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June 19, 2013

Ms. Jennifer B. Pennington
Attorney, Disclosure Unit
U.S. Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

Re: OSC File No. DI-12-1098

Dear Ms. Pennington:

As you know this office represents Carolyn Bogal (the "whistleblower") in regard to the above-referenced matter. Ms. Bogal is in receipt of your letter of June 13, 2013 which included a copy of a Supplemental Reports dated October 4, 2012 and April 1, 2013 received by OSC from the Department of Veterans Affairs along with copy of a Consent to Public Release form.

Kindly consider this correspondence to constitute Carolyn Bogal's response to those Supplemental Reports. In addition, Ms. Bogal encloses herein the signed Consent to Public Release form authorizing OSC to include these written comments in its public file.

The VA's October 4, 2012 Supplemental Report purports to set forth Four (4) Required Actions with an Action Plan for each to ensure each required action is carried out. The Supplemental Report dated April 1, 2013 purports to set forth status updates on the Action Plan items.

It is noted at the outset that Item 4 of the October 4, 2012 Action Plan required the VABHS to determine whether any disciplinary action is warranted against the PI in light of ORO's findings. In making this determination, the October 4, 2012 Action Plan called for discussions amongst the PI's Supervisor (Chief, Medical Services), the Associate Chief of Staff/R&D, the Chief of the Staff and the Medical Center Director. The Action Plan further called for these discussions to take place and a decision made no later than November 30, 2012.

Oddly, a review of the VA's April 1, 2013 Supplemental Report reveals that Item 4 of the Action Plan is never addressed. While progress reports are provided for Items 1-3, with specific references to what had been done with respect to each at various dates going back to October

2012, Item 4 pertaining to discipline against the PI is completely ignored. The whistleblower finds this completely unsatisfactory as the VABHS has not complied with its own Action Plan.

It is acknowledged that by way of a separate supplement dated December 18, 2012, Assistant General Counsel for the VA, Walter A. Hall, provided correspondence to OSC indicating that counseling was decided to be an appropriate response to a first offense where the PI's actions were not adjudged to be research misconduct. The December 18, 2012 submission indicates that the Chief of Medicine at the Boston VA Health Care System reviewed the findings of the report with the PI and the seriousness of the identified deficiencies was discussed. Despite this December 18, 2012 submission, the whistleblower finds it odd that if in fact this was the action taken in compliance with the Action Plan it was not included in the April 1, 2013 Supplement. Additionally, the December 18, 2012 correspondence provides absolutely no evidence that this alleged counseling was the result of discussions amongst the PI's Supervisor (Chief, Medical Services), the Associate Chief of Staff/R&D, the Chief of the Staff and the Medical Center Director as required by the Action Plan.

More importantly, the whistleblower vehemently disagrees with the VABHS's determination that no discipline (beyond perhaps a simple counseling) was deemed appropriate. As stated in a prior submission, it is beyond comprehension to the whistleblower as to how the VA could reach a determination that the PI's actions did not constitute research misconduct in light of ORO's specific findings that the PI did not fulfill all responsibilities required of investigators in violation of VHA Handbook 1200.05 § 9(e) and 9(h). Specifically, ORO found the PI to have failed to sufficiently oversee research staff to ensure that CSP Protocol #562 was implemented in accordance with the approved protocol.

Specific failures on the part of the PI as found by ORO included:

1. Having acknowledged Research Progress Notes indicating that the Un-Blinded Adverse Event (AE) Assessor had conducted full body skin examinations for research purposes, the PI did not identify this practice as a protocol deviation and did not intervene to ensure protocol compliance by study staff.

2. The PI did not ensure that the FBSE was documented prior to enrollment of at least one subject.

3. The PI did not ensure adherence to the protocol's "un-blinding" procedures.

4. The PI did not ensure that the study drug was prescribed only by an authorized provider.

When pressed by OSC, the VA conceded on October 3, 2012 that violation of VHA policies found in VHA Handbook 1200.05 rose to the level of a violation of "law, rule or regulation." Despite specific and numerous findings that a law, rule or regulation had been violated, the VA

determined that counseling for the PI was appropriate. No discipline issued and the PI was apparently never reported to the state licensing board.

The VA's treatment of the PI appears to be in direct contradiction with mandatory reporting requirements set forth under the law. Specifically, Massachusetts Law requires health care facilities, health care providers and others to report to the Board of Registration in Medicine certain information about physician's licensed in Massachusetts. These "mandated reports" include, but are not limited to, disciplinary action reports by health care facilities (M.G.L. c. 111, §§ 53B and 203, 243 CMR 2.07 (17) and 3.13). Quoting from the Board of Registration in Medicine's website, "a disciplinary action is defined [in pertinent part] as follows:

3. Any of the following actions or their substantial equivalents, whether voluntary or involuntary:

a.

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i. A course of education, training, counseling, or monitoring, only if such course arose out of the filing of a complaint or the filing of any other formal charges reflected upon the licensee's competence to practice medicine.

