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

In the Matter of the First Amended Accusation Against: Michael Ishu Yang, M.D. Physician's & Surgeon's Certificate No. A 112702 Respondent.	Case No. 800-2017-034199

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on March 30, 2022.

IT IS SO ORDERED: February 28, 2022.

MEDICAL BOARD OF CALIFORNIA

Richard E. Thorp, M.D.
Panel B

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

In the Matter of the First Amended Accusation Against:

MICHAEL ISHU YANG, M.D.,

Physician's and Surgeon's Certificate No. A 112702

Respondent.

Agency Case No. 800-2017-034199

OAH No. 2021040063

PROPOSED DECISION

Administrative Law Judge Karen Reichmann, State of California, Office of Administrative Hearings, heard this matter on December 6 through 8, 2021, by videoconference.

Deputy Attorney General Carolyne Evans represented complainant William Prasifka, Executive Director of the Medical Board of California.

Attorneys Kenneth Julian, C. Ryan Fisher, and Robert Hodges represented respondent Michael Ishu Yang, M.D., who was present.

The record remained open for complainant to submit a proposed modified probation condition. Complainant's submission was timely filed. The record closed and the matter was submitted for decision on December 10, 2021.

FACTUAL FINDINGS

Jurisdictional Matters

1. On June 2, 2010, the Medical Board of California (Board) issued Physician's and Surgeon's Certificate No. A 112702 (Certificate) to respondent Michael Ishu Yang, M.D. The Certificate was in full force and effect at all times relevant to the charges in the First Amended Accusation. The Certificate will expire on June 30, 2022, unless renewed. There has been no prior discipline against respondent's Certificate. Respondent is board-certified in anesthesiology and interventional pain management. He is in private practice in Santa Rosa.

2. On September 14, 2021, complainant William Prasifka filed the First Amended Accusation solely in his official capacity as the Board's Executive Director. Complainant seeks to discipline respondent based on false and inaccurate information contained on four authorization forms submitted in 2014 and 2015, in connection with respondent's prescribing the opioid Subsys.

Background

3. During the relevant time period, Subsys was a fairly new product. Subsys is a transmucosal immediate release fentanyl (TIRF) medication manufactured by INSYS Therapeutics. At all times relevant to the allegations, TIRF products including Subsys were subject to a risk evaluation and mitigation strategy (REMS) program. The

FDA implements REMS programs when there are concerns about serious potential side effects of a medication or class of medications. The FDA recommended that TIRF products only be prescribed to adult cancer patients with breakthrough pain who were already opioid tolerant (defined as taking the equivalent of at least 60 mg of morphine during the prior seven days). Prescribing TIRF products to a patient who is not opioid tolerant creates a risk of overdose. The Subsys product was unique because it did not contain sugar, which is an ingredient in other TIRF products.

4. The federal government maintains a website where payments made by pharmaceutical companies to physicians are documented. This website reflects that INSYS made payments to respondent totaling $20,587.66 in 2014, $34,159.07 in 2015, and $18,324.54 in 2016. These payments included compensation for consulting and for serving as a speaker for Subsys.

5. On June 28, 2017, Humana, a health insurance company, submitted an online complaint to the Board stating that respondent and/or his office staff submitted Subsys authorization requests containing false information indicating that patients were diagnosed with cancer-related conditions.

6. The Board conducted an investigation. It was not established that patients were falsely diagnosed with cancer in order to obtain authorization for prescribing Subsys. The investigation did uncover four authorization forms containing other inaccurate information which were submitted in connection to prescriptions for Subsys issued to three patients, and which were maintained in their medical records. These forms were faxed to INSYS. The forms were used by INSYS to obtain payment authorization from Humana, the patients' prescription drug insurer.

False Information

PATIENT 1 (C.E.)

7. Patient 1 was 56 years old in April 2014 when he first saw respondent. He had suffered chronic back pain for many years and had a history of failed back surgeries. He was referred to respondent by his primary care physician. He had been prescribed opioids for many years.

