State of New Hampshire
Board of Medicine
Concord, New Hampshire

In the Matter of:
Christopher Clough, P.A.
License No.: 0441

Docket No. 14-03

FINAL ORDER

Before the New Hampshire Board of Medicine ("Board") is an adjudicatory/disciplinary proceeding in *In the Matter of Christopher Clough*, P.A. ("Respondent" or "Mr. Clough") in Docket Number 14-03.

Background Information

The Board first granted a license to practice as a physician assistant in the State of New Hampshire to Respondent on August 7, 2002. Respondent holds license number 0441. During the relevant time period, respondent practiced as a physician assistant in Somersworth, New Hampshire with Pain Care of New Hampshire ("Pain Care").

John Schermerhorn, MD was Respondent's supervising physician beginning in 2011. Dr. Schermerhorn was originally named in the adjudicatory hearing, but entered into a Settlement Agreement to resolve the pending allegations.[1] He was publicly reprimanded for his failure to provide adequate supervision over Mr. Clough's performance in order to ensure that appropriate directions were given to, and understood and executed by Mr. Clough and that medical and surgical conditions were appropriately evaluated and treated by Mr. Cough.

On or about September 10, 2013, the Board office received a lengthy and detailed complaint from former Pain Care employee Joshua Greenspan, M.D. Dr. Greenspan alleged that Respondent provided medically unnecessary procedures to numerous patients. It was also alleged that Respondent's performance of these procedures fell below the standard of care and resulted in potential patient harm.

The Board's investigative staff obtained 17 patient records as part of the investigation into this complaint. This matter was originally investigated by a member of the Board's Medical Review Subcommittee (MRSC), but due to the nature of the treatment provided to these patients,

[1] *See* January 7, 2015 Settlement Agreement.

a pain specialist was required. Gilbert Fanciullo, MD, MS, Professor of Anethesiology at the Geisel School of Medicine at Dartmouth and Director of Pain Medicine Section at Dartmouth-Hitchcock Medical Center, served as the outside reviewer for this case.

As part of the investigation, Dr. Fanciullo analyzed copies of treatment records that were obtained for a number of Respondent Clough's patients. He noted problematic conduct related to injection procedures and prescribing practices on the part of Respondent Clough while under the supervision of Respondent Schermerhorn.

The Board reviewed Dr. Fanciullo's report on or around July 21, 2014 and issued a Notice of Hearing on August 11, 2014 with an original hearing date of September 3, 2014. On August 22, 2014, Respondent filed a *Partially Assented-To Joint Expedited Motion for Continuance and Partial Reconsideration of the Board's Notice of Hearing.* In this pleading Respondent specifically asked for a continuance without the imposition of practice restrictions.

During a prehearing on August 28, 2014, Respondent agreed to abide by certain restrictions during the pendency of this case.[2] Specifically, Mr. Clough was required to have all procedures preapproved by his new Registered Supervisory Physician (RSP) of record or a newly named Alternate Registered Supervisor Physician (ARSP). All prescriptions written by Mr. Clough were required to be reviewed, in writing, post issuance by the RSP or ARSP. Consequently, a continuance was granted until November 4, 2014.

On October 20, 2014, Respondent filed an *Assented to Motion for Reconsideration Regarding Scheduling* and the hearing was rescheduled to commence on November 20, 2014. The hearing continued on November 21, 2015, December 17, 2014, January 7, 2015, March 12, 2015, April 14, 2015 and April 21, 2015.

The prosecution was represented by Hearing Counsel Attorneys Matthew Mavrogeorge and Michelle Heaton of the Administrative Prosecutions Unit ("APU") of the Office of the Attorney General. The Respondent was represented by Attorney John Durkin, of Burns, Bryan, Cox, Rockefeller and Durkin, PA. On March 12, 2015, Attorney Durkin withdrew from this case and following a waiver of his right to retain counsel, Respondent elected to represent himself for the remainder of the hearing.

Findings of Fact

[2] *See* September 4, 2014 Prehearing Conference Order. These restrictions have remained in effect until the issuance of this *Final Order*.

