IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARK J. CERCIELLO, M.D.,	**:**	**CIVIL ACTION**
Plaintiff	**:**	
	:	
vs.	**:**	**NO. 13-3249**
	:	
KATHLEEN SEBELIUS, U.S.	**:**	
SECRETARY OF HEALTH, et al.,	**:**	
Defendants	**:**	

M E M O R A N D U M

STENGEL, J. **March 30, 2016**

Plaintiff Mark J. Cerciello, M.D., brings this action under the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*, seeking judicial review of the final decision of the United States Secretary ("Secretary") of Health and Human Services (the "Agency") which refused to remove his name from the National Practitioner Data Bank ("Data Bank").[1] The plaintiff and the Secretary have filed cross-motions for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. For the following reasons, I will grant the Secretary's motion, deny the plaintiff's motion, and enter judgment in favor of the Secretary.

[1] The Data Bank is a confidential information clearinghouse authorized by Congress and established by the Secretary with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States. See Title IV of the Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101, *et seq*; see also 45 C.F.R. 60.1.

I. BACKGROUND[2]

The plaintiff is an orthopaedic physician. In addition to the Secretary, the plaintiff filed this action against the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons (collectively referred to as "AAOS"), two interrelated not-for-profit corporations. On February 29, 2016, I granted AAOS's motion to dismiss.

On January 26, 2010, the plaintiff submitted an expert report criticizing fellow AAOS member Dr. Menachem Meller's care of a patient who sought treatment for her shoulder. See Administrative Record ("Tr.") 274-276. The expert report was made in support of the patient's medical malpractice claim against Dr. Meller. Id. In his expert report, the plaintiff opined that Dr. Meller had failed to diagnose properly and treat the patient's shoulder injury. Id. Specifically, Dr. Cerciello indicated that the patient had a "class 5 injury to the shoulder" that was considered a "surgical problem." Id. at 274.

On October 18, 2010, in accordance with AAOS procedures, Dr. Meller filed a grievance report against Dr. Cerciello with AAOS, alleging violations of mandatory standards 1, 2, 3, 4, 5, and 7 of AAOS's Standards[3] of Professionalism ("the SOP's") for

[2] The majority of the facts are taken from the defendant's statement of undisputed facts. Pursuant to Rule 56(e)(2) of the Federal Rules of Civil Procedure, because the plaintiff has failed to address the defendant's assertion of facts as required by Rule 56(c), I will consider the defendant's facts undisputed for purposes of these motions.

[3] The mandatory standards in question are:

1. An orthopaedic expert witness shall not knowingly provide testimony that is false.
2. An orthopaedic expert witness shall provide opinions and/or factual testimony in an impartial manner.
3. An orthopaedic expert witness shall evaluate the medical condition and care provided in light of generally accepted standards at the time, place, and in the context of care delivered.

Orthopaedic Testimony. Tr. 294-295. Several of these standards address compliance with generally accepted standards of care. Dr. Meller's grievance claimed that his conservative treatment of the patient's shoulder was warranted given the patient's history of seizures, her hospitalization for cocaine abuse which led to the orthopaedic referral, and the patient's ability to work at the U.S. Post Office without difficulty. Id. at 182-186. Dr. Meller diagnosed the patient with a Grade 3 shoulder separation which, when she was referred to him, was already two months old. Id. at 183. Dr. Meller disagreed with Dr. Cerciello's assessment that the shoulder injury was severe, and criticized him for stating "that there was some smaller (unspecified) intervention that I could have employed two months post-injury that would have obviated the need for a reconstruction." Id.

On October 27, 2010, AAOS informed Dr. Cerciello of the grievance filed by Dr. Meller against him, and sent him the grievance submission with exhibits. Tr. 188-191. AAOS asked the plaintiff to submit a written response to the grievance or other material, but the plaintiff ignored the invitation. On December 1, 2010, AAOS sent Dr. Cerciello another reminder to submit a response or additional material, id. at 193, and again the plaintiff did nothing. On January 4, 2011, AAOS informed Dr. Cerciello that it would

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4. An orthopaedic expert witness shall neither condemn performance that falls within generally accepted practice standards nor endorse or condone performance that falls outside these standards.

5. An orthopaedic expert witness shall state how and why his or her opinion varies from generally accepted standards.

7. An orthopaedic expert witness shall have knowledge and experience about the standard of care and the available scientific evidence for the condition in question during the relevant time, place, and in the context of medical care provided and shall respond accurately to questions about the standard of care and the available scientific evidence. See Tr. 155-157.

determine whether a *prima facie* violation had been established, and if a hearing was warranted. Id. at 195-96.

On January 24, 2011, AAOS notified Dr. Cerciello that a *prima facie* violation had been established and that a hearing would soon be convened for the grievance. AAOS invited both parties to submit additional material to the hearing board. Tr. 195-96. On May 11, 2011, AAOS told Dr. Cerciello that the grievance hearing would be held on July 16, 2011, and again asked him to submit a statement to support his position. Id. at 203-204.