Respondent prescribed Subsys in a spray form to Patient 1 at their first appointment on April 9, 2014. In connection with this prescription, a "Reimbursement Assistance/Prior Authorization Request" form was faxed to INSYS. The form contained a section titled, "Rationale for Prior Authorization." This section included 11 items that could be selected, and the instruction to check all that apply. All items were checked. The selected items made the following representations about Patient 1 which are not supported by his medical records: treatment failure with formulary equivalent; patient stable on medication over three months due to sample or previous insurance coverage; sleep disruption with previous treatment; patient has dental caries; generic drug is not reliable for the patient; patient cannot tolerate formulary medication due to side effects; patient is diabetic and current product patient is taking is sugar based.

The form required the signature of the prescribing physician. The form was signed with a rubber stamp representing respondent's signature, which he had provided to his staff. The form was faxed to INSYS, along with respondent's progress notes documenting Patient 1's visit. These notes contained accurate information, in contradiction to the misrepresentations on the INSYS authorization form.

8. On January 21, 2015, Barbara Kangas, a nurse practitioner working in respondent's practice, saw Patient 1 and refilled his prescription for Subsys. A slightly

different form was filled out and faxed to INSYS, titled "INSYS Reimbursement Center Patient Authorization & Referral Form." In the section titled "Rationale for Prior Authorization," items were selected which made the following representations about Patient 1 which are not supported by his medical records: patient cannot tolerate formulary medication due to side effects; patient has difficulty swallowing; patient is diabetic; patient has dental caries precluding the use of medications containing sugar. This form bears respondent's signature in two places. The form was faxed to INSYS along with the progress note from the patient's visit, which contained accurate information.

PATIENT 2 (B.L.)

9. Patient 2 was a 45-year-old male with a history of multiple surgeries and sarcoma. He was referred to respondent by a pain management physician in San Diego in December 2014. Patient 2 first saw respondent on December 19, 2014. Respondent prescribed Subsys to the patient on the December 19, 2014, visit. There is no record of any forms being submitted to INSYS in relation to this initial prescription.

10. The patient returned on January 16, 2015. At this appointment, respondent refilled the Subsys prescription and prescribed a Butrans[1] patch. An "INSYS Reimbursement Center Patient Authorization & Referral Form" dated January 16, 2015, was submitted to INSYS. In the section titled "Current 'Around-the-Clock' Opioid Medication(s)" the box "Patient is opioid tolerant (required)" is checked, the box labeled "hydrocodone" is checked, and the box "other" is checked, with a handwritten notation reading, "Butrans patch 20 mcg/hr weekly." This statement was false because

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[1] Butrans patches contain buprenorphine, an opioid.

the patient was only prescribed Butrans for the first time that day[2], and because the patient was not taking hydrocodone at that time (he had been prescribed hydrocodone by his previous physician, but respondent did not continue him on that drug at the December appointment). On the second page of the form, in the section labeled "Rationale for Prior Authorization," boxes are selected reflecting the following inaccurate information: patient stable on medication over three months due to sample or previous insurance coverage; formulary alternatives not clinically appropriate for this patient (possible drug interactions); generic not reliable; patient cannot tolerate formulary alternatives due to side effects; patient has difficulty swallowing; sleep disruption with previous treatment; patient is diabetic; presence of dental caries. On the signature line, there is a scribbled signature that is not respondent's handwriting. The form was faxed to INSYS along with respondent's progress note.

PATIENT 3 (E.H.)

11. Patient 3 was referred to respondent for pain management by his primary care physician, Jenny Sullivan, M.D., and started treatment with respondent in January 2015. Respondent adjusted his medications and administered an injection in February 2015, which was ineffective. At an appointment on March 15, 2015, respondent prescribed Subsys to Patient 3. A "INSYS Reimbursement Center Patient Authorization & Referral Form" was submitted to INSYS. The form included a signature of respondent's name, but it was not respondent who signed it. On this form, the following inaccurate information was provided in the section titled "Rationale for Prior

[2] The patient returned to respondent's clinic later that day and reported that it was too expensive to fill the Butrans prescription. Respondent prescribed an alternative. The prescription for Butrans was never filled.

Authorization": patient stable on medication over 3 months due to sample or previous insurance coverage; formulary alternatives not clinically appropriate for this patient (possible drug interactions); generic not reliable; patient cannot tolerate formulary alternatives due to side effects; patient has difficulty swallowing; sleep disruption with previous treatment; patient is diabetic; presence of dental caries. This form was faxed to INSYS, along with respondent's progress note.