The following Board members composed the quorum in this case:

Mark Sullivan, P.A., Board President
John Wheeler, D.O., Board Vice President
Edmund Waters, J.D., Public Member, Presiding Officer
Robert M. Vidaver, M.D., DHHS Commissioner's Designee
Gail Barba, Public Member

Hearing Counsel called the following individuals as witnesses:

1. Gilbert Fanciullo, MD
2. Christopher Clough, PA

Respondent testified on his own behalf and called the following individual as a witness:

1. David Tung, MD, with Pain Care

Dr. Fanciullo provided extensive testimony for Hearing Counsel and was rigorously cross-examined by Respondent's attorney. The Board found Dr. Fanciullo to be direct, forthright and credible. The Board further found Dr. Fanciullo to be articulate, candid and persuasive. Dr. Fanciullo did not receive any financial compensation for his work on this case.[3]

Dr. Tung provided testimony for Respondent and was cross-examined by Hearing Counsel. The Board found Dr. Tung to be direct, forthright and credible. Dr. Tung testified knowledgeably about his specialty; however the Board was concerned that while Dr. Tung accepted the role of RSP for the Respondent, he (Dr. Tung) had not actually read the Board's *Prehearing Order* which placed numerous restrictions on Respondent's ability to practice as a physician assistant.

Hearing Counsel submitted exhibits 1 through 33 and Respondent submitted exhibits A through CC. Respondent's exhibits included an expert report from Ronald Laub, MD.[4] Because Respondent did not call Dr. Laub to testify, Dr. Laub was never subject to cross-examination by opposing counsel or questioning from the Board. These processes are time honored techniques for assisting a trier of fact in judging the credibility of a witness.

Respondent could have presented testimony to rebut Dr. Fanciullo's expert opinion but he chose not to do so. Respondent, in his own testimony, had the opportunity to rebut Dr. Fanciullo's assessment of the care provided to each patient, but did not do so. Respondent's testimony made clear that he did recognize the seriousness of the quality of care concerns in

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[3] The Board's outside reviewers do receive Continuing Medical Education credits for their work.
[4] *See* Exhibits A and B.

front of the Board, but mistakenly believed that the only issue regarding his care was inadequate documentation.

In light of the testimony and exhibits, the Board finds the following facts by a preponderance of the evidence.

I. Procedures

A. Use of Local Anesthetic

Respondent engaged in professional misconduct by utilizing inappropriately high levels of local anesthetic in multiple procedures. This is especially concerning in medial branch blocks, which serve as a diagnostic tool. If the administration of anesthesia in a particular location results in relief to the patient, the provider proceeds to a separate therapeutic procedure (radiofrequency of the joint). Dr. Fanciullo testified that ¼ or ½ cc of lidocaine or buprivicaine should typically be used in order to numb the anatomical location of the spine.[5] Respondent's routine use of inappropriately high levels of the anesthesia impacted the diagnostic results in that other areas of the spine may have been blocked, thereby reducing the predictive accuracy of the procedure.[6]

During a 12-14-12 medial branch procedure on Patient 1, Respondent used four times the recommended dosage of lidocaine.[7] While performing the same procedure on Patient 2 on 11-8-12, Respondent inappropriately used 2mls 1% lidocaine x8.[8] On 4-8-13 Patient 3 received 2mls of 1% lidocaine.[9] On 1-11-13 Patient 4 received 2mls .5% bupivacaine x8 for the same procedure. On 5-10-12 Patient 7 received 2mls of .75% bupivacaine x3.[10]

Respondent relied on the 2006 article, *Therapeutic Cervical Medial Branch Blocks in Managing Chronic Neck Pain: A Preliminary Report of a Randomized, Double-Blind Controlled Trial* – authored by Laxmaiah Manchikanti, to show this these doses of local anesthesia were appropriate.[11] Respondent did not submit this text or any excerpt from this text as an exhibit. The Board did not find this evidence persuasive in addressing this particular concern. With regard to this argument, the Board agreed with Dr. Fanciullo's summation that "[t]here are

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[5] Day 2, p. 11. All such references refer to the transcript of this proceeding.
[6] Day 2, p. 9-10.
[7] Day 2, p. 56.
[8] Day 2, p. 68.
[9] Day 2, p. 94.
[10] Day 2, p. 124.
[11] Day 3, p. 237-239 and Exhibit BB.

always going to be outliers who may be using something that may not be consistent with what the majority of other providers provide."[12]

B. Contraindicated Procedures

Respondent engaged in professional misconduct by performing numerous injection procedures on patients when such procedures were contraindicated for the patient's diagnosis. During the last 3 ½ months of Patient 5's life, Respondent performed more than 13 injections on this individual. During that time period Patient 5 was being treated with Coumadin and had International Normalized Ratio (INR) results as high as 7. On more than one occasion during those injections the chart indicated Coumadin was being held as the result of an elevated INR. No evidence was presented to the Board indicating laboratory values were checked on the day of a procedure when Coumadin was on hold as the result of recent elevated INRs.

