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BY ELECTRONIC and FIRST CLASS MAIL

John U. Young
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1730 M Street, N.W.
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Re: OSC File No. DI-13-4505

Dear Mr. Young:

On behalf of Dr. Mohit Pawan Chopra, I am submitting the following comments on the Report and Supplemental Report of the VA's Office of Medical Inspector ("OMI") dated January 2, 2014 and May 1, 2014, respectively.

As a preliminary matter, Dr. Chopra has asked me to express his gratitude to the United States Office of Special Counsel Disclosure Unit for its work in relation to his whistleblower disclosures.

I. Facts Found by OMI

Based on the OMI's investigation of Dr. Chopra's whistleblower disclosures and his expressed concerns regarding the care being provided in the long-term care units of the Brockton VA's Community Living Center ("CLC"), his allegations were largely substantiated, and the following facts are incontrovertible:

Veterans 1 and 2 were 100 percent service-connected for psychiatric disorders and were admitted to the CLC primarily for mental health problems, but had to wait more than eight (8) and (7) seven years respectively before their needs were identified while residing as inpatients at a Brockton VA facility, which is administered by the VA Boston Healthcare System ("VABHS").

More specifically, the OMI's investigation and reports confirm that:

Veteran 1 is an Army combat Veteran of Vietnam, who is 100 percent service-connected for major depressive disorder with psychotic features, who was first admitted to the Brockton CLC in March 2003 due to suicidal ideation and has been a resident there ever since. Despite the reason for this Veteran's admission to the CLC, his pre-2003 history of eight (8) prior admissions to the VA due at least in part to psychiatric reasons, and his history of suicide attempts, including stabbing himself in the stomach and medication overdose, he did not receive his first significant psychiatric evaluation until more eight (8) years after his 2003

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admission. On June 17, 2011, Dr. Chopra provided this first psychiatric evaluation.

Veteran 2, who sadly is now deceased, was an Army Green Beret who was 100 percent service-connected for the mental illness known as Post-traumatic Stress Disorder ("PTSD"). He was initially admitted to the CLC, being transferred there from an inpatient psychiatry unit of the VABHS, on February 4, 2002, more than twelve (12) years before he was given psychiatric consultation by Dr. Chopra. In early 2002, this Veteran was discharged to a foster home, but three (3) years later, deemed to need "more intensive care" and, therefore, was re-admitted to the Brockton CLC on June 13, 2005 "with a diagnosis depression, psychosis, dementia and Parkinson's." Not until more than seven (7) years after his re-admission on the grounds that he required "more intensive care", did this Veteran receive care from a psychiatrist, specifically Dr. Chopra, on August 3, 2012. Unfortunately, due to his separation from employment on January 3, 2013, Dr. Chopra was no longer available to provide care, and this Veteran was never seen by another psychiatrist, dying on May 18, 2013, after being a resident at the CLC for almost eight (8) years.

As a former VA employee, Dr. Chopra has been required to operate based on his best memory of the facts, i.e. at the time of his whistleblower disclosures to the Office of Special Counsel, he no longer had access to these Veterans or their electronic health records (EHR).

II. Comments Regarding OMI's Factual Findings and Conclusions

A. Regarding Veteran 1:

• The OMI's January 2, 2014 report indicates that Dr. Chopra "recommended changes to [this Veteran's] antidepressant medication." (See page 4) Veteran 1 had major depressive disorder with psychotic symptoms. This is a condition that is extremely unlikely to respond to any intervention that does not include medications. It is Dr. Chopra's best recollection that, at the time he first provided care to this Veteran on June 17, 2011, this Veteran was not on any antidepressant medication and had not been for the eight (8) years prior to Dr. Chopra's visit and assessment. It is Dr. Chopra's best recollection that it was he who initiated this Veteran's treatment of antidepressant medication. If that recollection is correct, the use of the phrase "changes to" should be replaced with "initiation of."

• The OMI's January 2, 2014 report indicates that Dr. Chopra returned to see Veteran 1 on November 12, 2012 "... and noted that the resident had regressed and that his depressive symptoms had become more severe." (See page 5). As noted by the report, the Veteran was refusing at that time to take any medication, and Dr. Chopra urged the CLC team to convince Veteran 1 to change his mind.

Dr. Chopra's employment ended shortly thereafter. Unfortunately, based on the OMI's report, it appears that it was another nine (9) months before this Veteran was seen by another psychiatrist.