Board Interview

12. Respondent was interviewed by investigators for the Board on January 28, 2020. The focus of the interview was respondent's treatment and prescribing to the three patients, and respondent was not asked about the inaccuracies in the INSYS forms described above. At this interview, respondent reported that he had stopped prescribing Subsys about four years earlier, because of malfeasance by the manufacturer, and because of his observations in his practice that Subsys was not more efficacious than other products. He denied being paid incentives by INSYS for prescribing Subsys.

Expert Witnesses

GREGORY POLSTON, M.D.

13. Complainant retained Gregory Polston, M.D., as an expert witness in this matter. Dr. Polston is board certified in anesthesiology with qualifications in pain management. He is on the faculty at the University of California, San Diego. He reviewed documents, including the three patients' medical records. He wrote a report and testified at the hearing.

Dr. Polston explained that the standard of care requires the documentation of truthful information in medical records. Dr. Polston noted that it is within the standard of care for a physician to delegate the completion of forms to staff, but the standard of care requires a physician to review forms completed by staff if they pertain to controlled substances. Failing to ensure that these forms are filled out accurately is a departure from the standard of care and presents a risk to patient safety and public safety. Submission of a form with a physician's signature that contains inaccurate information is a simple departure from the standard of care.

Dr. Polston noted that although the prescriptions for Subsys were not for breakthrough cancer pain, off-label prescribing is very common and is not a departure from the standard of care. Dr. Polston did not find that respondent deviated from the standard of care in his treatment of the three patients, including by prescribing Subsys to them. Although off-label prescribing is not a deviation from the standard of care, an insurance provider such as Humana may have its own policy regarding coverage for off-label prescriptions, so accuracy in the authorization forms is important.

Dr. Polston concluded that respondent engaged in repeated simple departures from the standard of care by the submission of the four inaccurate Subsys authorization forms. Dr. Polston holds this opinion regardless of whether respondent signed the forms after they had been filled out, or whether he provided pre-signed forms to his staff, or whether he authorized his staff to complete the forms and sign them with or without his signature stamp. Dr. Polston's opinions were persuasive.

WILLIAM BROSE, M.D.

14. Respondent retained William Brose, M.D., as an expert witness in this matter. Dr. Brose is board certified in anesthesiology with added qualifications in pain

management. He has been a pain specialist for 33 years. He developed the pain management program at Stanford University in 1989 and remains affiliated with Stanford. He also developed and operated a large pain rehabilitation program with 15 locations statewide. Dr. Brose reviewed the patient records, Dr. Polston's report, and the Accusation. He wrote a report and testified at the hearing.

Dr. Brose agreed with Dr. Polston that respondent's treatment of all three patients, including the prescribing of Subsys, was within the standard of care.

Dr. Brose explained that it is common practice, and within the standard of care, for a physician to delegate the completion of forms such as the INSYS authorization forms to staff. If a physician provides pre-signed forms or a signature stamp to staff, the physician must have a quality control process to enable review of the delegated activities. Dr. Brose concedes that the four forms at issue contain false information, but noted that there was no evidence of intent on respondent's part to misrepresent the patients' conditions. He ultimately concluded that respondent committed a single deviation from the standard of care, namely failing to have an adequate quality assurance quality control process that ensured accuracy and precision in the completion of the Subsys authorization forms. He does not view the submission of four inaccurate forms to constitute repeated simple departures.

DISCUSSION

15. The only relevant point of disagreement between the two highly qualified experts is whether respondent committed a single or multiple deviations from the standard of care. On this point, Dr. Brose's opinions were less persuasive than the opinions of Dr. Polston. The submission of four forms containing grossly inaccurate

information between April 2014 and March 2015 constituted four separate departures from the standard of care.

Interview with Federal Agents

16. On July 2, 2020, respondent was interviewed by federal agents in connection to a criminal investigation. Respondent stated that in 2015 and 2016, one of the INSYS representatives encouraged him to write more Subsys prescriptions and prescriptions with higher doses, telling him that he would be given more paid speaking opportunities if he did so. Respondent reported that these conversations made him uncomfortable, and he removed himself from the INSYS speaking program due to his discomfort. Respondent also told the investigators that he believed that INSYS representatives had checked off the false boxes on the authorization forms and that he was shocked when he found out it had happened. He stated that his former office manager, Gracie Rodriguez, was fired for not revealing what the INSYS representatives had been doing.