On 2-14-11 Respondent performed a stellate ganglion block and a lumbar sympathetic block while Patient 5 had an INR of 2.5.[13] On 5-10-13 Respondent performed a stellate ganglion block even though Patient 5 had an INR of 2.7.[14]

Dr. Fanciullo testified about the inappropriateness of performing these procedures on patients who take anti-coagulants. There was no evidence that the anticipated benefits of performing these procedures on a patient with such a high INR outweighed the risks. In fact, the medical record showed that Patient 5 only received relief for about one week following these procedures.[15]

The Board finds on multiple occasions Respondent put patient 5 at increased risk for bleeding. There is no documentation of Respondent having adequate discussions with Patient 5 informing Patient 5 that the risk of bleeding was significantly higher than usual.

Respondent also performed numerous injections on Patient 5 despite the presence of two serious infections. Dr. Fanciullo provided the following testimony:

> [I]n general, we don't like to do any of these procedures while patients are on antibiotics for acute infection. If somebody has got an abscessed tooth and their dentist treated them for it with two weeks of Ampicillin, if it's thirteen days later and the patient comes into the office and they're still on antibiotics, we will not do it, we'll wait until they're off antibiotics until we do these injections if they have an acute infection…if it's for an acute

[12] Day 3, p. 243.
[13] Day 3, p. 98.
[14] Day 3, p. 102.
[15] Day 3, p. 98 – 104.

> infection, that is a real contraindication for doing this procedure....we're passing a needle through and creating a wound in a deep part of the body, and bacteria that are in your bloodstream have a tendency to land and stick to parts of the body where there is injury.[16]

On 5/20/10 Respondent performed a sympathetic block on Patient 5, despite a potential wound infection.[17] Respondent continued to perform injections on Patient 5 even after a MRSA diagnosis and a subsequent unrelated infection in Patient 5's foot. [18]

C. Inappropriate Procedures

Respondent performed numerous inappropriate procedures on patients. He performed a medial branch block on Patient 6 even though this patient had experienced 100% relief from a previous SI injection and thus had no demonstrable need for any additional procedures:[19]

> [Patient 6] got 100 percent relief from a transforaminal bilateral SI injection, and what makes me think she has facet arthritis? She got relief from it – 100 percent relief from a different injection. And it implies to me that that's the cause of her pain and why in the world would you do something – a completely different procedure when she had total relief from something else already?[20]

Respondent also performed a medial branch block on Patient 7 even though this patient had experienced 70% relief from an SI and Piriformis injection:[21]

> [Patient 7] got 70% relief again from her SI Joint injections and her Piriformis injections bilaterally and now her pain came back and now...these folks are proposing a different injection. So if you got 70% relief from one injection, why wouldn't you repeat that same injection? Why would you go ahead and do a different injection?[22]

Respondent performed a 7-12-13 Bilateral SI Transforaminal Epidural Steroid Injection on Patient 1. There was no documented justification for this procedure. The patient's complaint was low back pain, which traveled into the posterior leg to the knee and lateral thigh. A

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[16] Day 3, p. 69, 71.
[17] Day 3, p. 70. Respondent had actually prescribed Keflex for Patient 5 three days prior to this procedure.
[18] Day 3, p. 78, 96.
[19] Day 2, p. 114.
[20] Day 2, p. 114.
[21] Day 2, p. 120.
[22] Day 2, p. 120.

Bilateral SI Transforaminal Epidural Steroid Injection is not indicated for these symptoms and thus could not treat this pain.[23]

Respondent performed an 8/30/12 Bilateral SI injection on Patient 3 as well as bilateral T1, T2, T3 and T4 medial branch blocks. This was not indicated based on the patient's documented complaints of pain in the neck and scapular region. T1, T2, T3 and T4 could not have been responsible for pain in those locations.[24]

As Dr. Fanciullo testified, Respondent performed numerous unnecessary medial branch blocks on patients. The type of medial branch block performed in these cases is a diagnostic test which "should be done once or twice to determine whether or not a patient is a candidate for radiofrequency..."[25] However, Respondent performed additional unnecessary medial branch blocks on numerous patients, including Patients 1,[26], 3[27] and 7[28].