B. Regarding Veteran 2:

• The last line on page 6 of the OMI's report states, "There was no evidence of a systematic process or effort to reduce and/or eliminate the use of his antidepressant and psychotropic medications." It is Dr. Chopra's recollection that, in fact, the reason this Veteran was identified and a consult for this Veteran initiated in August of 2012 was because the VABHS clinical pharmacist (Meeaeng Meng) was asked in 2012, after Dr. Chopra's urging, to compile a list of Veterans at the Brockton CLC who were on antipsychotic medications.

• The January 2, 2014 OMI report also notes that this Veteran was "on a number of medications including several antidepressants and other psychotropics." (See page 6). It is Dr. Chopra's recollection that, in August of 2012 when he saw this Veteran, the "antidepressant" this Veteran was on was quetiapine. However, it is generally misleading to refer to quetiapine as an "antidepressant." Quietiapine (Seroquel®) is an antipsychotic medication. While, at certain high doses, it is approved by the FDA as an antidepressant for individuals diagnosed with bipolar disorder. Although in making his whistleblower disclosure, Dr. Chopra had recalled this Veteran had been diagnosed with schizo-affective disorder, according to the OMI's report, he did not have this diagnosis, nor was he diagnosed with bipolar disorder.

• It would also be important to point out that quetiapine, like other atypical antipsychotic medications and all similar medications in that class, carries an FDA black-box warning about the risk of stroke (or stroke-like events) and sudden death in persons with dementia, one of the diagnosed conditions of this Veteran. It is also Dr. Chopra's recollection that this Veteran was on high doses of quetiapine.

• Dr. Chopra recalls that, at the time of his August 2012 assessment, this Veteran was also on psychotropic medications, including sodium valproate (Depakote®). The OMI's report notes on page 6 that "while in the CLC, the Veteran had approximately two liver function tests per year and approximately three complete blood count tests per year." However, it is Dr. Chopra's recollection that, during the seven-year period prior to his assessment of this Veteran on August 3, 2012, his serum valproic acid level had not been checked. Thus, while Veteran 2 was found by OMI to have undergone some laboratory testing for potential side-effects, the testing was by no means comprehensive or complete.

• There is emerging evidence, some of which was available and known to Dr. Chopra in August of 2012, that the number needed to harm ("NNH") for valproate is less than the NNH for quetiapine, indicating that the Veteran was placed at potentially a much greater risk from unmonitored valproate therapy, with added on risk from treatment with the quetiapine. This research, which now includes the findings from a recent study from a very large dataset (45,699 matched pairs) of the VA's very own database, was presented at the American Association of Geriatric Psychiatry's Annual Meeting earlier this year (2014) and is referenced below. [1]

• This Veteran died at the age of 66, which is almost a full decade before what is considered to be the average life-expectancy for men in the United States.

• The OMI's conclusion that "[g]iven his extensive mental health issues, more frequent assessments by psychiatry service would have been beneficial" (see page 7) is an understatement that serves to obfuscate the extent of the neglect of this Veteran who waited no less than seven (7) years for a substantial and appropriate psychiatric assessment.

C. Regarding Veteran 3:

• Dr. Chopra alleged that "[b]enzodiazepine, a psychotropic medication, was administered to [this Veteran] for more than two years without any attempt to decrease or discontinue use, when specific clinical directions and indications stated that this medication should not be given to this individual." The OMI decided not to substantiate this allegation. Dr. Chopra disagrees with the OMI's decision.

• The motivating concern behind Dr. Chopra's whistleblower disclosure in relation to Veteran 3 was the fact that, for a period of two years, six months, and twenty-one days (give or take a few days) following his initial assessment on February 10, 2010, the primary medical care providers of an 82-year-old Veteran with diagnosed dementia made no apparent effort to evaluate the need for, or continue to decrease the dose of a benzodiazepine (in this instance, lorazepam) that has been shown to be associated with a multitude of problems in older adults, including an increased risk of mortality. [2] Dr. Chopra stands by his allegations and believes that the essence of his allegations with regard to Veteran 3 should have been substantiated by the OMI.

• The OMI's January 2, 2014 report states, "OMI did not find evidence in the EHR of clinical direction or indication that benzodiazepine should not be given to this Veteran." (See pages 7-8). Of course, the only way that Dr. Chopra could fully respond to the contents of the OMI's findings on this Veteran would be by

reviewing this Veteran's electronic health record (EHR), including Dr. Chopra's own notes from February 10, 2010 and August 31, 2012 and all notes by all providers from the surrounding period.