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5. If based only upon a failure to complete medical records in a timely fashion and/or failure to perform minor administrative functions, the action adversely affecting the licensee is not a "disciplinary action" for the purposes of mandatory reporting to the Board, provided that the adverse action does not relate directly or indirectly to:

   a. the licensee's competence to practice medicine, or

   b. a complaint or allegation regarding any violation of law or a Board regulation, whether or not the complaint or allegation cites violation of a specific law or regulation.

There can be no dispute that as a result of her actions, not only was the PI counseled as to the seriousness of her deficiencies[1], but she was also placed into a course of education and monitoring. As set forth in VA's October 4, 2012 submission, Item 1 of the Required Actions was to audit each study involving the PI once a month for a period of six months. Item 2 of the Required Actions consisted of the implementation of a new educational program that included

[1] It is the whistleblower's contention that the PI's deficiencies go directly to the issue of her competence to practice medicine. Even if they do not, the whistleblower contends that the VA was still required to report them to the licensing board under section 5 as the action taken against her by the VA was the result of a complaint involving not only a violation of VA policy but also a conceded violation of law, rule or regulation.

topics pertaining to regulatory requirements associated with the conduct of drug studies/clinical trials. Under this program the PI was required to submit weekly lab meetings and to provide minutes of those meetings to the IRD and R&DC. The audits were to be presented for discussion to the IRB and the R&DC for input and determinations about the need for modifications and/or PI sanctions as applicable.

Despite the PI being placed into both a course of education and monitoring, and despite the VA conceding on October 3, 2012 that not only did the actions of the PI constitute a violation of VHA policies found in VHA Handbook 1200.05 but also rose to the level of a violation of "law, rule or regulation", for reasons unexplained the VA chose not to report this matter to the state licensing board as required.

The VA's treatment of the PI also lies in stark contrast to its treatment of the whistleblower. As conveyed to OSC in her November 14, 2012 submission, subsequent to the whistleblower's contacting the national coordinator of the study to report her concerns about protocol violations with respect to the initial skin exams, both the PI and Chief of Medicine questioned her clinical competence. This included allegations that the whistleblower had failed to properly identify the presence of skin cancers during skin exams performed in her clinical practice (i.e. outside the study). The whistleblower received a series of communications from the VA in late 2011 into early 2012 alleging clinical incompetence and threatened of the potential reporting of the matter to the state licensing board. The whistleblower believes this sudden questioning of her clinical competence in late 2011 to be retaliatory in light of her earlier complaints to the national coordinator, especially when one considers that the alleged events at issue dated back to 2010 and early 2011 and the whistleblower had not even worked for the VA since going out on disability in the spring of 2011.

Despite raising concerns as to the whistleblower's clinical competence in late 2011, and despite the VA last communicating with the whistleblower about them in early February, 2012, it was not until October 2, 2012 that the VA took action to report the matter to the Massachusetts Board of Registration in Nursing.[2] The retaliatory nature of the VA's actions is again inferred as a review of the record in this matter shows that it was on April 4, 2012 that OSC contacted the VA regarding this matter, that the VA, through its ORO, spent the better part of the summer conducting an investigation into the whistleblower's complaint expending an enormous amount of time and effort, and that it was only after OSC questioned ORO's findings and requested further information on September 12, 2012, which ultimately forced the VA to concede that violation of laws, rules and regulations had occurred, that the VA initiated its complaint against the whistleblower with the state licensing board. The whistleblower finds no irony in the fact that the VA's complaint to the Board of Registration in Nursing is dated October 2, 2012, one day prior to its October 3, 2012 Supplement Report to OSC conceding a violation of law, rules or regulations.

A review of the entire record in this matter leads one to conclude that the decision not to issue discipline to the PI appears to be a direct offshoot of the VA's belief that despite the PI's

[2] The whistleblower was not aware of this reporting until early February 2013 when she received notice of it from the Healthcare Investigator assigned to the matter. The mater is currently under initial investigation and no determination has been made as to whether any action on the VA's complaint will be taken.

shortcomings, her actions were not considered to be research misconduct and did not impact the scientific data or results. In fact, as one of its major findings, ORO determined that its Focused For-Cause Review did not suggest that the scientific data or results obtained in CSP Protocol #562 at VABHS were inaccurately represented. As such, ORO determined that despite protocol irregularities having been found, there was no substantial and specific danger to public health.

By way of this submission, the whistleblower, as she did in detail in her November 2012 submission, again calls attention to this determination by ORO. The reason the whistleblower calls attention to this matter is because in order for that to be an accurate statement, the determination must have been reached by ORO that despite the PI having had the whistleblower conduct many of the initial skin examinations in violation of the protocol, the same results were obtained as if the PI had done them herself as she was required. In other words, ORO, based on the information it received during its investigation, must have been fully satisfied with the whistleblower's ability to conduct skin exams.