On July 1, 2011, AAOS sent a letter to Dr. Cerciello that contained additional evidence submitted by Dr. Meller, including a letter written in support of Dr. Meller by Dr. Glaser, the orthopaedic surgeon who subsequently operated on the patient in question. Tr. 206-207. AAOS stated: "[a]s of this date, the Office of General Counsel has not received any communication from you in response to this grievance matter." Id. at 206. Dr. Cerciello neither attended the grievance hearing on July 16, 2011, nor presented any evidence to the six physicians who composed the Committee on Professionalism's ("COP") grievance hearing panel. Id. at 209-212.

On August 17, 2011, after the hearing, the COP issued a grievance hearing report to the AAOS Board of Directors, stating that it had unanimously found that Dr. Cerciello violated standards 2, 3, 4, 5, and 7 of AAOS's SOP's.[4] Tr. 218-223. In so doing, the COP criticized Dr. Cerciello for failing to apply the appropriate standard of care and thus

[4] I note that the COP also unanimously found that the plaintiff did not violate Mandatory Standard #1.

criticized his medical judgment. In its grievance hearing report, the COP indicated, *inter alia*, that it:

> 3. Unanimously found that Dr. Cerciello violated Mandatory Standard No. 3. [Dr. Cerciello] did not evaluate the patient's condition based on generally accepted standards and within the context of care delivery. The vast majority of orthopaedic surgeons would have treated this patient conservatively, especially in light of the patient's drug addiction and seizures. Surgical repair is generally considered an elective or cosmetic procedure and performed at the discretion of the surgeon and the election of the patient.
>
> 4. Unanimously found that Dr. Cerciello violated Mandatory Standard No. 4. [Dr. Cerciello] condemned conservative treatment by [Dr. Meller] that fell within the generally accepted standards for managing a grade II-III AC separation.
>
> 5. Unanimously found that Dr. Cerciello violated Mandatory Standard No. 5. [Dr. Cerciello] did not state why his recommendation for immediate shoulder surgery varied from generally accepted standards.
>
> 6. Unanimously found that Dr. Cerciello violated Mandatory Standard No. 7. [Dr. Cerciello] did not have knowledge about the standard of care and/or the available scientific evidence for treating the patient's grade II-III AC separation. His expert report incorrectly classified the injury as "class five," and condemned [Dr. Meller's] conservative management of the patient.

Tr. 222.

As a result of these violations, the COP grievance hearing panel unanimously recommended that Dr. Cerciello be suspended by AAOS for a period of two years. Id. Although Dr. Cerciello was sent a copy of the grievance hearing report along with a

transcript of the hearing, and was informed that he could appeal the COP recommendation, id. at 225-226, he chose not to appeal, id. at 233.

On September 24, 2011, the AAOS Board of Directors met to consider Dr. Meller's grievance and the COP's recommendation to suspend Dr. Cerciello. After reviewing the record and the grievance hearing report, the sixteen physician members of the AAOS Board of Directors unanimously adopted Dr. Cerciello's two-year suspension. Id. at 240.

On October 24, 2011, AAOS filed an Adverse Action Report with the Data Bank concerning the two-year suspension of Dr. Cerciello from its ranks. Tr. 293-295. The report summarized the allegations in the grievance process, AAOS's grievance hearing, and Dr. Cerciello's suspension. Id. In commenting on Dr. Cerciello's conduct which led to the filing of the report, AAOS stated:

> The Panel recommended that Dr. Cerciello be suspended from the AAOS for a period of two years. In making its recommendation, the Hearing Panel found that Dr. Cerciello did not provide his opinion in a fair and impartial manner when he stated that the patient had a severe shoulder injury requiring immediate surgery. The evidence and literature indicated that the patient had a lesser injury and Dr. Cerciello, in his report, had incorrectly classified the Grade II-III AC separation as a Class 5. Furthermore, he condemned conservative management of the patient's injury when conservative care was reasonable and fell within the generally accepted standards for managing a Grade II-III separation. Dr. Cerciello also did not evaluate the care within the context in which it was delivered. The Grievance Hearing Panel believed that the vast majority of orthopaedic surgeons would have treated this patient conservatively, particularly in light of the patient's drug addiction and untreated seizures. Dr. Cerciello did not

> state why his recommendation for immediate shoulder surgery varied from the generally accepted standards and the Hearing Panel found that Dr. Cerciello's expert opinion did not demonstrate he had knowledge about the standard of care and/or the available scientific evidence for treating a Grade II-III AC separation. Dr. Cerciello did not appeal the findings and recommendation of the Grievance Hearing Panel and on September 24, 2011, the AAOS Board of Directors voted to suspend Dr. Cerciello for a period of two years due to violation of Mandatory Standards Nos. 2, 3, 4, 5, and 7 of the SOP for orthopaedic expert witness testimony.

Tr. 294-295.