• The OMI report notes that "[e]vidence-based recommendations of the American Geriatrics Society (2012) updated the criteria for potentially inappropriate medication use in older adults." (See page 8) The OMI report further notes that the American Geriatrics Society "... stated that older adults have increased sensitivity to benzodiazepines, which increases the risk of cognitive impairment, delirium, falls, fractures, and motor vehicle accidents, and should be reduced or eliminated if clinically appropriate." (See page 8) Veteran 3 was an 82-year old man and, therefore, qualified as an "older adult." Additionally, if there was no necessary reason for the administration of the benzodiazepine, it would be considered an "unnecessary" medication. [See relevance to 42 CFR § 483.25(l)(1) below].

• It is Dr. Chopra's recollection that during his initial evaluation of this Veteran on February 10, 2010, which was not requested until more than 100 days after the Veteran was admitted to the CLC, he determined that the most likely contributor to this Veteran's "worsening mental status" was the very high dose of olanzapine. (Dr. Chopra submits that it fair to characterize a 35 mg dose of olanzapine for an 82-year-old male as alarmingly high). The report notes that Dr. Chopra "... recommended a trial decrease in the dose of olanzapine." (See page 7)

• Dr. Chopra recalls that this Veteran was residing in [redacted] and under the care of Jack Earnshaw, Physician Assistant ("PA"), who supervised by Juman Hijab, MD.

• The OMI's report asserts that Dr. Chopra "recommended no changes in the doses for lorazepam." (See page 7). This assertion is inconsistent with Dr. Chopra's recollection of the facts. It is Dr. Chopra's belief that, sometime after his February 10, 2010 visit with this Veteran, he realized that the Veteran was also on a very high dose of the benzodiazepine. Dr. Chopra has a recollection of communicating to Mr. Earnshaw that it would be important to also decrease (until discontinued) the dose of lorazepam. Dr. Chopra regrets that he may not have documented this communication in his own note on February 10, 2010 in this Veteran's EHR. Dr. Chopra believes that it was as a result of his communication with Mr. Earnshaw that he (Earnshaw) decreased the Veteran's lorazepam dose by half (50 percent). Dr. Chopra has a recollection of being surprised, when he was again consulted by the CLC concerning Veteran 3 two and a half years later (August 31, 2012), to find that the medical staff had reduced the lorazepam dose only once and only down to 50 percent.

• The statement on page 8 of the OMI's report supports Dr. Chopra's recollection: "Between February 10, 2010 and August 31, 2012, Veteran 3's benzodiazepine (lorazepam) was reduced by 50 percent, from a maximum of 4 mg to a maximum of 2 mg. in a 24-hour period." Unfortunately, the OMI report does not indicate the date of the dosage reduction and only indicates that it took place on some unspecified date.

• As noted in the OMI's report, the Veterans at the Brockton CLC were under the direct care of the medical team (at the relevant time under Dr. Juman Hijab) Dr. Chopra, a psychiatrist, functioned entirely in a consultation-liaison role in the CLC, his "... visits and consultations ... [had] to be initiated by the unit psychologist, and [Dr. Chopra's] recommendations for treatment [were] passed on to the [CLC's] medical team." (See report at page 5). As noted above, Dr. Chopra has a recollection of being surprised and concerned when, upon being asked in August of 2012 to re-evaluate Veteran 3, he discovered that in the intervening two and a half years since his first visit, he found no apparent effort by the medical staff to reduce and discontinue the administration of the benzodiazepine or even progressively decrease the maximum dose of the benzodiazepine administered to this older Veteran. (The OMI's report makes it clear that any effort at reducing the benzodiazepine was partial, only reducing it to half of its 2010 level.)

D. Other Important Findings Contained in OMI's January 2, 2014 Report:

• The OMI's January 2, 2014 report states that the "VA has made a transition from an institutional medical model (nursing home) to a person-centered care model (CLC) in its long-term care facilities." (See page 2) The report continues, "The heart of person-centered care is the relationship between the resident and the frontline staff who care for the resident daily. The life of the resident is enriched when his or her desires are honored each and every day." (See pages 2-3). Based on the OMI's report and its substantiation of Dr. Chopra's allegations, there were instances of a deplorable failure to achieve the goals of a person-centered model at the Brockton CLC.

• The OMI's January 2, 2014 report describes the CLC at the VABHS's Brockton campus. (See pages 1 and 3) Specifically, the report elaborates that the "[c]urrent CLC strategy is to phase out existing long-term residents..." and further notes that "... the CLC has not admitted a new long-term care resident in over 3 years." (See page 3). (Since the report was written by OMI in January of 2014 based on a site visit in December of 2013, it is reasonable to infer that the last long-term care resident was admitted to the Brockton CLC sometime in 2010.) Further, the OMI report clarifies that the "CLC's changing focus is on short term stay and rehabilitative services." (See report at page 3). Dr. Chopra finds it deeply troubling that the neglect of long-term residents occurred during a period when

the VABHS management was actively pursuing a strategy to "phase out existing long-term residents."

