



**PSQIA Case Law Alert:
Hyams v. CVS Health Corporation**

Kathryn E. Brown, Esq. & CIPP/US, Staff Counsel
October 6, 2020

In December 2019, the United States District Court for the Northern District of California issued its opinion in the case of *Hyams v. CVS Health Corporation*, No. 18-cv-06271-PJH (LB) (N.D. Cal. Dec. 11, 2019) regarding a disputed discovery request for Patient Safety Work Product (“PSWP”)¹ protected by the Patient Safety and Quality Improvement Act of 2005 (“PSQIA”).²

Summary

The Court in *Hyams v. CVS Health Corporation* analyzed the scope of the PSQIA privilege for PSWP created under the Deliberations and Analysis Pathway³ in a discovery order pursuant to a discovery dispute in an employment discrimination case brought by a former CVS Health Corporation (“CVS”) employee. CVS did not assert the PSQIA privilege for PSWP under the Reporting Pathway (i.e., collected in their PSES or reported to its PSO).

The Court ordered CVS to produce all “[s]urveillance video and still photographs collected from store cameras that monitor and record [CVS’] retail pharmacies in the regular course of business” because such videos and photographs “cannot be construed as ‘deliberations’ or ‘analysis’ under any plausible construction of those terms” to be considered PSWP created under the Deliberations and Analysis Pathway.⁴ Based on the scope of the PSWP privilege created under the Deliberations and Analysis Pathway as interpreted by the Court, the Court also ordered CVS to produce the underlying facts and documents that were subject to the deliberations and analysis but that were not separately privileged.⁵

Background

This discovery dispute arises from an employment discrimination lawsuit. Ryan Hyams (“Hyams”) sued his former employer, CVS, for racial discrimination, alleging that CVS terminated his employment because of his race and/or color.⁶ CVS alleged that it terminated Hyams’ employment for falsification of records and misrepresentations.⁷

¹ “Patient Safety Work Product” is defined at 42 C.F.R. § 3.20.

² 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).

³ PSWP can become privileged through a Reporting Pathway or a Deliberations and Analysis Pathway. See *Quality Improvement Privileges for Illinois Hospitals*, ILLINOIS HEALTH AND HOSPITAL ASSOCIATION, <https://www.team-iha.org/files/non-gated/legal/quality-improvement-privileges-illinois-hospitals.aspx?ext=>. (Mar. 11, 2019) more information on how privilege and confidentiality protections are obtained through the Reporting and Deliberations and Analysis Pathways.

⁴ *Id.* at 10.

⁵ *Id.*

⁶ First Amended Complaint at 14, *Hyams v. CVS Health Corporation*, No. 4:18-cv-06271-PJH (N.D. Cal. June 27, 2019).

⁷ Order Regarding Motion for Summary Judgment at 4, *Hyams v. CVS Health Corporation*, No. 4:18-cv-06271-PJH (N.D. Cal. Dec. 12, 2019).

In May 2017, Hyams was selected by CVS for a Drug Utilization Review system audit, which consisted of CVS creating a digital record of a fictitious patient with various ailments and drug prescriptions⁸ and was conducted within CVS' Patient Safety Evaluation System ("PSES").⁹ The audit was designed to test pharmacists' detection of possible drug interactions.¹⁰ CVS alleged that during the audit Hyams bypassed a warning screen, indicated he contacted the prescriber but did not actually do so, and then approved the prescription.¹¹ Hyams countered that he had planned on discussing the drug interaction with the patient, made notations in the test patient's file, marked the physical bag containing the prescription for an in-person, oral consultation, and then approved the prescription.¹² Ultimately, CVS terminated Hyam's employment in August 2017 leading to Hyams' lawsuit for racial discrimination.¹³

Discovery Dispute

During discovery, Hyams sought surveillance video and photographs contained within 71 documents withheld by CVS as privileged PSWP under the Deliberations and Analysis Pathway.¹⁴ CVS alleged that the 71 documents contain "data collected, and the analysis performed concerning" the audit which constituted PSWP within CVS' PSES.¹⁵ CVS did not assert the PSQIA privilege for PSWP under the Reporting Pathway (i.e., collected in their PSES or reported to its PSO). The Court analyzed the scope of the PSQIA privilege for PSWP created under the Deliberations and Analysis Pathway and CVS' PSES policies and procedures.