On May 14, 2012, Dr. Cerciello filed a dispute of the Adverse Action Report with the Data Bank. Over a month later, he requested that the Secretary of the Agency review the Adverse Action Report, and have it removed from the Data Bank. On May 30, 2013, the Agency denied the plaintiff's request in a "Secretarial Review Decision." The Secretary added that she would insert the following statement into the report:

> The practitioner requested Secretarial Review of the Report. The Secretary can only review (1) whether the action is reportable under applicable law and regulations and (2) whether the report accurately describes the reporter's action and reasons for action as stated in the reporter's decision documents. The Secretary cannot conduct an independent review of the merits of the action taken by the reporting entity, review the "due process" provided by the entity, or substitute her judgment for that of the entity. After review of the available information, the Secretary determined that some of the issues raised by the practitioner are beyond the scope of the Secretary's review authority. After review of the remaining issues, the Secretary determined that there is no basis to conclude that the Report should not have been filed or that for agency purposes it is not accurate, complete, or relevant. Accordingly, the Report shall be maintained as submitted by the reporting entity.

Tr. 291-292.

The Secretary's decision also noted that AAOS was required to notify the Data Bank of the plaintiff's suspension pursuant to 45 C.F.R. § 60.11(a) and the Data Bank's Guidebook.[5] Id. at 290 ("The AAOS, as a professional society, was legally obligated to report adverse action taken against your membership because the suspension was an adverse membership action taken as a result of professional review.") The decision also noted that the suspension was related to clinical competence or patient care, referring to documentation that AAOS provided which demonstrated that patient care and clinical competence were implicated. Id. at 290 ("In your second dispute point, you argue that the suspension is not related to clinical competence or patient care, and should not have been reported to the Data Bank. Documentation provided by AAOS indicates otherwise.") Further, the decision referred to the findings of AAOS that the plaintiff had violated mandatory standards of AAOS which "they determined pertain to professional competence and conduct." Id. at 291.

The Secretary also rejected the plaintiff's contention that AAOS had never given him notice that the suspension would be sent to the Data Bank or the consequences of the suspension. Id. The Secretary indicated that AAOS was not required to provide the plaintiff with such notice. Finally, the decision informed the plaintiff that the remainder of his issues were outside the scope of the Agency's review:

> We do not have the authority to investigate whether another orthopedist performed that surgery that you said

[5] The Guidebook is found online at: www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf

> the patient needed, whether the AAOS altered its bylaws, whether the doctor you testified about is a serial grievant with the AAOS, or whether others experienced retaliatory tactics of the doctor you testified about. We can only determine if the Report (1) is legally required or permitted to be filed and (2) accurately depicts the action taken and the reporter's basis for action as reflected in the written record. Since the information in the Report is reflected by the documentation provided by the AAOS, we determined that the Report is both legally required and accurate as submitted.

Id. at 291. The Secretary denied the plaintiff's dispute and ruled that the Adverse Action Report would remain in the Data Bank. Id. The Agency placed a statement with the report noting that the Adverse Action Report had been reviewed by the Secretary along with the parameters of that review, that the report was properly filed, and that it accurately depicted the action taken. Id.

The plaintiff filed this complaint against the Secretary and the AAOS Defendants, seeking the following injunctive relief: he asks that the Secretary be ordered to remove the suspension report from the Data Bank; and that the AAOS Defendants be ordered to "follow its bylaws and only report suspensions and expulsions that relate to patient health and welfare and cease and desist from using the National Practitioner Data Bank to sanction physicians who testify against physicians." See Compl. at 6.

II. STANDARD OF REVIEW

A. Under The Administrative Procedure Act

The Administrative Procedure Act (the "APA"), 5 U.S.C. §§ 701-06, provides a right to judicial review for a "person suffering legal wrong because of agency action." See 5 U.S.C. § 702. Under the APA, a court has jurisdiction to review a "final agency

action for which there is no other adequate remedy." 5 U.S.C. § 704. In determining whether there has been "final agency action" under the APA, the "core question is whether the agency has completed its decision-making process, and whether the result of that process is one that will directly affect the parties." Franklin v. Massachusetts, 505 U.S. 788, 797 (1992).

The APA provides that the court must uphold an agency's final action unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). It is well-settled that an agency's action is entitled to a "presumption of regularity." Citizens to Preserve Overton Park. Inc. v . Volpe, 401 U.S. 402, 415 (1971); SBC Inc. v. Federal Communications Commission, 414 F.3d 486, 503 n.l0 (3d Cir. 2005) (reviewing court must presume the validity of agency action). The Supreme Court has emphasized that although the court's "inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one" and the court "is not empowered to substitute its own judgment for that of the agency." Volpe, 401 U.S. at 416; see also CBS Corp. v. Federal Communications Commission, 535 F.3d I 67, 174 (3d Cir. 2008).

Under the APA's arbitrary and capricious standard, the court's inquiry is limited to determining whether the agency "considered the relevant factors and articulated rational connections between the facts found and the choice made." Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 105 (1983); Volpe, 401 U.S. at 416 (court must determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of

judgment"). Judicial review pursuant to the arbitrary and capricious standard "focuses on the agency's decision making process, not on the decision itself." NVE, Inc. v . Department of Health and Human Services, et al., 436 F.3d 182, 190 (3d Cir. 2006) (emphasis in original); Greenberg v. England, 213 F.App'x 100, 102 (3d Cir. 2007) (the court determines "whether the Secretary's decision making process was deficient, not whether his decision was correct"). An agency's action may be found to be arbitrary and capricious where "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Manufacturers Association of the United States, Inc., et al. v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43 (1983). An agency's action will survive judicial scrutiny as long as it is rational. Frisby, et al. v. U. S. Department of Housing and Urban Development, et al., 755 F.2d 1052, 1055 (3d Cir. 1985). Reversal is appropriate only where the administrative action is irrational or not based on relevant factors. NVE, Inc., 436 F.3d at 190.

