reported that there was no change in severe pain when the fentanyl patch was added, and Respondent prescribed a second fentanyl patch. Respondent instructed Patient C to decrease the immediate-release morphine when adding the second patch. But Respondent continued to prescribe the same amount of morphine (extended-release and immediate-release), along with two-at-a-time fentanyl patches. The morphine prescriptions were filled two days early at this encounter. At this encounter, Patient C also gave a urine sample for toxicology screening.

56. The January 4, 2018 urine sample from Patient C came back positive for illicit drug use. However, Respondent continued to prescribe fentanyl, morphine, and clonazepam at the same rate.

57. Respondent said there would be continued urine toxicology testing. There were positive illicit drug tests on March 1 and March 30, and a negative illicit drug test on April 3. Patient C's fentanyl refill was due on April 8, but because of the positive urine toxicology screen, Respondent's office did not fill the prescription. However, on April 19, 2018 and in light of Patient C's negative test on April 3, Respondent refilled the fentanyl, instructing Respondent that she must test negative weekly otherwise opiates would be discontinued. A few months later, on June 19, 2018, Patient C's urine toxicology screen had a suspicious result—no illicit drug use or prescribed medication (i.e. opiates or benzodiazepines) use. This was not consistent with the urine of a patient who is regularly taking prescribed opiates and benzodiazepines. Respondent noted that she could no longer prescribe medication.

58. Respondent prescribed a high amount of opiates to Patient C and failed to adequately try safer non-addictive medication, such as additional NSAIDS other than ibuprofen, pregabalin, muscle relaxants, and over the counter glucosamine/chondroitin.

59. Patient C had elevated risk factors for opioid addiction, a history of including tobacco use disorder, anxiety, and illicit drug use.

60. During the period from May 1, 2015 to June 1, 2018, Respondent prescribed Patient C excessive amounts of opiate medication—around 700-800 morphine equivalents per day. This went even higher (more than 800 morphine equivalents per day) when Respondent added 25 mcg/hour of fentanyl, which Respondent quickly increased to 50 mcg/hour. This excessive amount increased the risk of accidental overdose. But despite this excessive dosage, Patient C's chronic pain syndrome was clearly not well maintained. Patient C's persistent pains were likely caused by opioid-induced hyperalgesia syndrome, a paradoxical increase in pains in response to long-term opiate therapy. The appropriate response would have been opiate tapering. Respondent's prescribing exposed Patient C to unnecessary increased risks of respiratory failure and overdo age—risks magnified by Patient C's chronic obstructive lung disease.

61. Respondent's medical record documentation of opiate monitoring was insufficient. It did not regularly include relevant physical examinations of painful shoulders, knees, and wrists. The records failed to regularly include information regarding the opiate treatment, including analgesia, adverse side effects, functional activities, and affect. This detailed review of symptoms was vital to safe monitoring of long-term opiate therapy.

62. Throughout the time Respondent prescribed morphine, Respondent also prescribed benzodiazepine medication—specifically clonazepam, one of the strongest benzodiazepines available. Benzodiazepines have serious risks of dependency, tolerance, abuse, amnesia, and withdrawal symptoms. Patient C was addicted and dependent on benzodiazepines due to her long-term use for many years, and when treating Patient C's anxiety, Respondent did not attempt to use a different, less-risky medication to replace the benzodiazepines.

63. Benzodiazepines are risky on their own. And when combined with opiates, that risk is heightened. Both benzodiazepines and opiates can cause central nervous system depression and can decrease respiratory drive. Using both benzodiazepines and opiates at the same time puts patients at greater risk for potentially fatal overdose, compared with opiate prescription alone. For the past several years, the FDA has had a black box warning regarding the dangerous risks of combining opiates and benzodiazepines. Clinicians should strongly avoid prescribing both opiates and benzodiazepines at the same time, as the risks outweigh the benefits. Patient C had this increased risk of accidental fatal overdose due to the combination of high dosage opiates and benzodiazepines. Patient C's respiratory failure risks were only magnified by her chronic obstructive lung disease. There was no clear indication for this combination of medications, and Respondent should have tried to taper Patient C off of either of the medications to mitigate their toxicity.

64. Respondent did not have a signed pain agreement and informed consent with Patient C, despite the high addiction risks for opiate therapy.