PSWP Created under the Deliberations and Analysis Pathway

Based on the U.S. Department of Health and Human Services ("HHS") commentary in its proposed rules to implement the PSQIA and case law on the application of a "deliberative process privilege,"¹⁶ the Court held that the PSQIA privilege for PSWP created under the Deliberations and Analysis Pathway does not extend to facula material or the underlying facts or documents that are the subject of the deliberation and analysis.¹⁷ Instead, the privilege only applies to materials that are "predecisional" and "deliberative" and reflective of the deliberative process.

⁸ *Id.* at 2.

⁹ "Patient Safety Evaluation System" means the collection, management, or analysis of information for reporting to or by a patient safety organization. 42 C.F.R. § 3.20.

¹⁰ Order Regarding Motion for Summary Judgment, *supra* note 8, at 2.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.* at 3.

¹⁴ Discovery Order, *supra* note 4, at 10.

¹⁵ *Id.* at 3.

¹⁶ The deliberative process privilege is a common law privilege that has been incorporated into a FOIA exemption that "permits nondisclosure of 'inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.'" *Desert Survivors v. U.S. Dep't of the Interior*, 231 F.

Supp. 3d 368, 379 (N.D. Cal. 2017) (citing *Nw. Envtl. Advocates v. U.S. E.P.A.*, No. CIV 05-1876-HA, at 3 (D. Or. Feb. 11, 2009)). See also *Karnoski v. Trump*, 926 F.3d 1180 (9th Cir. 2019); *Loving v. Dep't of Def.*, 550 F.3d 32 (D.C. Cir. 2008); and *FTC v. Warner Commc'ns Inc.*, 742 F.2d 1156 (9th Cir. 1984).

¹⁷ Discovery Order, *supra* note 4, at 3-4.

The Court found it reasonable to conclude that the Deliberations and Analysis Pathway does not protect the facts underlying the deliberations or analysis because HHS' commentary from the 2008 proposed rule, in accord with the Final Rule (i.e., the Patient Safety Rule), is consistent with how courts have interpreted the similar deliberative process privilege.¹⁸

The deliberative process privilege, as applied in cases involving Freedom of Information Act, applies to government materials that are predecisional (meaning they are generated before the adoption of a policy or decision) and deliberative (meaning they contain opinions, recommendation, or advice).¹⁹ The proposed rule states: "The deliberations and analysis are protected, whether the provider chooses to report the underlying information to a PSO or not. *However, the underlying information, separate and apart from the analysis or deliberation, becomes protected only when reported to a PSO.*"²⁰

The commentary in the proposed rules are in accord with the Final Rule, but HHS took a broader approach in the Final Rule to protecting factual material:

"Comment: Several commenters sought clarification whether information underlying analyses within a patient safety evaluation system was protected. One commenter suggested that data used to conduct an analysis should be protected at the same time as the analysis.

Response: As indicated in the definition of patient safety work product, information that constitutes the deliberation or analysis within a patient safety evaluation system is protected. *Information underlying the analysis may have been either reported to a PSO and protected or collected in a patient safety evaluation system.* Information documented as collected within a patient safety evaluation system is protected based on the modification to the definition of patient safety work product. Thus, information underlying an analysis may be protected. However, underlying information that is original medical records may not be protected if it is excluded by the definition of patient safety work product."²¹

HHS' broader approach aligns with the Reporting Pathway portion of the PSWP definition, which protects certain materials that are "*assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system.*"²² CVS did not assert the underlying

¹⁸ *Id.* at 5 (explaining that while FOIA case law does not necessarily control the scope of the PSQIA's Deliberations and Analysis Pathway, it provides reasonable support that HHS' construction of the Deliberations and Analysis Pathway, and the plain language "deliberations and analysis," does not necessarily extend to factual material underlying deliberations or analyses).

¹⁹ *Desert Survivors*, 231 F. Supp. 3d at 379 (citing *FTC v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984)).

²⁰ Patient Safety and Quality Improvement, 73 Fed. Reg. 8,112, 8122 (Feb. 12, 2008) (proposing rules) (emphasis added), *accord* Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,743 (Nov. 21, 2008).

²¹ Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,743 (Nov. 21, 2008) (emphasis added).