B. Under Rule 56 of the Federal Rules of Civil Procedure[6]

A court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A dispute is "genuine" if the evidence is such that a

[6] The same standards apply on cross-motions for summary judgment. Appelmans v. City of Philadelphia, 826 F.2d 214, 216 (3d Cir. 1987).

reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is "material" if it might affect the outcome of the case under governing law. Id.

A party seeking summary judgment always bears the initial responsibility for informing the court of the basis for its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the movant's initial Celotex burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." Id. at 325. A party asserting that a fact is genuinely disputed must support the assertion by: citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, admissions, interrogatory answers or other materials. FED. R. CIV. P. 56(c)(1)(A). That is, summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

Under Rule 56, the court must view the evidence presented on the motion in the light most favorable to the opposing party. Anderson, 477 U.S. at 255. The court must decide not whether the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented. Id. at 252. If the non-moving party has exceeded the mere scintilla of evidence threshold and

has offered a genuine issue of material fact, then the court cannot credit the movant's version of events against the opponent, even if the quantity of the movant's evidence far outweighs that of its opponent. Big Apple BMW, Inc. v. BMW of North Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

III. DISCUSSION

As someone who believes that he suffered legal wrong because of the Secretary's action and that he has no other adequate remedy, Dr. Cerciello filed this complaint in federal court seeking review of the Agency's decision. See 5 U.S.C. § 702. Because the Agency has completed its decision-making process and the result directly affects Dr. Cerciello, the decision is a final agency decision which supplies this court with jurisdiction. See 5 U.S.C. § 704; see also Franklin, 505 U.S. at 797.

In reviewing this decision, I am mindful that the Agency's action is entitled to a presumption of regularity, and that I must uphold that action unless it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. In doing so, I am limited to determining whether the Agency considered the relevant factors and articulated rational connections between the facts found and the choice made.

In her decision, the Secretary indicated that "after review of the information available and the Report presented to this office, the Secretary finds as follows:

> There is no basis on which to conclude that the Report should not have been filed in the [Data Bank] or that it is not accurate. Your request that the Report be voided from the [Data Bank] is hereby denied. The Report will remain in the [Data Bank]."

Tr. 287. The Secretary proceeded to review the evidence available and to discuss Dr. Cerciello's points of dispute regarding AAOS's reporting of his suspension to the Data Bank:

> The first issue you raise in disputing the Report is that the AAOS is a private, non-licensing organization and the adverse actions that they take should not be included in the NPDB. . . .The AAOS, as a professional society, was legally obligated to report the adverse action taken against your membership because the suspension was an adverse membership action taken as a result of professional review.

Tr. 290. In arguing that the Secretary's decision is fatally flawed and arbitrary and capricious, Dr. Cerciello insists that his suspension for testifying against another physician should not have been reported to the Data Bank. A review of the relevant law and of the evidence of record shows that this claim is meritless.

In 1986, Congress enacted the Health Care Quality Improvement Act (the "Act"), Pub. L. 99-660, 42 U.S.C. §§ 11101, *et seq*., after specifically finding that:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.

(2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.

(3) This nationwide problem can be remedied through effective professional peer review.

(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.

(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review. See 42 U.S.C. § 11101.

To address these concerns, the Secretary established the Data Bank to provide for the collection and dissemination of information that relates to the professional competence and conduct of physicians. See 45 C.F.R. § 60.l.

The Act imposes reporting requirements on a number of health care entities,[7] including professional societies, medical malpractice payers, State licensing boards, and hospitals. See 42 U.S.C. §§ 11131-11134; 45 C.F.R. §§ 60.7-60.9. A health care entity is required to file a report with the Data Bank if it:

> (A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;
>
> (B) accepts the surrender of clinical privileges of a physician:
>
> > (i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct: or
> >
> > (ii) in return for not conducting such an investigation or proceeding; or

[7] The Act defines a "health care entity" for our purposes as "a professional society (or committee thereof) of physicians or other licensed health care practitioners that follows a formal peer review process for the purpose of furthering quality health care (as determined under the regulations of the Secretary)." 42 U.S.C. § 11151(4)(iii). Thus, AAOS is clearly a health care entity, contrary to Dr. Cerciello's contention.

> (C) in the case of such an entity which is a professional society, takes a professional review action which adversely affects the membership of a physician in the society.

See 42 U.S.C. § 11133(a)(1). Subsection (C) is the relevant provision for our purposes here. The Act defines "professional review action" as an action or recommendation of a professional review body: [8]

> "which is taken or made in the conduct of professional review activity,[9] which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action."