Respondent presented evidence that a 2006 article entitled *Therapeutic Cervical Medial Branch Blocks in Managing Chronic Neck Pain: A Preliminary Report of a Randomized Double-Blind, Controlled Trial* indicated that medial branch blocks can be used therapeutically.[29] The Board was not persuaded by this argument. Instead, the Board found Dr. Fanciullo's testimony to carry significantly more weight than a dated article. Additionally, a review of the medical record exhibits revealed that in the vast majority of medial branch blocks performed by Respondent the patient's pain level did not improve.[30] In some cases, the patient's pain level worsened after the medial branch blocks. Respondent's own documentation undercuts any argument that these procedures were used for therapeutic purposes.

D. **Inefficacious and/or Wrong Site Procedures**

Respondent engaged in professional misconduct by continuing to perform injections on patients despite the absence of significant or long lasting pain relief. He also performed numerous procedures without confirming that he had correct needle placement.

In numerous Bilateral Sacroiliac (SI) injections, there is no documentation that Respondent entered the sacroiliac joint and, if there were images saved, they do not reflect the

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[23] Day 2, p. 179.
[24] Day 2, p. 71.
[25] Day 2, p. 52.
[26] *See* Exhibit 1-a.
[27] *See* Exhibit 3-a.
[28] *See* Exhibit 7-a.
[29] Day 3, p. 234-243 and Exhibit BB.
[30] *See* Exhibits 1, 1-a, 3, 3-a, 7 and 7-a.

correct placement of the needle. Additionally, Respondent failed to use a contrast agent. Dr. Fanciullo provided the following summary of this procedure:

> [T]here's an anterior and posterior margin of the joint...the general technique is to try to line up the anterior and posterior margins so if you put a needle straight down, and those anterior and posterior margins are lined up, the needle will go into the joint and so the technique is to use your fluoroscopy machine to line up those two margins...[t]he needle is inserted into the joint, dye is injected to prove that you're in the joint and whatever you're injecting follows that local anesthetic and the steroid follows that.[31]

Respondent did not follow this procedure in any of the Bilateral SI injections reviewed. Respondent engaged in professional misconduct by failing to utilize appropriate diagnostics and diagnostic imaging during the course of Bilateral SI injections, thereby increasing the risk of harm to patients, including, but not limited to, increasing the risk of damage to internal organs, nerves, and blood vessels and reducing the likely efficacy of the procedures. Even when his patients experienced no pain relief, Respondent repeated this procedure numerous times.

Following a 10-20-11 injection on Patient 1, Patient 1 indicated that the injection made the pain worse.[32] Respondent did not document entering the joint, he failed to save any images and he did not use contrast dye. This injection was repeated on 12-20-11 and again there was no documentation of entering the joint, no saved images, and no contrast agent used.[33] During an office visit two days later Patient 1 reported no pain relief. Despite this, Respondent performed the procedure again on 1-17-12. Respondent did not document entering the joint, he failed to save any images and he did not use contrast dye[34] During a 1-23-12 visit, Patient 1 report no pain relief from these procedures.[35]

Respondent also performed numerous Bilateral SI injections on Patient 2. For an 8-4-12 injection, Respondent saved an image but it did not show proper needle placement and no contrast agent was used. The same procedure was conducted on 9-28-12. There is no documentation that the needle went into the joint. Although two images were saved, the placement was incorrect in one and unreadable in the second. Again, no contrast agent was used.

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[31] Day 1, p. 306-307.
[32] Day 1, p. 328.
[33] Day 1, p 325.
[34] Day 1, p. 327.
[35] Day 1, p. 328.

Respondent performed a 1-11-13 procedure on Patient 2. The procedure note does not say that the needle entered the joint, no images were saved and no contrast agent was used.

Respondent also performed numerous Bilateral SI injections on Patient 3. For an 8-30-15 injection, the procedure note does not document that the needle entered the joint. Images were saved but do not show the needle touching the joint and no contrast agent was used. According to a 9-4-12 phone note, Patient 3 did not experience any pain relief from this procedure. During a 6-3-13 procedure, the procedure note does document that the needle entered the joint. One image was saved and it shows the needle 1 centimeter medial to the joint.[36] During a 6-20-13 office visit, Patient 3 reported no relief from this procedure. There was no reason to perform additional procedures after these two because there is no documentation that patient received any significant or lasting relief. However, Respondent performed another Bilateral SI injection on 6-27-13. Again, the procedure note does not say that the needle entered the joint. Both saved images show the needle far medial to the joint and again no contrast agent was used. [37] A subsequent office visit confirms that Patient 3 received no relief from this procedure.[38]