²² 42 C.F.R. § 3.20 (emphasis added).

facts were protected as PSWP under the Reporting Pathway (i.e., collected in their PSES or reported to its PSO) and the Court therefore did not extend protection to the facts.

CVS PSES Policies and Procedures

The definition of PSWP only extends to the deliberations or analysis of a PSES; therefore, the Court analyzed CVS' PSES policies to determine what information would have been created in CVS' PSES. CVS' PSES policies defined the scope of its PSES expansively: "[A]nywhere CVS Retail collects, analyzes, maintains or reports PSWP, or where CVS or its Affiliated Providers conduct Patient Safety Activities relating to CVS's Retail pharmacy business."²³ As well, the CVS PSES policies provided the following requirements:

- PSWP "shall be marked with the following: '**Privileged & Confidential: Patient Safety Work Product Under Federal Law/PSES Date _____**'";
- "PSWP reports 'are securely maintained in electronic format by the CVS Retail patient safety team"; and
- "[P]aper copies of such analyses and reports are securely stored in locked file drawers maintained by the head of the CVS Retail patient safety team."²⁴

The Court took issue with the breadth of CVS' PSES and the fact that CVS did not assert that the documents at issue complied with the requirements listed above,²⁵ but it did not express an opinion on whether those issues were detrimental to CVS' privilege claim. The Court seems to argue that a Provider cannot rely on the expansiveness of its PSES policies if it is failing to comply with relevant specifications contained within the policies.

Note that on the issue of the breadth of the PSES policy, HHS permits PSESs of all sizes based upon the specific Provider's patient safety activities. HHS intended for PSESs to be "flexible and scalable to meet the specific needs of particular provider" because a PSES is "unique and specific to a provider."²⁶ The PSES "exists whenever a provider engages in patient safety activities for the purpose of reporting to a PSO."²⁷

Although HHS does not require a Provider to document its PSES, HHS highly recommends doing so.²⁸ Failure to comply with a PSES policy does not necessarily equate to a violation of or non-

²³ Discovery Order, *supra* note 4, at 7.

²⁴ *Id.* at 8.

²⁵ *Id.* at 8–9.

²⁶ Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,739 (Nov. 21, 2008).

²⁷ *Id.* at 70,738.

²⁸ *Id.* HHS recommends a PSES policy include "how information enters the patient safety evaluation system; what processes, activities, physical space(s) and equipment comprise or are used by the patient safety evaluation system; which personnel or categories of personnel need access to patient safety work product to carry out their duties involving operation of, or interaction with, the patient safety evaluation system; the category of patient safety work product to which access is needed and any conditions appropriate to such access; and what procedures the patient safety evaluation system uses to report information to a PSO or disseminate information outside of the patient safety evaluation system." *Id.*

compliance with the PSQIA or the Patient Safety Rule,²⁹ but such failure could be used as evidence that certain activities or documents are within the scope of the PSES and thus are protected or outside of the PSES and not protected.

Key Takeaways

- The Court’s concerns about the scope of a proper PSES and the legal landscape of the PSQIA³⁰ highlight the importance of the PSES policy. The PSES policy can help defend a privilege claim by providing evidence that the Provider created the document or other material at issue within a PSES and squarely within the privilege. However, failure to follow the policy may provide a court reason not to uphold the privilege claim.

PSES policies should accurately reflect the actual policies and operational procedures in place – in short, say what the Provider does and do what is stated. In light of this case, Providers may consider building flexibility into their PSES Policies. For example, instead of stating “PSWP must be stamped,” the policy could read “PSWP should be stamped, but the lack of such stamp does not mean the document or other material is not PSWP.”

Providers may also consider whether their PSES policies are structured in a way that protects the factual information underlying the Providers’ deliberations and analyses. In accordance with the Patient Safety Rule, such protection can be achieved by either reporting the facts to a PSO or documenting the facts as having been collected within the Provider’s PSES.