65. Respondent is guilty of unprofessional conduct and Respondent's certificate is subject to discipline pursuant to section 2234 subd. (a) and/or section 2234 subd. (b) and/or section 2234

subd. (c) and/or section 2266 of the Code based upon gross negligence and/or repeated negligent acts and/or inadequate medical recordkeeping, including but not limited to the following:

a. Failing to adequately try safer non-addictive pain medication.

b. Failing to adequately monitor long-term opiate therapy.

c. Failing to have properly risk stratification for opiate pain medication.

d. Failing to recognize opioid-induced hyperalgesia syndrome and thus recommend opiate tapering.

e. Deciding to prescribe more than 800 morphine equivalents per day (morphine and fentanyl) to a patient with obstructive lung disease, as it exposed Patient C to unnecessary risks of respiratory failure.

f. Inadequately documenting opiate monitoring in the medical record.

g. When treating Patient C's anxiety, Respondent failed to attempt to trial a different, less-risky medication to replace the benzodiazepines.

h. Concurrently prescribing both opiates and benzodiazepines to Patient C.

i. Failing to have a signed pain care agreement for opiate treatment.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct re: Patient D: Gross Negligence, Repeated Negligent Acts, Inadequate Medical Recordkeeping)

66. Respondent Michele Allegra Gomez, M.D. is subject to disciplinary action for unprofessional conduct through her acts and omissions regarding Patient D under section 2234 subd. (a) [violation of Medical Practice Act]; and/or section 2234 subd. (b) [gross negligence] and/or subd. (c) [repeated negligent acts] and/or under section 2266 [inadequate medical recordkeeping] of the Code. The circumstances are as follows:

67. Paragraphs 10-65 are included in this disciplinary cause as if set forth herein.

68. Respondent treated Patient D, a middle-aged male patient, for many years, including from April 23, 2015 to September 2019. Before 2015, Patient D had been on high doses of opiates. Patient D's April 23, 2015 medical record reflects a primary encounter diagnosis of chronic pain. He had a history of alcohol dependence and illicit drug abuse. At this time period,

for chronic pain, Respondent was prescribing 300 mg per day of extended-release morphine and 350 mg per day of carisoprodol. Shortly after that, hydrocodone was also added to replace an immediate-release morphine prescription and the 300 mg per day of extended release morphine was lowered to 200 mg per day. At this time period, for anxiety, Respondent was prescribing 4 mg per day of the benzodiazepine clonazepam.

69. Carisoprodol is a powerful muscle relaxant with abuse potential similar to a benzodiazepine. The drug is often abused for its sedative and relaxant effects.

70. At an encounter with Patient D on August 24, 2015, Respondent increased the clonazepam prescription to 2.5 mg per day.

71. At an encounter with Respondent on November 12, 2015, Patient D reported that he got confused about how many carisoprodol tablets he had taken and took too many. Patient D told Respondent he no longer wanted to be on the carisoprodol medication. It was no longer prescribed after this encounter.

72. At a March 7, 2016 encounter, Patient D reported that he had run out of his hydrocodone medication more than a week before the refill date. A few months after that, Respondent prescribed immediate-release morphine to replace the hydrocodone. At an encounter a few days after Patient D filled his new prescription for immediate-release morphine, Patient D reported that he thought he would need an extra pill during the day. Respondent accordingly increased the immediate-release morphine prescription, now at 90 mg day.

73. In 2016, Respondent replaced Patient D's clonazepam with a different benzodiazepine—diazepam. At a July 7, 2016 encounter, Respondent noted that Patient D said his psychiatrist did not want Patient D on benzodiazepines, and that the psychiatrist was aware that Patient D was on benzodiazepines. In August 2016, the diazepam prescription was 30 mg per day, and by this point the immediate-release morphine was discontinued.

74. For several years, from August 2016 through September 2019, Respondent continued prescribing opiates and diazepam to Patient D. The opiate amounts prescribed changed somewhat from time to time, and various additional opiates were added at times, including periods of time where hydromorphone or additional immediate-release morphine was prescribed.

The opiate prescriptions ranged from around 200-260 morphine equivalency units per day. For the vast majority of time, the diazepam prescriptions were for between 30 and 40 mg per day. As of August 5, 2019, Respondent was prescribing 260 mg per day of morphine and 30 mg per day of diazepam.