Respondent's Evidence

17. Respondent is 44 years old. He was born in Taiwan to parents with very modest resources. He was sent to the United States at age 6 to live with an aunt and uncle in Florida. Eventually he was reunited with his parents and the family settled in California. Respondent earned his bachelor's degree from Johns Hopkins University and his medical degree from University of California, San Francisco (UCSF). He completed a one-year internship through UCSF, working with underserved patients in Fresno. He then completed a residency in anesthesiology at Cornell University.

After receiving his Certificate, he went to work for a private practice in Santa Rosa in late 2010. He left this practice after about a year when a promised increase in

pay did not materialize. Respondent founded his own practice, Summit Pain Alliance, in early 2012, and he continues to operate the practice. The practice's focus is chronic pain management and includes a large number of patients with cancer and failed orthopedic surgeries. Respondent employs a multi-modal approach and frequently refers his patients for psychiatric care, physical therapy, acupuncture, and chiropractic care. Respondent's goal is to get his patients off of opioids and improve their quality of life. There have been other physicians and nurse practitioners working at Summit Pain Alliance, and there are medical assistants and office managers on the staff. It is a busy practice; there is currently a two-to-three month long waiting list. Respondent sees 40 or more patients a day in clinic, and spends a day to a day and a half performing surgeries and procedures offsite.

18. Respondent acknowledged that the forms were inaccurate and that it was unacceptable for them to be submitted containing these inaccuracies. He added that it would be extremely rare for one patient to have all the conditions identified on the forms, and he would never have personally signed a form containing such flagrant inaccuracies. Respondent credibly denied being aware that the forms were submitted with the misinformation and he credibly denied directing his staff to make any misrepresentations on the forms. Respondent asserted that he trained his staff to fill out paperwork accurately and to rely on his progress notes. A signature stamp was provided for use on documents delegated to staff, such as referrals and lab and imaging orders. Staff members were not authorized to sign for respondent by any other means.

19. Respondent denied profiting by prescribing Subsys. He noted that he did not dispense the medications and he did not receive a commission or bonus for his prescriptions. He denied that his role as a consultant and speaker for INSYS influenced

the care or treatment of his patients, or caused him to falsify documents. Respondent added that he has performed consulting and speaker work for other entities, and that this work has generated equal or greater income.

20. Respondent conceded that he could have had a better quality control at the time the inaccurate forms were submitted. He stated that he subsequently improved his process. He trains his staff to always fill out documents accurately. He performs frequent checks of documents completed by newly hired staff and regularly performs spot checks of documents completed by more senior staff. He has modified his signature so that he can sign documents more quickly. He has gotten rid of the signature stamp. He also noted that there has been an increase in the use of electronic signatures since the time of the allegations.

21. Respondent completed a two-day medical record keeping class at the University of California, Irvine, School of Medicine in July 2021. He reported that he found the information presented relevant to his practice, although he had already implemented many changes to his record keeping practices on his own.

22. Respondent completed a course titled "Opioid and Diversion Awareness: The Current State of the Opioid Epidemic" in August 2021. Respondent is committed to keeping his medical knowledge and understanding of the standard of care current.

23. Respondent is a member of a tri-county commission of physicians in the north bay area who have developed guidelines for opioid management and weaning. Respondent participates in "operation access," a program providing pro bono medical care to uninsured patients.

Summit Pain Alliance Office Staff

24. Gracie Rodriguez signed a declaration and testified at the hearing. She was an office manager at Summit Pain Alliance during the time of the fraudulent Subsys authorization forms. She assisted in preparing the forms and tried to be accurate. She denied ever selecting all the boxes in the "Rationale" section of the forms, and denied being directed to do so by respondent. She remembered being provided with forms pre-signed by respondent and with a signature stamp, and she remembered attaching respondent's progress notes when faxing the forms. She stated that INSYS representatives came by the office and would also assist in preparing the forms and were available by telephone for questions. Rodriquez denied that INSYS representatives had access to patient records. Rodriquez testified that respondent never encouraged her to engage in dishonesty and would never have condoned staff engaging in acts of dishonesty.

25. Adriana Ambriz has worked for respondent's practice for seven years. She started as a receptionist and has been a medical assistant since September 2015. In the course of her work at Summit Pain Alliance, she has filled out INSYS authorization forms such as the ones at issue in this matter. She was trained to be accurate and to rely on patient records when filling out the forms. She denied being trained to select all the various boxes in the "Rationale for Prior Authorization" section.