Respondent's counsel challenged Dr. Fanciullo's testimony on the need for contrast dye for SI injections. Respondent relied on the 1998 text *Atlas of Interventional Pain Management*, which stated "in most instances there is no need for contrast injection to confirm needle location" for SI injections.[39] Respondent only submitted the cover pages and copyright pages of this text. During the December 17, 2014 hearing and in response to a Board request, Respondent's counsel stated that he would submit the excerpts as well. This did not happen.[40]

The Board finds that Respondent engaged in professional misconduct by performing an excessive amount of injections on numerous patients. Dr. Fanciullo testified regarding the acceptable frequency of various injection procedures:

1. Epidural steroid injections – limit to 3/year
2. Trigger point injections – every 6 weeks or 1/month
3. Medical branch block – 2-3/year
4. Radio frequencies – 2/year
5. Stellate ganglion blocks – 2-3/year

[36] Day 1, p. 351.
[37] Day 1, p. 353-354.
[38] Day 1, p. 354.
[39] Day 3, p. 196 and Exhibit X.
[40] Day 3, p. 200.

6. Lumbar sympathetic blocks – 2-3/year

7. Cervical epidural steroid – 3/year

8. Lumbar epidural steroid – 3/year

Patient 1 had approximately 15 injections during a two-year period beginning in October of 2011. The treatment record did not justify this many injections.[41]

Patient 3 had approximately 20 injections in a one-year period beginning in July of 2012. There was inadequate documentation to justify this many different procedures.

Patient 5 had approximately 134 injections over an 18-month period beginning in January of 2010. This includes approximately 68 lumbar sympathetic block procedures. Respondent repeated these procedures despite no significant or long lasting improvement in the patient's pain or function. There was inadequate documentation to justify this many injection procedures.[42]

Patient 7 had approximately 21 injections over a 27-month period beginning on July 2011. There was inadequate documentation to justify this many procedures.[43]

The Board agreed with Dr. Fanciullo's summary that the Repondent "performs the same procedures over and over despite the fact that there is no substantial long-lasting relief that the patients get and that there are barely, if ever indications for actually conducting those procedures and often the indications that are cited are not really indications for the procedure."[44]

E. Inadequate Use of Diagnostics

Respondent performed numerous epidural steroid injections without first obtaining an MRI of the patient. The Board agreed with Dr. Fanciullo's testimony that the standard of care requires an MRI prior to such procedures.[45] Respondent also failed to use fluoroscopy and contrast dye during these procedures.[46] Dr. Fanciullo provided testimony on the serious neurological injuries that can result from cervical epidural injections and Respondent's failure to utilize fluoroscopy and contrast dye with this particular procedure falls below the standard of care.[47]

II. Prescribing Issues

A. Inadequate Patient Assessments

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[41] Day 3, p. 110.
[42] Day 3, p. 129.
[43] Day 3, p. 132.
[44] Day 3, p. 134.
[45] Day 2, p. 161.
[46] Day 2, p. 159.
[47] Day 2, p. 163.

The Board agreed with Dr. Fanciullo's testimony that Respondent's "[o]piate management was done hastily, dangerously, and without adequate documentation." The Board finds that Respondent engaged in professional misconduct by prescribing opioids to patients without first obtaining a patient history, including alcohol and substance abuse. This information is critical for any clinician to perform an adequate risk assessment to determine if a patient is a good candidate for opioid therapy. Dr. Fanciullo testified that such an assessment stratifies patients as low, moderate or high risk.

> Have you ever had a problem with alcoholism or drug abuse? … [H]ave you ever been incarcerated? We ask that of all of our patients to whom we prescribe opioids. Do you smoke cigarettes? We know there is a correlation between cigarette smoking and substance abuse, and cigarette smoking along can increase your risk category from… low to moderate…Do you have a family history of alcoholism or drug abuse? Have you been a victim of physical or sexual abuse? All of these elements will increase your risk of using these drugs and it's important for us to question our patients if not about all of them, about a lot of them.[48]

Respondent failed to obtain an adequate personal and family history on Patient 1. He also failed to conduct a risk stratification on this patient. The Board agreed with Dr. Fanciullo that the form filled out by patients at an initial visit is inadequate for these purposes. Even if the patient filled out the form when he or she came in, those same topics should be discussed and documented in the medical record.[49]

Respondent failed to obtain an adequate personal and family history for Patients 3 and 7. Consequently, the risk stratification for these patients is either absent or inadequate. "[For Patient 3] it is impossible to manage pain in somebody with untreated severe psychiatric illness either with medications or with procedures"[50] There was no medical indication to "there is no medical indication for [Patient 7] to be treated with high dose opioids."

