



**PSQIA Case Law Alert:**

**Shands Jacksonville Medical Center, Inc. d/b/a UF Health Jacksonville v. Azar and Nadia Caro**

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In May 2019, Shands Jacksonville Medical Center, Inc. (“Shands”) instituted the lawsuit Shands Jacksonville Medical Center, Inc. d/b/a UF Health Jacksonville v. Azar and Nadia Caro, No. 3:19-cv-00579-TJC-MCR, in the U.S. District Court for the Middle District of Florida.

Shands sought “declaratory and injunctive relief regarding the status of information in Shands’ possession”<sup>1</sup> under the Patient Safety and Quality Improvement Act of 2006 (“PSQIA”).<sup>2</sup> This case is still pending.

**Background**

In February 2019, Nadia Caro (“Caro”), a patient at Shands, sent a letter to Shands seeking “all adverse medical incident documents” relating to her care.<sup>3</sup> The letter listed twenty seven types of documents that Caro was seeking, including specifically “any and all documents put in a patient safety evaluation system (PSES) as patient safety work product (PSWP).”<sup>4</sup> Meaning, Caro expressly sought information protected by the PSQIA as PSWP.

This request was based on the Florida Constitution, Amendment 7 (“Amendment 7”), which gives individuals the “right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.”<sup>5</sup>

**Lawsuit Filed**

In May 2019, Shands instituted this lawsuit against Caro and Alex Azar in his official capacity as Secretary of the U.S. Department of Health and Human Service (“HHS”). Shands claimed that it possesses information that Caro would likely believe is responsive to her request,<sup>6</sup> but that those potentially responsive materials are protected by the PSQIA.<sup>7</sup>

Shands is a member of a patient safety organization (“PSO”), and the information at issue was created within Shands’ patient safety evaluation system and reported to the PSO.<sup>8</sup> Consequently,

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<sup>1</sup> Amended Complaint at 1, Shands Jacksonville Medical Center, Inc. v. Azar and Caro, No. 3:19-cv-00579-TJC-MCR (M.D. Fla. Aug. 30, 2019).

<sup>2</sup> Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C. §§ 299b-21 to 299b-26).

<sup>3</sup> Amended Complaint at 3.

<sup>4</sup> *Id.*

<sup>5</sup> Fla Const., art. X, § 25(a).

<sup>6</sup> Amended Complaint at 3 & 7.

<sup>7</sup> *Id.* at 7.

<sup>8</sup> *Id.* at 6–7.

Shands argued, the information is “privileged and confidential under the PSQIA, which expressly preempts all other laws governing the disclosure of PSWP.”<sup>9</sup>

Shands acknowledged that Florida’s Supreme Court decision *Charles v. Southern Baptist Hospital of Florida*<sup>10</sup> would appear to require Shands to produce these materials,<sup>11</sup> but under the PSQIA, Shands is obligated to protect the materials and is subject to significant, mandatory penalties<sup>12</sup> if it fails to do so.<sup>13</sup> Under the PSQIA, the Secretary of HHS may impose civil monetary fines of up to \$10,000 per act constituting a knowing or reckless disclosure of identifiable PSWP in violation of the PSQIA’s confidentiality provisions.<sup>14</sup>

Shands asked the Court to declare that the PSQIA preempts Amendment 7 and that the information at issue is privileged and confidential under the PSQIA and not subject to disclosure to Caro.<sup>15</sup> Shands also requested the Court to enjoin Caro from pursuing her request for the privileged information,<sup>16</sup> or alternatively, to enjoin the Secretary of HHS from enforcing the mandatory penalty provisions of the PSQIA to the extent Shands is requested to disclose the privileged information in state courts.<sup>17</sup>

### **Caro Motion to Dismiss**

Caro filed a motion to dismiss in November of 2019, arguing that Shands did not have standing to sue Caro because Shands had not suffered an actual injury traceable to her.<sup>18</sup> Caro asserted that the “mere fact of Ms. Caro’s request for Amendment 7 documents . . . is not enough” to show an injury.<sup>19</sup>

In response, Shands argued that “[b]y their very nature, declaratory judgments are ‘sought before an injury-in-fact occurs’”<sup>20</sup> and a party is not required to “wait for a violation of a right”<sup>21</sup> or for damages to be incurred before asking the court for relief.<sup>22</sup> Shands asserted that it has a “current and very real obligation under Florida law to provide the Amendment 7 document, which is coupled with its real and reasonable apprehension that it will be sanctioned under the PSQIA’s

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<sup>9</sup> *Id.* at 7.

<sup>10</sup> 209 So. 3d 1199 (Fla. 2017), cert. denied, 138 S. Ct. 129, 199 L. Ed. 2d 185 (2017). In *Charles*, the Florida Supreme Court held that the PSQIA privilege was preempted by state law – namely by, Amendment 7.

<sup>11</sup> Plaintiff’s Response In Opposition to Defendant Caro’s Motion to Dismiss Amended Complaint at 3, Shands Jacksonville Medical Center, Inc. v. Azar and Caro, No. 3:19-cv-00579-TJC-MCR (M.D. Fla. December 13, 2019).

<sup>12</sup> See 42 C.F.R. § 3.404.

<sup>13</sup> Plaintiff’s Response In Opposition to Defendant Caro’s Motion to Dismiss Amended Complaint at 3.

<sup>14</sup> See 42 U.S.C. § 299b-22(f)(1); 42 C.F.R. § 3.402(a).

<sup>15</sup> Amended Complaint at 9.

<sup>16</sup> *Id.* at 10.

<sup>17</sup> *Id.*

<sup>18</sup> Defendant Caro’s Motion to Dismiss at 9, Shands Jacksonville Medical Center, Inc. v. Azar and Caro, No. 3:19-cv-00579-TJC-MCR (M.D. Fla. Nov. 19, 2019).

<sup>19</sup> *Id.* at 10.

<sup>20</sup> Plaintiff’s Response In Opposition to Defendant Caro’s Motion to Dismiss Amended Complaint at 6 (citing *Goleta Nat’l Bank v. O’Donnell*, 239 F. Supp. 2d 745, 751 (S.D. Ohio 2002)).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

mandatory penalty for knowingly disclosing its PSWP.”<sup>23</sup> For those reasons, Shands argued, it has standing to seeking declaratory judgement because its injury is traceable to Caro’s request.<sup>24</sup>

Caro also argued in her motion to dismiss that Shands, in its complaint, failed to allege any facts to justify enjoining her from pursuing any state-provided rights to the documents.<sup>25</sup> In its response, Shands simply stated that it disagrees and that its complaint sufficiently alleged a claim for an injunction against Caro.<sup>26</sup>

The Court has not issued a decision on the motion to dismiss. Nor has Azar filed its answer to Shands’ complaint.

For information about how to join a patient safety organization, contact the Midwest Alliance for Patient Safety (“MAPS”) at [MAPSHelp@team-iha.org](mailto:MAPSHelp@team-iha.org) or 630-276-5657. MAPS is a federally certified patient safety organization and an IHA company.

*This document is intended to be a guide for IHA members and MAPS participants and does not constitute legal advice. For questions about this document, please contact the IHA Legal Affairs Department at [legal@team-iha.org](mailto:legal@team-iha.org) or 630-276-5506.*

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<sup>23</sup> *Id.* at 9.

<sup>24</sup> *Id.*

<sup>25</sup> Defendant Caro’s Motion to Dismiss at 19–20.

<sup>26</sup> Plaintiff’s Response In Opposition to Defendant Caro’s Motion to Dismiss Amended Complaint at 16.