Ambriz related that staff had been given forms that were pre-signed by respondent. They attached the patient's medical record when faxing the INSYS forms. Ambriz was adamant that respondent would not tolerate dishonesty in his practice.

26. In a declaration dated September 1, 2021, Barbara Kangas, N.P., wrote that she has worked at Summit Pain Alliance since 2012. She wrote that respondent

never asked her to provide inaccurate information on any paperwork, including INSYS authorization forms. She wrote that INSYS representatives frequently came to the Summit Pain Alliance office from 2014 through 2016, bearing food and drink. She related seeing INSYS representatives assisting medical staff, especially Gracie Rodriguez, complete the INSYS authorization forms.

LEGAL CONCLUSIONS

1. It is complainant's burden to demonstrate the truth of the allegations by "clear and convincing evidence to a reasonable certainty," and that the allegations constitute cause for discipline of respondent's Certificate. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

2. Business and Professions Code section 2227 authorizes the Board to take disciplinary action against licensees who have been found to have committed violations of the Medical Practice Act. Business and Professions Code section 2234, included in the Medical Practice Act, provides that a licensee may be subject to discipline for committing unprofessional conduct (Bus. & Prof. Code, § 2234), repeated negligent acts (Bus. & Prof. Code, § 2234, subd. (c)), any act involving dishonesty or corruption that is substantially related to the functions of a licensee (Bus. & Prof. Code, § 2234, subd. (e)), knowingly making or signing a false document (Bus. & Prof. Code, § 2261), and knowingly making a false claim for payment (Bus. & Prof. Code, § 810).

3. Cause for discipline for unprofessional conduct, repeated negligent acts, and acts involving dishonesty, all arising from the submission of four inaccurate INSYS authorization forms, was established in light of the matters set forth in Findings 7 through 11, 13, and 15. Because the evidence failed to establish that respondent

knowingly engaged in the making of false statements or false claim for payment, cause for discipline under Business and Professions Code sections 2261 and 810 was not established.

4. In exercising its disciplinary functions, protection of the public is the Board's highest priority. (Bus. & Prof. Code, § 2229, subd. (a).) The Board is also required to take disciplinary action that is calculated to aid the rehabilitation of the physician whenever possible, as long as the Board's action is not inconsistent with public safety. (Bus. & Prof. Code, § 2229, subds. (b), (c).)

5. The Board's Manual of Disciplinary Orders and Disciplinary Guidelines (12th ed., 2016; Cal. Code Regs., tit. 16, § 1361) provide for a minimum discipline of five years' probation and a maximum discipline of revocation for licensees who have committed repeated negligent acts. A one year suspension and seven years' probation is the minimum recommended discipline for licensees who have committed dishonest acts.

Complainant recommends a five-year period of probation with special conditions to provide additional education and oversight of respondent's billing and practice.

6. The evidence established that on four occasions in 2014 and 2015, grossly inaccurate authorization forms pertaining to Subsys prescriptions were generated at respondent's practice, submitted under respondent's signature, and maintained in the patients' medical records. It was not established that respondent knowingly made false representations on these forms, or that he was aware of the false information contained on them. These forms were used to obtain authorization for insurance coverage for Subsys, as opposed to other TIRF products. Although it

could not be established who provided the false information contained on the four forms, the evidence suggests that the manufacturer's representatives were directly or indirectly involved. The misrepresentations did not pose a risk of patient harm.

Respondent's denial of intentional dishonesty was credible. Respondent's own encounter notes for the patients do not contain any inaccuracies. Cause for discipline is based on respondent's negligence in not preventing false information from being disseminated. It is apparent that respondent failed to provide adequate oversight of his staff and failed to prevent interference by INSYS representatives.

Since the time of respondent's negligent conduct more than five years ago, he has altered his practices in an attempt to avoid further similar issues. This effort has included attending a medical record keeping course. There were no allegations, and no evidence, that respondent's treatment of his patients deviated in any way from the standard of care. To the contrary, the evidence demonstrated that respondent is providing high quality care to patients with chronic pain. A period of probation is not necessary to protect patients or the public. A public reprimand, with requirements that respondent complete professional ethics and professional boundaries courses, is the appropriate discipline in this case.