Respondent's risk assessment for Patient 4 was both inadequate and inaccurate, in light of this patient's prior heroin use. The Board agreed with Dr. Fanciullo's testimony that the risks of opioid prescribing did not outweigh the benefits with this particular patient.[51]

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[48] Day 1, p. 61-64.
[49] Day 1, p. 89 – 90.
[50] Day 1, p. 139.
[51] Day 1, p. 182.

B. Inadequate Informed Consent and Lack of Treatment Plan

Respondent engaged in professional misconduct by prescribing opioids to patients without first discussing the risks and benefits of such therapy and creating a treatment plan

Respondent failed to establish a treatment plan with multiple patients who were receiving high opioid doses for pain relief. Treatment plans and goals should have been established as early as possible in the treatment process and should have specified the objectives that would be used to establish treatment progress.

Respondent did not develop a treatment plan or goals for Patient 1 and there was no documentation to indicate that the treatment agreement had been reviewed and signed by the patient.[52] Respondent did not develop a treatment plan or goals for Patients 2,[53] 4, or 7.[54]

Patient 3 had previously been kicked out of practice for "failure to take medications as prescribed."[55] Reestablishing treatment requires risk assessment and stratification but this was not done.[56] She is at high risk for developing a problem with addiction or diversion due to family history and her own mental health diagnoses, but there was no documented discussion of risks and benefits of opioid therapy in the record.

While a simple notation that "risks and benefits discussed" may suffice in some instances, this was inadequate with Patient 4, based on the polysubstance abuse history. Respondent also neglected to develop treatment goals for this patient.

C. Unjustified Opioid Prescribing

Respondent engaged in professional misconduct by failing to document any justification for the initial prescription and/or increasing the doses of multiple opioid prescriptions for numerous patients. It is well established that the standard of care for opioid prescribing for chronic non-cancer pain requires that patients be started on the lowest possible doses of opioids.[57] Respondent repeatedly started patient at high doses and ordered dangerous and unjustified increases. Dr. Fanciullo provided the following testimony when asked about the risks associated with rapidly titrating a patient to a high dose of opioids.

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[52] Day 1, p. 182.
[53] Day 1, p. 117-118.
[54] Day 1, p. 235.
[55] Day 1, p. 147.
[56] Day 1, p. 149.
[57] Day 1, p. 68.

> The risk is death, [that] is the thing that we most worry about…I don't have to go into the fact that there's a public health crisis in the State of New Hampshire right now regarding the use of opioids…if you walked into my office and I gave you 100 milligrams of morphine equivalence per day, there's a fair chance that you would die from that dose if you took it all…it may be that we would titrate you up to that dose…[b]ut it would be irresponsible to start you on that high dose because I would risk harming you.[58]

Following an unsuccessful injection on Patient 1 Respondent increased the dose of oxycodone by almost 50% during an 11-8-11 phone call. Respondent failed to assess this patient's pain before this increase and there was no justification in the medical record.[59] Two months later, Respondent again increased Patient 1's oxycodone dose by 60 milligrams (morphine equivalent dose of 270 mg). Less than two months later, (on 4-25-13), Respondent added eight milligrams of exalgo.[60] A month later (5-23-13), Patient 1's pain assessment is a 9 out of 10, and Respondent doubles the dose of exalgo, putting this Patient at almost 300 mg of morphine dose equivalent. There is no evidence in this record that Patient 1's pain score went down, [or] function or mood improve[d].[61] "Once you hit a dose above 200 milligrams we have no idea what the risks are, and that needs to be discussed with the patient."[62] On a 7-8-13 visit Patient 1's dose of exalgo was doubled to 16 milligrams twice a day and her documented pain level was 8 out of 10.[63] The Board agrees with Dr. Fanciullo's assessment that "[g]iven the documentation in this medical record, those doses are entirely inappropriate."[64]

Over the course of one month, Respondent increased Patient 3's exalgo prescription from 8 milligrams to 32 milligrams without a sufficient rationale. Respondent initiated Patient 3's opioid therapy with 8 milligrams of exlago daily which is equal to about 60 milligrams of morphine/day. There was no indication in the record that Patient 3 had been taking opioids prior to this script. The Board agrees with Dr. Fanciullo's assessment that this is a high dose for opioid naïve patient. At Patient 3's second appointment, Respondent prescribed flexeril, exalgo,

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[58] Day 1, p. 70-71.
[59] Day 1, p. 93-94.
[60] Day 1, p. 98-99.
[61] Day 1, p. 103.
[62] Day 1, p. 104.
[63] Day 1, p. 108.
[64] Day 1, p. 108.