With this being the case, the whistleblower would again like to know whether or not those individuals identified as being interviewed by ORO disclosed to ORO that both the PI and Chief of Medicine have since raised concerns about the whistleblower's clinical competence (specifically her ability to properly identify the presence of skin cancers during skin exams) during the same time period as this clinical study. The VA's alleged concern over the whistleblower's clinical competence was so great that it repeatedly threatened to report this alleged clinical incompetence to the state licensing board and eventually did so in late 2012. While again the whistleblower vehemently denies allegations that she was clinically incompetent at any time, based on the allegations raised by the PI and the Chief of Medicine in those communications from 2011 and resulting in a report to the state licensing board in late 2012, the whistleblower wonders whether the PI and Chief of Medicine disclosed these concerns to ORO during their interviews. Certainly this information would be relevant to a determination of whether or not the actions of the PI in allowing the whistleblower to perform initial skin examinations in violation of the protocol had any impact on the accurate representation of scientific data or results obtained.

ORO's report contains no information that the PI or Chief of Medicine offered up information about their concerns (or lack thereof) with respect to the whistleblower's clinical competence. Was this information purposely withheld from ORO by the PI and Chief of Medicine in order to bring about a determination that there was no impact on results? Was this information provided to ORO but for some reason held out of ORO's report? Did the PI and/or Chief of Medicine inform ORO that they had no concerns about the whistleblower's clinical competence?

Unless ORO was complicit in a greater cover it, it would only seem reasonable that had the PI and/or Chief of Medicine shared information with them that there was concern over the whistleblower's ability to conduct skin exams, this information would have appeared in ORO's report. The fact that no such information appears in ORO's report suggests that none of the key personnel identified as being interviewed expressed such a concern. This failure to express such a concern can be seen as the product of one of two possibilities – 1) Neither the PI or the Chief of Medicine was truly concerned about the whistleblowers ability to conduct skin exams and

their allegations and threats against the whistleblower which are playing out in another forum are unfounded and retaliatory in nature; or 2) The PI, Chief of Medicine and other key personnel identified as having been interviewed by ORO purposely withheld this information from ORO in order to shape the outcome of ORO's investigation.

Before this matter is closed by OSC, the whistleblower strongly urges it to make further inquiry into these matters.

Very truly yours,

Marc J. Levy

MJL/mjl
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The Official Website of the Executive Office of Health and Human Services (EOHHS)

Health and Human Services

Departments & Divisions

Overview

Massachusetts law requires health care facilities, health care providers and others to report to the Board of Registration in Medicine certain information about physicians licensed in Massachusetts.

These "mandated reports" include, but are not limited to, the following:

- disciplinary action" reports by health care facilities (M.G.L. c.111, §§ 53B and 203; 243 CMR 2.07 (17) and 3.13);
- disciplinary action" reports by professional medical associations or organizations (M.G.L. c. 112, §5B);
- allegations of physician misconduct by health care providers, referred to as "peer reports" (M.G.L. c. 112, §5F);
- allegations of physician misconduct by government agencies and other governmental entities (including their officers or employees) who have oversight of medical or health services (M.G.L. c. 112, §5D);
- "closed claim" reports by medical malpractice insurers (M.G.L. c. 112, §5C);
- court reports of medical malpractice matters (M.G.L. c. 231, §60B); and
- court reports of criminal convictions (M.G.L. c. 221, §26).

This section contains links to instructions and forms for submitting certain of these mandated reports to the Board.

This information is provided by the Board of Registration in Medicine.

Definition of Disciplinary Action

1. An action of any entity, including, but not limited to, a governmental authority, a health care facility, an employer, or a professional medical association (international, national, state or local).
2. An action which is:
   a. formal or informal, or
   b. oral or written. (Except an oral reprimand or admonition is not a "disciplinary action.")
3. Any of the following actions or their substantial equivalents, whether voluntary or involuntary:
   a. Revocation of a right or privilege.
   b. Suspension of a right or privilege.
   c. Censure.
   d. Written reprimand or admonition.
   e. Restriction of a right or privilege.
   f. Non-renewal of a right or privilege.
   g. Fine.
   h. Required performance of public service.
   i. A course of education, training, counseling, or monitoring, only if such course arose out of the filing of a complaint or the filing of any other formal charges reflecting upon the licensee's competence to practice medicine.
   j. Denial of a right or privilege.
   k. Resignation.
   l. Leave of absence.
   m. Withdrawal of an application.
   n. Termination or non-renewal of a contract with a licensee.
4. Divisions (e), (f) and (j) through (n) above are "disciplinary actions" only if they relate, directly or indirectly, to:
   a. the licensee's competence to practice medicine, or
   b. a complaint or allegation regarding any violation of law or regulation (including, but not limited to, the regulations of the Board) or bylaws of a health care facility, medical staff, group practice, or professional medical association, whether or not the complaint or allegation specifically cites violation of a specific law, regulation, or bylaw.
5. If based only upon a failure to complete medical records in a timely fashion and/or failure to perform minor administrative functions, the action adversely affecting the licensee is not a "disciplinary action" for the purposes of mandatory reporting to the Board, provided that the adverse action does not relate directly or indirectly to:
   a. the licensee's competence to practice medicine, or
   b. a complaint or allegation regarding any violation of law or a Board regulation, whether or not the complaint or allegation specifically cites violation of a specific law or regulation.

If you have questions concerning reporting requirements, or completion of the Board's disciplinary action forms, please call the Board's Data Repository Counsel at (781) 876-8200.

This information is provided by the Board of Registration in Medicine.