ORDER

Physician's and Surgeon's Certificate No. A 112702, issued to respondent Michael Ishu Yang, M.D., is hereby reprimanded within the meaning of Business and Professions Code section 2227, subdivision (a)(4). Respondent also must complete the following educational courses, and failure to do so in accordance with this order may be cause for further disciplinary action.

1. Professionalism Program (Ethics Course)

Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California Code of Regulations (CCR) section 1358.1. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six (6) months after respondent's initial enrollment, and the longitudinal component of the program not later than the time specified by the program, but no later than one (1) year after attending the classroom component. The professionalism program shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A professionalism program taken after the acts that gave rise to the charges in the First Amended Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the Board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

2. Professional Boundaries Program

Within 60 calendar days from the effective date of this Decision, respondent shall enroll in a professional boundaries program approved in advance by the Board or

its designee. Respondent, at the program's discretion, shall undergo and complete the program's assessment of respondent's competency, mental health and/or neuropsychological performance, and at minimum, a 24 hour program of interactive education and training in the area of boundaries, which takes into account data obtained from the assessment and from the Decision(s), Accusation(s) and any other information that the Board or its designee deems relevant. The program shall evaluate respondent at the end of the training and the program shall provide any data from the assessment and training as well as the results of the evaluation to the Board or its designee.

Failure to complete the entire program not later than six (6) months after respondent's initial enrollment shall constitute cause for discipline unless the Board or its designee agrees in writing to a later time for completion. Based on respondent's performance in and evaluations from the assessment, education, and training, the program shall advise the Board or its designee of its recommendation(s) for additional education, training, psychotherapy and other measures necessary to ensure that respondent can practice medicine safely. Respondent shall comply with program recommendations. At the completion of the program, respondent shall submit to a final evaluation. The program shall provide the results of the evaluation to the Board or its designee. The professional boundaries program shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

The program has the authority to determine whether or not respondent successfully completed the program.

A professional boundaries course taken after the acts that gave rise to the charges in the First Amended Accusation, but prior to the effective date of the

Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision.

If respondent fails to complete the program within the designated time period, respondent shall cease the practice of medicine within three (3) calendar days after being notified by the Board or its designee that respondent failed to complete the program.

DATE: 01/06/2022

Karen Reichmann

KAREN REICHMANN

Administrative Law Judge

Office of Administrative Hearings

Attached: First Amended Accusation 800-2017-034199

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

In the Matter of the First Amended Accusation Against: **Michael Ishu Yang, M.D.** **392 Tesconi Ct.** **Santa Rosa, CA 95401-4653** **Physician's and Surgeon's Certificate No. A 112702,** Respondent.	Case No. 800-2017-034199 **FIRST AMENDED ACCUSATION**

PARTIES

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

2. On June 2, 2010, the Board issued Physician's and Surgeon's Certificate Number A 112702 to Michael Ishu Yang, 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 June 30, 2022, unless renewed.

JURISDICTION

3. This First Amended 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.

4. 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.

5. 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.
>
> . . .
>
> (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.
>
> . . .
>
> (e) The commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon.
>
> (f) Any action or conduct that would have warranted the denial of a certificate."

6. Section 2261 of the Code states:

"Knowingly making or signing any certificate or other document directly or indirectly related to the practice of medicine or podiatry which falsely represents the existence or nonexistence of a state of facts, constitutes unprofessional conduct."

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7. Section 810 of the Code states in relevant part:

"(a) It shall constitute unprofessional conduct and grounds for disciplinary action, including suspension or revocation of a license or certificate, for a health care professional to do any of the following in connection with his or her professional activities:

(1) Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss under a contract of insurance.

(2) Knowingly prepare, make, or subscribe any writing, with intent to present or use the same, or to allow it to be presented or used in support of any false or fraudulent claim. ..."

FACTUAL ALLEGATIONS

Patient P-1[1]

8. In 2014, Patient P-1, a then 56 year-old male, was referred to Dr. Yang for pain management. Patient P-1 had a history of lumbar radiculopathy,[2] post-laminectomy syndrome,[3] and knee pain. In April 2014, Dr. Yang began prescribing Subsys[4] 400 mcg (120 sprays per month) to Patient P-1. Dr. Yang continued prescribing Subsys to Patient P-1 until July 14, 2015. In addition to prescribing Subsys, Dr. Yang also prescribed other opioids to Patient P-1, including methadone[5] and oxycodone[6].