16 milligrams/day and Cymbalta 30 milligrams/daily. This is 100 percent increase in dose.[65] On 8-13-12 Respondent doubled the exalgo to 16 milligrams twice/day.[66] In April of the following year, Respondent doubled Patient 3's dose of Percocet from 40 milligrams/day to 80 milligrams/day. Patient ultimately prescribed (10) 30 milligram oxycodone tablets/day and 16 milligrams 4x/day. As Dr. Fanciullo testified, this is an "astoundingly high dose and dangerous for the patient and the community."[67]

Subsys is an oral fentanyl spray, which is about 80 times as strong as morphine and is very short-acting. Prescribers must take and pass an on-line course to prescribe Subsys and they must sign an affidavit that they will not prescribe except for the treatment of cancer pain. Usual starting dose is 100 micrograms and package insert recommends not starting above that even in patients who are familiar with opioids because the response is unpredictable. The package insert states "the initial dose of subsys is always 100 micrograms with the only exception of patients already using Actiq [fentanyl lollipop]."[68]

On 7-30-13, Respondent prescribed 400 micrograms, four times the recommended dose, for Patient 7. This Patient did not have cancer. On 9-12-13, Patient 7's pain level had actually increased after taking subsys.[69] Patient 7 was on opioid therapy for nine months without any indication that her condition had improved in any way. There is no indication that this patient's pain level decreased or functionality increased. There is no indication that she was receiving any benefit from opioid therapy.[70]

Dr. Fanciullo testified that "[o]f the patients that I reviewed, he did not manage them with any pharmacological or other skill whatsoever."[71] The Board agrees with this assessment and finds that Respondent's prescribing put both his patients and the public at risk.

D. Aberrant Drug Behavior

Respondent engaged in professional misconduct by continuing to prescribe opioids for numerous patients despite drug screen results showing the patient's non-compliance with the medication regimen. Patient 1 underwent a drug screen which was negative for exalgo although the patient claimed to have taken that medication on the previous day. Dr. Fanciullo testified

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[65] Day 1, p. 154-155.
[66] Day 1, p. 159-160.
[67] Day 1, p. 177-178.
[68] Day 1, p. 247-255 and Exhibit 26.
[69] Day 1, p. 248-255.
[70] Day 1, p. 238.
[71] Day 1, p. 258-259.

that this result "[i]mplies either that the patient is binging on the drug, using a lot of the drug early in the month and running out, or is diverting the drug." Respondent continued to prescribe exalgo at this office visit and even noted in the record that the drug screen was fine. [72]

Patient 4 underwent a urine drug screen on or about 12-6-12. While this screen was appropriately positive for opiates and benzodiazepines, it was also positive for amphetamines and cocaine.[73] Neither of these substances was appropriate. Two days earlier, Respondent approved Patient 4 taking "a few extra pills" for increased pain and authorized the filling of her next prescription two days early. On 12-20-12, Patient 4 called the Respondent stating that her next office visit is beyond the date of her next refill. Despite documenting, in response to that call, that Patient 4 needed to come into the office with her mom to discuss her recent drug test results, Respondent proceeded to prescriber her 42 tablets of Roxicodone (oxycodone HCL) 30mg two weeks later. There was no documentation of a corresponding office visit or an explanation as to why that prescription was necessary. Further, there is no documentation that the drug test results were discussed with Patient 4 at her next office visit with Respondent.

During a 1-10-13 office visit, Patient 4 disclosed to Respondent that she met with her parole officer who noted that her pills were different. She claimed that she changed her pills with her mom because her mom's pills work better. Respondent documented that he instructed Patient 4 that he would no longer prescribe her Roxicodone and that he would place her on a trial of Oxymorphone and refer her to the Suboxone clinic. However, without an adequate documented justification, Respondent prescribed 75 tablets of Roxicodone (oxycodone HCL) 30mg to Patient 4 just 11 days later. Also, there is no documentation to indicate that the Respondent referred Patient 4 to a Suboxone clinic at or around the time of that visit. It was not until July 19, 2013 that Respondent Clough referred Patient 4 to a Suboxone program.

Patient 6 had a drug screen on 10-5-11. She had a low level for amphetamine but it was below the cut off and should have tested positive for oxycodone and possibly oxymorphone. There was no discussion of these results at her next visit on 11-4-11 and she was issued prescriptions for morphine and oxycodone.[74]

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[72] Day 1, p. 109-111.
[73] Day 1, p. 186-188.
[74] Day 1, p. 219-220.