42 U.S.C. § 11151(9) (footnote added).

Here, AAOS fits the parameters of the Act. It is a health care entity which conducts professional reviews of its members when requested, and is thus considered a professional review body. In this role, upon such review, it suspended Dr. Cerciello's membership for two years. Accordingly, the Secretary properly determined that AAOS,

[8] The Act defines the term "professional review body" as a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity. 42 U.S.C. § 11151(11).

[9] The term "professional review activity" is defined as an activity of a health care entity with respect to an individual physician: (A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity, (B) to determine the scope or conditions of such privileges or membership, or (C) to change or modify such privileges or membership. 42 U.S.C. § 11151(10).

as a professional society, has a mandatory obligation to report professional review actions related to competence or professional conduct that adversely affected a physician's membership with AAOS. See 42 U.S.C. § 11133(a)(1)(C) (a professional society is required to file a report with the Data Bank if it takes "a professional review action which adversely affects the membership of a physician in the society."); see also 45 C.F.R. § 60.12(a)(1)(iii) (noting a professional society must report to the Data Bank when it takes a professional review action concerning a physician); see also Data Bank Guidebook at E-53 ("professional societies *must* report professional review actions based on reasons related to professional competence or professional conduct that adversely affect the membership of a physician or dentist.") (Emphasis in original).

Next, the Secretary discussed Dr. Cerciello's second challenge to AAOS's reporting of the suspension to the Data Bank:

> In your second dispute point, you argue that the suspension is not related to clinical competence or patient care, and should not have been reported to the Data Bank. Documentation provided by the AAOS indicates otherwise. As previously stated, the AAOS Board of Directors determined that you violated mandatory standard numbers 2, 3, 4, 5, and 7 of the SOP's, which they determined do pertain to professional competence and conduct. Additionally, the January 24, 2011 letter from the AAOS to you indicates that ". . . the AAOS Committee on Professionalism (COP) has reviewed all submitted material and has concluded that a *prima facie* case of unprofessional conduct has been established.

Tr. 290-91. Dr. Cerciello also seeks review of this determination of the Secretary, arguing that his expert report did not impact patient medical care, and thus should not have been reported. The evidence of record belies this argument.

Dr. Cerciello claims that "in informal conversations with representatives of AAOS, it was suggested that any time a doctor testifies in a malpractice case against a physician, he is impacting patient welfare." In this circuit, hearsay statements such as this one, can be considered on a motion for summary judgment if they are capable of admission at trial. Shelton v. University of Med. & Dentistry, 223 F.3d 220, 223 n.2 (3d Cir. 2000) (citing Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc., 63 F.3d 1267, 1275 n.17 (3d Cir. 1995)). This bald assertion could not become admissible at trial, and I will not consider it here.

Dr. Cerciello also argues that "it is difficult to fathom how anyone can claim that Dr. Cerciello's report dated January 26, 2010 could have in anyway impacted the patient about whom he authored the report." Notwithstanding this argument, it is clear that no one has claimed that Dr. Cerciello's expert report negatively harmed Dr. Meller's patient. Instead, AAOS determined that the contents of the expert report revealed that Dr. Cerciello did not have knowledge of the proper standard of care and thus *could* cause harm to a future patient. That significant difference is contemplated in the Act.

The Act indicates that a physician's conduct which *could* affect patient welfare or health qualifies as a reportable event. See 42 U.S.C. § 11151(9) (defining "professional review action" as an action based on the "competence or professional conduct of an individual decision (which conduct affects or *could* affect adversely the health or welfare of patients")) (emphasis added). The Act thus does not require actual harm to a patient but is satisfied if there is the potential for future harm. It is well-established that the potential for future patient safety issues qualifies for reporting to the Data Bank.

At the grievance hearing held on July 16, 2011 before AAOS's Committee on Professionalism, Dr. Meller offered the following uncontroverted testimony about the condition of his patient and the care he provided her:

> Briefly, [the patient] was brought to my hospital emergency room on October 10, 2006. She had been on a crack cocaine binge and was confused, had a general medical workup. In the process, it was noted she had a right shoulder AC separation which, according to the records, had full range of motion.
>
> She presented to my office two months later with a prominence as noted. She was also noted to have a seizure disorder, was not on her seizure medications and had been performing her normal manual work duties for the United States Postal Service, these duties involves casing the mail and extensive use of both upper extremities, including the one involving the right shoulder AC separation. At the time, she informed me she had not seen her neurologist or had been taking her medications for her seizure disorder.
>
> Since the discovery was completed in this matter, I have discovered that, in fact, she had seen a neurologist, had an EEG done with an active seizure focus, but still was not on her seizure medications. She was on naproxen provided by a family physician, the same medication she had been taking for her chronic pain preceding this injury.
>
> My instructions were simple, this is an AC separation, this is not a dislocated glenohumeral joint as might have occurred in the context of seizure disorder, it is two months old, the urgency is gone. Some people manage to live with it and choose not to have surgery. If you feel you must have surgery, anesthesia will not allow you to be anesthetized without the proper medical clearance.
>
> The expectation was for her to return in one month; she, in fact, returned six months later. The bump had improved and her function, being her shoulder motion

> and strength, had essentially normalized. The pain was not localized and was more consistent with her chronic pre-injury complaints of pain.