9. Dr. Yang completed two authorization forms for Patient P-1's Subsys prescriptions and submitted them to INSYS Therapeutics (INSYS) for the purpose of obtaining insurance

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[1] The patients are identified as P-1, P-2, and P-3 to preserve confidentiality. The Respondent knows the names of the patients and can confirm their identity through discovery.

[2] Lumbar radiculopathy refers to disease involving the lumbar spinal nerve root.

[3] Post-laminectomy syndrome is a condition where a patient suffers from persistent pain in the back following back surgery.

[4] Subsys is a sublingual fentanyl spray, a powerful, but highly addictive, opioid painkiller. Subsys is also a considered a TIRF medication (Transmucosal Immediate Release Fentanyl).

[5] Methadone is a synthetic narcotic analgesic.

[6] Oxycodone is an opioid pain medication.

authorization and payment for the Subsys prescriptions.[7] The first authorization form ("INSYS Reimbursement Assistance/Prior Authorization Request") is dated April 9, 2014, and under "Rationale for Prior Authorization (Select all that Apply)," Dr. Yang checked the following as positive for Patient P-1:

- Treatment failure formulary medication;
- Patient stable on medication over 3 months due to sample or previous insurance coverage;
- Formulary alternatives NOT clinically appropriate for this patient (possible drug interactions);
- Patient cannot tolerate formulary medications due to side effects;
- Generic not reliable for patient;
- Provider preferred product;
- Sleep disruption with the previous treatment;
- Patient is a diabetic; medications containing sugar are not desirable;
- Application Site Irrigation with previous product;
- Inadequate analgesic effect;
- Dental caries.[8]

10. The second authorization form ("INSYS Reimbursement Center Patient Authorization and Referral Form") that Dr. Yang completed and submitted to INSYS is dated January 21, 2015, and under the "Rationale for Prior Authorization (Select all that Apply)" section, the following were all checked as positive:

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[7] INSYS Therapeutics (INSYS) is a pharmaceutical company that manufactures Subsys. The INSYS authorization forms that Dr. Yang completed and submitted state that the prescriber of Subsys (i.e. Dr. Yang) authorizes INSYS to: "be my designated agent and act as my business associate... to use, disclose, and receive any protected health information . . . about any of my patients enrolled with the INSYS Reimbursement Center or related Insys (sic) programs, including disclosure to any pharmacies, insurance plans, or insurer(s) and other third parties to perform the following services: (I) *verifying or coordinating insurance coverage or obtain payment for my Patients' treatment with INSYS medications . . .*" (emphasis added).

[8] Dental caries refer to dental cavities.

- Formulary alternatives NOT clinically appropriate for this patient (possible drug interactions);
- Generic not reliable for patient;
- Patient cannot tolerate formulary medications due to side effects;
- Provider preferred product;
- Patient has difficulty swallowing/cannot tolerate medication by mouth (PO);
- Sleep disruption with the previous treatment;
- Patient is a diabetic; medications containing sugar are not desirable;
- Inadequate analgesic effect;
- Presence of dental caries precludes use of medications containing sugar.

11. Although Dr. Yang represented in the INSYS authorization and reimbursement forms that Patient P-1 had difficulty swallowing, diabetes, and dental caries, and that the patient had previously used transmucosal immediate release fentanyl products, there is nothing in Patient P-1's medical records that support these medical diagnoses and/or medical conditions and/or prior medication history.

Patient P-2

12. In 2014, Patient P-2, a then 45-year-old male, was referred to Dr. Yang for pain management. Patient P-2 had a history of post-laminectomy syndrome, sciatica, muscle spasm, chronic pain syndrome, cervical radiculopathy, and sarcoma (cancer). The sarcoma was in remission. In December 2014, Dr. Yang began prescribing Subsys 600 mcg (120 sprays per month) to Patient P-2. Dr. Yang prescribed Subsys again on January 16, 2015, and February 16, 2015. Dr. Yang also prescribed oxycodone to Patient P-2.