Patient 6 had a drug screen on 3-23-12 which was inappropriately negative for morphine and oxycodone. Patient 6 then failed to come in for a pill count but when Respondent next saw her on 4-20-12 he again prescribed morphine and oxycodone.[75]

E. Prescribing Despite Contraindications

Respondent engaged in professional misconduct by writing numerous prescriptions when such medications were contraindicated for the patient due to other medications and/or underlying health conditions.

Respondent simultaneously prescribed Vicodin and Percocet to Patient 2. Dr. Fanciullo testified that both of these drugs are short-acting analgesics and there is "no pharmacological reason to use both."[76] Patient 2 had Hepatitis C and therefore should not consume Tylenol (acetaminophen). This contraindication was noted in the record. Vicodin contains acetaminophen and Respondent actually prescribed the dose with the highest level of acetaminophen for this patient.[77] This put the patient at risk for acute hepatic necrosis.[78]

Respondent prescribed Patient 3 Percocet, ultram, butrans and flexeril. Dr. Fanciullo testified that it was clinically inappropriate to provide Butrans, Percocet and Ultram at the same time. "Butrans is an opioid antagonist and it binds to the same receptors that Percocet binds to…the Butrans and Percocet are fighting for the same receptors. Butrans in general binds to these receptors much more strongly than Percocet, so the Percocet would really have no affect at all . . . [U]ltram is a partial new agonist. It binds to the same receptors also…"[79]

Respondent stopped Risperdal for Patient 7 which was being prescribed by another provider – complex pharmacology and he does not appear to have any expertise in this area.[80]

Violations

There were additional examples of the violations noted above, but the examples detailed above represent the most egregious illustrations. The Board finds that the conduct detailed above constitutes violations of RSA 328- D:6, III, RSA-D:6, IV, RSA 328-D:6, XI, Med 609.01 (a) (5),

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[75] It was not until May 10, 2012 that a letter was sent to Patient 6 advising that Pain Care will no longer prescribe "opioid/narcotic medications" due to repeated non-compliance with a pill count. Day 1, p. 229.
[76] Day 1, p. 123.
[77] Day 1, p. 120.
[78] Day 1, p. 121.
[79] Day 1, p. 171.
[80] Day 1, p. 242

Med 609.01 (a) (6), Med 609.01 (8) and (10), and the *American Academy of Physician Assistants* Guidelines regarding competency.

Insufficient Evidence

The Board concluded that Respondent did not engage in professional misconduct regarding the remaining allegations.[81]

Disciplinary Action

After making its findings of fact and rulings of law, the Board deliberated on the appropriate disciplinary action, pursuant to its authority in RSA 329:17, VII. In reviewing both the procedures conducted and the opioids prescribed, it is clear that the Respondent repeatedly put his patients at risk.

Based upon the above, the Board has voted to impose discipline as follows:

IT IS ORDERED that Respondent's license to practice as a Physician Assistant is permanently restricted to exclude the practice of chronic pain management. Respondent shall be permanently restricted from prescribing all scheduled II-IV controlled drugs. Respondent shall be permanently restricted from performing pain procedures.

IT IS FURTHER ORDERED that the Respondent's license to practice as a Physician Assistant is suspended for a period of ninety (90) days.

IT IS FURTHER ORDERED that Respondent is reprimanded.

IT IS FURTHER ORDERED the Respondent to meaningfully participate in a program of thirty (30) hours of continuing medical education in the area of medical record documentation. These hours shall be in addition to the hours required by the Board for renewal of licensure and shall be completed within twelve (12) months from the effective date of this Order. Within fifteen (15) days of completing these hours, the Respondent shall notify the Board and provide written proof of completion.

IT IS FURTHER ORDERED that this Final Decision and Order shall become a permanent part of the Respondent's file, which is maintained by the Board as a public document.

IT IS FURTHER ORDERED that this Final Decision and Order shall take effect as an Order of the Board on the date an authorized representative of the Board signs it.

BY ORDER OF THE BOARD/*

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[81] Day 1, p. 328.

Dated: October 13, 2015

Penny Taylor

Penny Taylor, Administrator
Authorized Representative of the
New Hampshire Board of Medicine

/* Board members, Amy Feitelson, M.D., Robert Andelman, M.D., and Lou Rosenthall, M.D., recused. Members Emily Baker, M.D., Michael Barr, M.D. and Daniel Morrissey did not participate.