Tr. 210. Dr. Meller then proceeded to discuss with the Committee Dr. Cerciello's expert report:

> In his report, Dr. Cerciello describes that I violated the standard of care by not operating upon her. He does not identify the diagnostic studies reviewed, nevertheless, his findings are distinctly worse than those found in the opinions of other practicing physicians in this matter. He used insulting, inflammatory language which is not worthy of a Board-certified member of the American Academy of Orthopaedics.
>
> Let us remember, we're not here today about medical malpractice, this is about bad professional behavior, behavior that is reprehensible enough to have crossed a line. It does not take into account differing opinions in this matter, it ignores mainstream peer-review publications. He asserts unconditionally that this is a surgical problem. He provides no explanation how she was harmed by having the surgery done by Dr. Glaser approximately one year after her presentation in my office rather than by myself in December of 2006 or January of 2007.
>
> He misrepresents the injury as a failure of treatment, describing tearing of the ligaments as having been caused by the interval delay is completely unfounded as it was certainly caused by the injury itself. He misrepresents the surgery performed by Dr. Glaser as having been massive, which, in fact, the very same procedure I would have performed had she chosen to carry out the instructions optimizing medical care.
>
> One could also say Dr. Glaser's operation was smaller, as in the interval, the distal clavicle underwent osteolysis and did not require the Mumford portion of the procedure. . . .

> Additionally, Dr. Cerciello is unaware that Dr. Glaser had stated he could not understand why [the patient] was so insistent on having her surgery. The question remains is there any time frame interval following her emergency room visit where Dr. Cerciello would have felt that I did not owe her an operation. For argument sake, had she shown up five years later, would he still feel as strongly that I owed her an operation?
>
> If, in fact, this delay harmed her, did not also Dr. Ernest Gentchos, M.D., also fall below the standard of care by not having her operated immediately. Did not also Dr. David Glaser himself upon being notified of the condition whisk her away to surgery immediately. Clearly, these suggestions are ludicrous. I find it particularly problematic in that it is now a liability not to operate on an individual who presents with a Grade 3 AC shoulder separation following an index injury. . . .
>
> If this opinion is allowed to stand, the bar is raised to a level where no orthopaedist can function. If I am unable to advise a patient that their condition may not be surgical, but the condition may not need to be treated surgically or, in fact, if she could be worse off with the surgery, then the balance would be weighted heavily to operating on anything that is not absolutely perfect or even mildly injured. This includes conditions which have been treated forever non-surgically. Clearly, this is not a direction that the mainstream orthopaedic community wishes to go.

Tr. 210-211. The COP composed a grievance hearing report addressed to AAOS's Board of Directors, and unanimously found that Dr. Cerciello had violated five Mandatory Standards. The Committee indicated that it had considered "the profound mischaracterization of the classification of the degree of disruption of the AC joint as well as an abject lack of understanding of the standard of care for the management of AC separations," and "the absolutism of the statements made by [Dr. Cerciello] in his expert

report." Tr. 219-22. Finally, the Committee recommended that Dr. Cerciello be suspended by AAOS for a period of two years due to unprofessional conduct in the performance of expert witness testimony. Id. at 222. AAOS informed Dr. Cerciello of the Committee's findings and recommendations, and of his right to appeal. Id. at 225-26. Dr. Cerciello chose not to appeal.

On September 24, 2011, AAOS's Board of Directors met to consider the Committee's recommendation. Dr. Murray Goodman, Chairman of AAOS's Committee on Professionalism, presented the case to the Board:

> Thank you. The orthopaedic case involved a 56-year-old woman with a past history of seizures and falls who was brought to the emergency room on October 10, 2006. She was unresponsive after a cocaine overdose.
>
> When she woke up, she complained of right shoulder pain and radiographs revealed an AC separation, although the radiologist interpreted the images as normal. She was given a sling and left the emergency room before treatment was completed. She was advised to seek follow-up with the grievant, Dr. Meller, in several days.
>
> When seen for the first time by Dr. Meller on December 5, [2006] evaluation revealed the prominence of the distal clavicle and raised a question of deltoid atrophy or evulsion. She was referred to her neurologist for untreated seizures. Examination by the grievant on June 7, 2007, again showed deltoid atrophy and prominence of the distal clavicle.
>
> Shoulder range of motion and function [were] said to be excellent, although the patient was unhappy with the cosmetic appearance of the shoulder. MRI and radiographs were ordered and an EMG was said to be unremarkable.