III. Comments on the OMI's Recommendations

Dr. Chopra has the following comments with regard to the OMI's recommendations for the VABHS.

Regarding Recommendation 1:

"All CLC residents receiving antipsychotic/psychotropic medications should be assessed at least annually by the consultative liaison psychiatrist to ensure the particular medication and dosage amount is consistent with the desired effects and with VA standards of care." (See Supplemental Report at page 1)(Emphasis added).

Dr. Chopra notes that Policies and Procedures of the VABHS that were in existence at the time of this neglect of these Brockton CLC Veterans included the Patient Care Memorandum (PCM)-181-001-GEC, dated December 2010 and titled "Use Of Psychotropic Medications In The Nursing Home." The Memorandum states under Section 5.H, "It is recommended that such attempts must be made at least every six months in residents with stable conditions."

Dr. Chopra questions why the OMI's Recommendations set standards that are less rigorous than the VABHS's own existing policies, like increasing the inter-evaluation interval from six months to one year, rather than reinforcing and retaining the minimum of assessments every six months.

When, in September of 2012, Dr. Chopra made these disclosures of patient neglect internally to the Chief of Psychiatry at VABHS, Dr. John Bradley, his immediate response was that we, the Department, should strive to provide "at least out-patient levels of care" to these in-patient Veterans, which would translate into a consult visit every three to four months.

Regarding Recommendation 2:

"Current residents on these drugs who have not been seen by psychiatry in the past 12 months should be seen as soon as possible."

See comment above.

Regarding Recommendation 3:

"Develop a process to minimize or eliminate the necessity for psychotropic medications by considering other methods such as behavioral techniques, counseling, etc., to try for the desired resident outcomes."

Dr. Chopra is largely in agreement with the process outlined by the OMI in Recommendation 3. Dr. Chopra believes an additional recommendation is appropriate: Early identification of CLC Veterans needing psychiatric evaluations - particularly long term care residents who are most vulnerable to neglect - followed by regularly scheduled follow-up evaluations, preferably at four month, and no longer than six-month, intervals.

IV. Violation of Laws, Rules, or Regulations

The OMI's investigation "...did not find violation of statutory laws, rules, or regulations." (See January 2, 2014 report's Executive Summary at page iii.) Based on the OSC's request for clarification, the OMI's Supplemental Report of May 1, 2014 continued to assert that there was no violation of law, rule, or regulation and that no patient's rights were violated.

Dr. Chopra's comments concerning the OMI's assertions regarding violations of law, rule, or regulation are as follows:

A. VA Regulations at 38 CFR 51.120

The OMI's Supplemental Report asserted that 38 CFR 51.120(m)(1) and (m)(2) is not applicable to the VA's CLC in that the referenced regulation "sets forth the standards for State Veterans Homes, which are operated by various states." (See Supplemental Report at page 3)(emphasis added).

Dr. Chopra finds it troubling that the VA's Office of Medical Inspector seems prepared, without discussion or analysis, to hold state-run veterans' homes to a higher standard of care than the standard of care required of the VA's own facilities. To put it another way, Dr. Chopra is distressed by the OMI's failure to discuss or analyze the Brockton CLC's failure to monitor the use of unnecessary drugs, in general, and antipsychotic drugs in particular in ways that, assuming applicability, would violate 38 CFR 51.120(m)(2) and (38 CFR 51.120(m)(1). The OMI approach seems dismissive and aimed at avoiding, based on a technicality, any substantive discussion of the law and violation thereof.

In addition, VHA Handbook Sections 1145.01, titled "Survey Procedures for State Veterans Homes (SVH) Providing Nursing Home and Adult Day Health

Care" and VHA Handbook Section 1143.2, titled "VHA Community Nursing Home Oversight Procedures", both clearly specify that Long-Term Care ("LTC") institutions outside the VA have to meet VA standards in order to qualify as VA designated facilities. In other words, based on VA policies set forth in the foregoing VHA Handbooks, the standard of care for facilities outside the VA are the same as those within the VA's own facilities, and would therefore be illogical for the standards outlined in 38 CFR 51.120(m)(1) and (m)(2) to be inapplicable to the CLCs.

B. VA Regulations at 38 DFR 17.33

In response to OSC's belief that the OMI's findings in relation to Dr. Chopra's whistleblower disclosures suggest violations of 38 CFR 17.33 (entitled Patients' Rights), OMI's Supplemental Report denies any violation of 38 CFR 17.33 and concludes, "OMI feels that in some areas their care could have been better but OMI does not feel that their patient's rights were violated."