75. At the end of 2019, Patient D saw another provider in Respondent's practice, and Patient D began an opiate taper.

76. Various other NSAIDs more potent than ibuprofen could have been attempted to reduce Patient D's opiate dependency. Additionally, gabapentin and pregabalin were two other neuropathic pain medications that would have been ideal, but were not tried. Non-addictive muscle relaxants for back pains should have been tried, instead of the dangerous and addictive carisoprodol and diazepam medications. Topical creams and over-the-counter joint supplements should also have been strongly considered.

77. Respondent did not properly risk stratify Patient D before providing long-term opiate therapy. Patient D had multiple social factors, such as history of alcohol abuse and illicit drug use, and tobacco addiction, that were warning signs of high risk for opiate addiction. Between 2015 and 2019, there was no referral for monitoring by an addiction medicine or pain management specialist. For a patient like Patient D with high daily opiate dosage, regular urine toxicology should have been done more frequently

78. Between 2016 and 2019, Patient D was generally prescribed between 200 and 260 morphine equivalents per day. Patient D had continued pain complaints and lengthy experience with high-dosage opiates made it highly likely that he had developed opioid-induced hyperalgesia syndrome. The appropriate management during this time should have been opiate tapering while using non-opiate medication for pain control. There were also lengthy periods of time between 2016 and 2019 where Respondent was aware that Patient D was consuming marijuana, along with opiates and benzodiazepines. This concurrent use of marijuana with high-dosage morphine increased the risks of accidental respiratory and opiate overdose.

79. Respondent's medical record documentation for Patient D did not support Patient D's need for high dosage opiates. Since 2015, there was little relevant musculoskeletal physical examination.

80. Instead of prescribing carisoprodol, Respondent should have prescribed safer and non-addictive alternatives like cyclobenzaprine or methocarbamol for pain management. Carisoprodol can potentially suppress respiration, thus making its addition to Patient D's high opiate dosage and benzodiazepine dosage an unnecessary exposure to risks of accidental overdose.

81. In July 2016, the medical record shows that Patient D's psychiatrist did not want Patient D on benzodiazepines. However, from 2016-2019, Respondent kept prescribing benzodiazepines. This reliance on long-term benzodiazepine therapy was not advisable. Moreover, prescribing benzodiazepines for several years to a patient on high levels of opiates unnecessarily increased the risks of accidental overdose.

82. Respondent did not have a signed pain agreement with Patient D, despite the high addiction risks for opiate therapy.

83. Respondent is guilty of unprofessional conduct and Respondent's certificate is subject to discipline pursuant to section 2234 subd. (a) and/or section 2234 subd. (b) and/or section 2234 subd. (c) and/or section 2266 of the Code based upon gross negligence and/or repeated negligent acts and/or inadequate medical recordkeeping, including but not limited to the following:

a. Failing to adequately try safer non-opiate pain medication.

b. Failing to properly risk stratify Patient D's opiate addiction.

c. Failing to have a multi-disciplinary management to reduce the elevated addiction risks.

d. Failing to have more frequent urine toxicology testing to monitor for compliance and diversions of medication.

e. Failing to recognize opioid-induced hyperalgesia syndrome and thus taper down Patient D's opiate prescriptions to safer levels.

f. Allowing Patient D to continue using marijuana with high-dose morphine.

g. Not maintaining adequate records documenting examination and opiate treatment of Patient D's pain complaints.

h. Failing to try other, safer non-addictive muscle relaxants before prescribing carisoprodol.

i. Adding carisoprodol to additional central nervous system depressants (opiates and benzodiazepines) and unnecessarily increasing risks of accidental drug overdose.

j. Prescribing long-term benzodiazepine therapy for Patient D, despite the contrary recommendation from Patient D's psychiatrist.

k. For several years prescribing benzodiazepines and opiates at the same.

l. Failing to safely and adequately initiate monitor long-term opiate therapy.

m. Failing to have a signed pain care agreement for opiate treatment.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number A 77883, issued to Respondent Michele Allegra Gomez, M.D.;

2. Revoking, suspending or denying approval of Respondent Michele Allegra Gomez, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent Michele Allegra Gomez, M.D., to pay the Board the costs of the investigation and enforcement of this case, and if placed on probation, the costs of probation monitoring; and

4. Taking such other and further action as deemed necessary and proper.

DATED: APR 0 4 2022

WILLIAM PRASIFKA
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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