> At the next visit on September 11, 2007, Dr. Meller advised continued conservative treatment. The patient sought the advice of a second orthopaedic surgeon and underwent a right AC joint reconstruction in January 2008 by a third orthopedist. Post-operatively, the patient complained of ongoing right shoulder pain aggravated by a fall on November 7, 2008.
>
> In his expert report dated January 26, 2010, Dr. Cerciello stated that review of the emergency room radiographs showed an AC separation of the shoulder, a serious injury which he categorized as Class V and considered this to be a surgical problem. He went on to state that it was hard for him to believe that Dr. Meller could not distinguish the distal end of the clavicle with an AC separation, he went on to say that even a second-year resident could identify this.
>
> He stated that despite the plan to undergo neurologic workup to look for an underlying cause for the shoulder problem, no appropriate treatment was undertaken. He opined that Dr. Meller failed to properly diagnose and treat this patient and that this negligence caused ongoing damage to the shoulder, ultimately leading to massive surgery which could have been avoided with early intervention.
>
> Expert review of the case by Dr. David Rubenstein, an orthopaedic surgeon in defense of Dr. Meller's care, stated that an AC separation that was no worse than Grade II, and that Dr. Meller's care was appropriate and well within the standards of a Board certified orthopaedic surgeon.

Tr. 235-37. After Dr. Goodman's presentation, the Board went into Executive Session and voted unanimously in support of the recommended two-year suspension of Dr. Cerciello. Id. at 240.

Other courts have also held that physician misconduct that could result in harm to a patient is properly reportable under the Act. See Leal v. Sec'y U.S. Dept of H.H.S.,

620 F.3d 1280, 1286 (11th Cir. 2010) (when a physician was suspended after "pitch[ing] a fit" and breaking a photocopy machine and a telephone, scattering papers, and yelling at a nurse, the court held that such disruptive and abusive behavior, "even if not resulting in actual or immediate harm to a patient, poses a serious risk to patient health or welfare"); Moore v. Williamsburg Reg'l Hosp., 560 F.3d 166, 172 (4th Cir. 2009) (the term professional conduct is not limited to past medical conduct that has already affected patient welfare. Nothing in the statute requires peer review committees to wait until medical disaster strikes.); Gordon v. Lewistown Hosp., 423 F.3d 184, 203 (3d Cir. 2005) (Such unprofessional conduct on the part of a physician is within the purview of a professional review action under the Act. The plain language of the statute indicates the breadth of conduct encompassed within the definition of professional review action by the inclusion of conduct that could affect adversely the health or welfare of a patient (quoting 42 U.S.C. § 11151(9)).

Here, AAOS determined that Dr. Cerciello did not evaluate the patient in question based on generally accepted standards and did not have knowledge of the standard of care. It further found that he misdiagnosed the severity of the shoulder injury and rejected conservative treatment which the vast majority of orthopaedic surgeons would have ordered. Tr. 294-295. The COP unanimously found that Dr. Cerciello violated five SOP's which particularly deal with physician competence. In the Adverse Action Report, AAOS discussed how Dr. Cerciello did not apply the correct standard of care or was unaware of it. Id. at 295 ("The Hearing Panel found that Dr. Cerciello's Expert Opinion did not demonstrate he had knowledge about the standard of care and/or the available

scientific evidence for treating a Grade II-III AC separation"). It is reasonable to assume that a physician who failed to use applicable standards of care in authoring an expert report, or was unaware of those standards of care, could cause harm to a future patient. See Austin v. Am. Ass'n of Neurologic Surgeons, 253 F.3d 967, 974 (7th Cir. 2001) (noting that although the physician did not treat the malpractice plaintiff for whom he testified, that if his testimony reflected the quality of his medical judgment then he was probably a poor physician).

In reaching her decision, the Secretary confirmed that AAOS had suspended Dr. Cerciello's membership for two years for professional misconduct that could have affected patient health or welfare. Because the evidence plainly shows and AAOS properly determined that Dr. Cerciello did not evaluate the patient in question based on generally accepted standards and did not have knowledge of the standard of care, the Secretary appropriately found that there was no basis for her to conclude that the Adverse Action Report should not have been filed in the Data Bank or that the report was not accurate.

Dr. Cerciello also argues that "his actions were pure speech, protected by the First Amendment, in that he was merely opining on the adequacy of care provided by Dr. Meller to a particular patient using the existing standard of care under judicial oversight." Dr. Cerciello contends that although his expert witness testimony should be protected against government intrusion, the government nevertheless interfered with his right to free speech.

The First Amendment to the United States Constitution provides:

> "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

U.S. CONST. AMEND. I.

It is axiomatic that the First Amendment governs only state action, not the actions of private entities. Max v. Republican Comm., 587 F.3d 198, 200 (3d Cir. 2009). Here, the Secretary did not violate Dr. Cerciello's First Amendment rights because the Agency took no action to restrict his right to free speech. In fact, the private entity AAOS also took no action to restrict Dr. Cerciello's free speech rights. At the time of his report, Dr. Cerciello was free to author any type of document, including expert witness reports. He still enjoys that freedom today. AAOS did not suspend Dr. Cerciello for two years merely because he expressed his opinion by submitting an expert witness report against a fellow member of AAOS. To the contrary, AAOS suspended him after a thorough investigation when it determined that Dr. Cerciello did not evaluate Dr. Meller's patient's condition based on generally accepted standards and within the context of care delivery; that Dr. Cerciello condemned conservative treatment by Dr. Meller that fell within the generally accepted standards for managing a grade II-III AC separation; that Dr. Cerciello did not state why his recommendation for immediate shoulder surgery varied from generally accepted standards; and that Dr. Cerciello did not have knowledge about the standard of care and/or the available scientific evidence for treating the patient's grade II-III AC separation. Based on these deficiencies, AAOS reasonably assessed that Dr. Cerciello could adversely affect the health or welfare of a future patient.