Dr. Chopra believes that all three of the Veterans on which his disclosures were based suffered from neglect and their rights were violated under 38 CFR 17.33. Dr. Chopra finds the OMI's cursory response, denying the suggestion that these Veterans' rights under 38 CFR 17.33 were violated, to be similarly dismissive and, therefore, troubling.

In particular, as to Veterans 1 and 2, he asserts that two individuals who were rated as 100 percent service-connected for psychiatric disorders and admitted to LTC for reasons of mental illness should not have waited for more than eight (8) and seven (7) years, respectively, for a thorough and appropriate psychiatric assessment. Such a long wait for appropriate care is neither safe nor humane.

Dr. Chopra believes that the facts support the conclusion that both Veteran 2 and Veteran 3 were not "free from any unnecessary or excessive medications," and that this fact also created an unsafe condition in violation of their rights under 38 CFR 17.33(e).

As the OMI January 2, 2014 report noted, prior to Dr. Chopra's August 3, 2012 assessment, Veteran 2 "was placed on a number of mediations including several antidepressants and other psychotropics." (See page 6 of the Report; emphasis added). In point of fact, Dr. Chopra's recalls that Veteran 2 was rendered so severely incapable from the combination of his neuro-psychiatric disorder and the high doses of unmonitored medications he had been on for so long at the time of his August 2012 evaluation that this Veteran was unable to talk

and ask for help, let alone inform his nurse that he has not been seen by a psychiatrist or other physician for many years.

Further, 38 CFR § 17.33 (e) Medication requires, "A review by an appropriate health care professional of the drug regimen of each inpatient shall take place at least every thirty (30) days." With regard to the Veterans who are the subject of Dr. Chopra's whistleblower disclosures, the review of drug regimen by an appropriate health care professional did not occur every thirty days, and that in case of Veteran 2, it occurred only once during the "rest-of-his-life" between June 13, 2005 and May 18, 2013. Additionally, for Veteran 3, while there might have been a one-time dose reduction over a 24 hour period, it is evident from the OMI's report that no progressive attempt to reduce or eliminate "unnecessary" medication occurred over the more than 2.5 year period between Dr. Chopra's first and second visits, or over the last three and a half years of his life as a resident of the Brockton CLC.

C. OBRA '87

Dr. Chopra notes that the VABHS's CLC at the Brockton campus purports to follow the guidance of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87")(Public Law 100-203), particularly the section referred to as the Federal Nursing Home Reform Act (42 CFR § 483). (OBRA '87 enacted broad nursing home-related reforms and applies to all nursing homes in the U.S. that are certified by CMS.) Even if, as a technical matter, VHA facilities are not subject to OBRA '87 or Centers for Medicare and Medicaid ("CMS") regulations, the VA, as a matter of policy, has adopted the same CMS standardized assessment and treatment instrument for its CLCs "... as means of ensuring consistency with national nursing home standards, meeting the accreditation standards of [The Joint Commission], and facilitating comparisons between VA CLCs and nursing homes in the community and private sector." (See VHA Handbook 1142.03 at page 1.)

The OBRA '87 regulations that Dr. Chopra believes were violated are:

- **42 CFR § 483.15** (Quality of Life);

- **42 CFR § 483.25** (Quality of Care), especially **Section (l)(1)** *Unnecessary drugs in General* and **(l)(2)** *Antipsychotic drugs;* and

- **42 CFR § 483.114 (a)(iii)** *Annual review of NF residents - Individuals with mental illness,* and **(c)(1)** and **(2)** *Frequency of review*

It is Dr. Chopra's firmly held belief that the OMI's January 2, 2014 findings support his whistleblower allegations and that, by the neglect he reported with respect to Veteran 1, Veteran 2, and Veteran 3, the Brockton CLC violated VABHS policies as well as other laws and regulations. Due to the nature of these three Veterans' illness(es), they represent the most vulnerable individuals in the patient population being served by the VA, and Dr. Chopra is steadfast in his conviction that the rights of these Veteran-patients, two of whom are now deceased, were violated. Dr. Chopra reaffirms his belief that the conduct he has disclosed with regard to these three Veterans demonstrates a pattern of gross mismanagement and a specific danger to public health and safety.

On Dr. Chopra's behalf, thank you for your attention the foregoing comments.

Very truly yours,

Sheilah F. McCarthy

References:

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2. Weich S, Pearce HL, Croft P, Singh S, Crome I, Bashford J, Frisher M. Effect of anxiolytic and hypnotic drug prescriptions on mortality hazards: retrospective cohort study. BMJ, 2014 Mar 19; 348:g1996. doi: 10.1136/bmj.g1996