13. Dr. Yang completed an INSYS reimbursement authorization form for Patient P-2's Subsys prescriptions and submitted them to INSYS for the purpose of obtaining insurance authorization and payment for the Subsys prescriptions. The reimbursement form is dated January 16, 2015, and is titled "INSYS Reimbursement Center Patient Authorization and Referral Form" and under "Rationale for Prior Authorization continued (Select all that Apply)," Dr. Yang checked the following as positive:

- Patient stable on medication over 3 months due to sample or previous insurance coverage;
- Formulary alternatives NOT clinically appropriate for this patient (possible drug interactions);
- Generic not reliable for patient;
- Patient cannot tolerate formulary medications due to side effects;
- Provider preferred product;
- Patient has difficulty swallowing/cannot tolerate medication by mouth (PO);
- Sleep disruption with the previous treatment;
- Patient is a diabetic; medications containing sugar are not desirable;
- Inadequate analgesic effect;
- Presence of dental caries precludes use of medications containing sugar.

14. Although Dr. Yang represented in the Subsys authorization and reimbursement forms that Patient P-2 had difficulty swallowing, diabetes, and dental caries, and that Patient P-2 had previously used transmucosal immediate release fentanyl products, there is nothing in Patient P-2's medical records to support these medical diagnoses and/or medical conditions and/or prior medication history.

15. Dr. Yang also represented on the Subsys authorization and reimbursement forms that Patient P-2 was taking Butrans[9] 20 mcg patch on a weekly basis. However, Patient P-2's use of Butrans patches are not reflected in CURES or in the patient's medical records. In fact, Dr. Yang documented in the medical records that Patient P-2 notified Dr. Yang that the Butrans patches were too expensive and that he would not be using them.

Patient P-3

16. In 2014, Patient P-3, a then 49 year-old male, was referred to Dr. Yang for pain management. Patient P-3 had a history of post-laminectomy syndrome, sciatica, lumbar

[9] Butrans patches contain buprenorphine, which is a partial opioid agonist. The patches are used to treat severe chronic pain.

radiculitis, and lumbar degenerative disc disease. In March 2015, Dr. Yang prescribed Subsys 400 mcg (120 sprays per month) to Patient P-3.

17. Dr. Yang completed an INSYS reimbursement authorization form for Patient P-3's Subsys prescriptions and submitted them to INSYS for the purpose of obtaining insurance authorization and payment for the Subsys prescriptions. The reimbursement form is dated March 13, 2015, and is titled "INSYS Reimbursement Center Patient Authorization and Referral Form" and under "Rationale for Prior Authorization continued (Select all that Apply)," Dr. Yang checked the following as positive:

- Patient stable on medication over 3 months due to sample or previous insurance coverage;
- Formulary alternatives NOT clinically appropriate for this patient (possible drug interactions);
- Generic not reliable for patient;
- Patient cannot tolerate formulary medications due to side effects;
- Provider preferred product;
- Patient has difficulty swallowing/cannot tolerate medication by mouth (PO);
- Sleep disruption with the previous treatment;
- Patient is a diabetic; medications containing sugar are not desirable;
- Inadequate analgesic effect;
- Presence of dental caries precludes use of medications containing sugar.

18. Although Dr. Yang represented in the Subsys authorization and reimbursement forms that Patient P-3 had difficulty swallowing, diabetes, and dental caries, and that the patient had previously used transmucosal immediate release fentanyl products, there is nothing in Patient P-3's medical records to support these medical diagnoses and/or medical conditions and/or prior medication history.

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CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Repeated Negligent Acts and/or Dishonest and Corrupt Acts and/or Making False Statements in a Document and/or Making False Statements for Payment)

19. The allegations of paragraphs 8 through 18 are incorporated by reference as if set out in full. Respondent is subject to disciplinary action under sections 2234 (unprofessional conduct) and/or 2234 subdivision (c) (repeated negligent acts); and/or 2234 subdivision (e) (dishonest and corrupt acts); and/or 2261 (knowingly making or signing a false document); and/or 810 (making a false claim for payment) in that as described above, Respondent provided false and inaccurate information to obtain authorization and payment for a controlled substance (Subsys) from insurance companies with respect to Patients P-1, P-2, and P-3.

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 112702, issued to Respondent Michael Ishu Yang, M.D.;

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

3. Ordering Respondent Michael Ishu Yang M.D.'s, if placed on probation, to pay the Board the costs of probation monitoring; and

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

DATED: SEP 14 2021

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