AAOS provided repeated notice to Dr. Cerciello about every phase of the investigation including the scheduled hearings and his right to appeal its decision. AAOS also repeatedly requested Dr. Cerciello to submit his own statement at every stage of the investigation before it reached any decision. Dr. Cerciello was free to respond to any and all challenges to his medical competence, yet he chose to not participate in any part of AAOS's investigation.

Although Dr. Cerciello claims government intrusion and interference with his rights to free speech, it must be emphasized that Dr. Cerciello himself sought the Secretary's review of AAOS's conduct in accordance with the provisions of the Act.[10] There would have been no government review or intervention without his invitation. The government became involved only as a result of AAOS's suspension of Dr. Cerciello and its subsequent reporting to the Data Bank in an Adverse Action Report. It is the Adverse Action Report and not the issuance of an expert report that triggered any governmental action. Upon Dr. Cerciello's request, the Secretary followed the procedures provided by Congress in the Act, and determined that Dr. Cerciello's suspension was accurate and legally required under the Act. Her decision was based neither on the fact that Dr.

[10] The Secretary has established procedures allowing a physician who is the subject of a Data Bank report, i.e., an adverse action report, to dispute the accuracy of the report. 42 U.S.C. § 11136; 45 C.F.R. § 60.21. Under these procedures, the Secretary will, upon request of the subject physician, review the written information provided by both parties, i.e., the physician and the reporting entity. 45 C.F.R. § 60.21(c)(2). If the Secretary determines that the report is accurate, the Secretary will include in the report "a brief statement by the physician . . . describing the disagreement concerning the information, and an explanation of the basis for the decision that it is accurate." Id. at § 60.21(c)(2)(i). The Secretary reviews disputed reports only for accuracy of the reported information and to ensure that the information was required to be reported. The Secretary does not review the appropriateness of, or basis for, a health care entity's professional review action. See Data Bank Guidebook at F-3.

Cerciello authored an expert witness report nor on the veracity of the contents of that report. To the contrary, it was based on the requirements of the Act pertaining to adverse actions taken by professional societies and whether evidence supporting that action was set forth in the written record. The Secretary properly retained the Adverse Action Report in the Data Bank because AAOS had suspended Dr. Cerciello and the Secretary verified the accuracy of that report through the Agency's narrow review. Rather than restricting his access to free speech, the Agency requested Dr. Cerciello to submit his own statement to be included with the Adverse Action Report. Dr. Cerciello submitted several statements challenging the Adverse Action Report, and those statements will accompany the Adverse Action Report whenever it is produced in response to an appropriate request. Accordingly, I find that, contrary to Dr. Cerciello's allegations, the Agency did not restrict Dr. Cerciello's First Amendment rights to free speech.

I also note that even if it could be said that the government somehow restricted Dr. Cerciello's free speech, it would have had a compelling rationale for doing so. The regulations and procedures governing the Data Bank are reasonable and compelling in light of the well-established purpose of the Data Bank. That purpose is to protect public health by preventing incompetent or unprofessional physicians from moving from state to state with no ability for health entities to learn about any allegations of misconduct. To reach that end, Congress envisioned a peer review system supplemented by the Agency's narrow review. These compelling government interests would outweigh any perceived or real restriction of Dr. Cerciello's First Amendment rights.

Finally, some of Dr. Cerciello's arguments in his motion for summary judgment are irrelevant to my determining whether the Secretary's decision was arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. For example, Dr. Cerciello argues that Pennsylvania law provides broad immunity for expert witnesses testifying in medical malpractice cases. He hypothesizes that if Dr. Meller had filed suit against Dr. Cerciello in court because of Dr. Cerciello's opinion in the medical malpractice case, Dr. Meller's claim would be barred by expert witness immunity. Further, Dr. Cerciello asks me to consider that Dr. Meller's insurance carrier paid a settlement to resolve the matter in which Dr. Cerciello authored his expert report. He also argues that Dr. Meller is a serial grievant who uses AAOS to retaliate against medical expert witnesses. Dr. Meller is not a party in this action, and any arguments based on his alleged conduct have no impact on the issues in this case, and will not be considered here.

In conclusion, under the APA, the Secretary's decision is entitled to a presumption of regularity, and I must presume its validity. Unless that decision is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law, it must be upheld. In reviewing that decision, my inquiry was limited to determining whether the Secretary considered the relevant factors Congress intended and articulated rational connections between the facts found and the choice made. After a searching and careful inquiry into the facts of this case, I find that Dr. Cerciello has failed to show that the Secretary's refusal to remove the Adverse Action Report was arbitrary and capricious or not in accordance with law. The Secretary's decision making process was in no way

deficient and her decision was rational. Accordingly, I will grant the Secretary's motion for summary judgment, deny Dr. Cerciello's motion for summary judgment, and enter judgment on behalf of the Secretary.

An appropriate Order follows.