- This is one of few cases where the court has recognized the Deliberations and Analysis Pathway for PSWP.³¹ See [Quality Improvement Privileges for Illinois Hospitals](#) for more information on how privilege and confidentiality protections are obtained through the Reporting and Deliberations and Analysis Pathways.
- Providers should assert both the Reporting Pathway and the Deliberations and Analysis Pathway when protecting their PSWP. Having to parse out what is facts versus analysis may ultimately have a chilling effect on Providers voluntarily reporting PSWP if they believe

²⁹ For example, the PSQIA does not require PSWP to be stamped in order for it to constitute PSWP, and a failure to mark PSWP in accordance with the terms of a PSES policy should not mean the document or materials at issue do not constitute PSWP. Note that at least one court has found that the stamp can serve as evidence that the document or other materials at issue is in fact PSWP. In the absence of a definitive statement that the information is PSWP maintained in a PSES and provided to a PSO (e.g., an affidavit), a stamp identifying the PSO and designating the documents and other materials as PSWP is sufficient to find the documents and other materials fall within the ambit of the PSQIA. See *Quimbey v. Cmty. Health Sys. Prof’l Servs. Corp.*, 222 F. Supp. 3d 1038 (D. NM. 2016). Note also that the PSQIA does not require that Providers maintain PSWP in a single location, such as a locked file drawer maintained by the Chief Quality Officer. See 42 C.F.R. § 3.106 for the security requirements which apply to PSOs, not Providers.

³⁰ Discovery Order, *supra* note 4, at 10. The Court questioned, but did not opine, on whether a PSES that complies with the requirements set forth in CVS’ PSES policies and procedures would be a proper PSES under PSQIA and whether the documents at issue were deliberations or analyses of a “proper [PSES], “as opposed to a putative deliberations or analyses that are unrelated to a [PSES].” *Id.*

³¹ See *Rumsey v. Guthrie Medical Group, P.C.*, No. 4:18-CV-01605 (M.D. Pa. Sept. 26, 2019) which was one of the first published opinions upholding the privilege under the Deliberations and Analysis Pathway.

the information will not receive the full protections to which it is entitled under the PSQIA.³²

- This case is a good reminder that while many cases involving the PSQIA privilege arise in the medical malpractice context, the PSQIA and privilege can apply in a variety of lawsuits.³³ Therefore, Providers may find it prudent to educate, at minimum, their employment counsel on the PSQIA. As well, it may be helpful to gauge outside counsel's familiarity with this law and take steps to ensure outside counsel understand the PSQIA and its protections.

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

This document is for informational purposes only and does not constitute legal advice. For questions about this document, please contact the IHA Legal Affairs Department at legal@team-iha.org or 630-276-5506.

³² There may be some support against requiring Providers to parse out facts from deliberations and analyses. The FOIA deliberative process privilege relied upon by the Court is not an absolute privilege. It does not extend to "[p]urely factual material that does not reflect the deliberative process." On the other hand, the privilege applies where the "factual material is so interwoven with the deliberative material that is not severable." *Desert Survivors*, 231 F. Supp. 3d at 379 (citing *FTC v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984); *Binion v. Dep't of Justice*, 695 F.2d 1189, 1193 (9th Cir. 1983)). A root cause analysis or other similar analysis, for example, cannot be done without gathering facts to help answer questions about whether there is a quality or safety issue and reviewing secondary sources. The facts are a critical part of the analytic process and are part of the analysis itself; whether the facts are so interwoven that they cannot be severed from the deliberations and analysis would likely be a case by case determination made by a court. Note also that *Daley v. Teruel* seems to provide an alternative option to severing the underlying information from the deliberations and analysis. While addressing plaintiff concerns that upholding the PSQIA privilege for the documents at issue would allow Providers to hide valuable information during discovery, the *Daley* court stated "nothing about these documents being privileged renders the facts that underlie the patient safety work product as privilege. *Plaintiff can still obtain medical records, as plaintiff did in this case, have their experts analyze and make opinions about those records, and depose doctors and nurses regarding an incident.*" *Daley*, 107 N.E.2d at 1044 (emphasis added). Although the *Daley* court does not state that the underlying information is protected as PSWP under the Deliberations and Analysis Pathway, the court seems to direct plaintiffs to obtain the underlying facts elsewhere, outside the PSES in un-privileged material (e.g., a medical record). This alternative option is contrasted with the FOIA approach which seems to always require severance if possible: "[T]he deliberative process privilege does not protect documents in their entirety; if the government can segregate and disclose non-privileged factual information within a document, it must." *Loving*, 550 F.3d at 38 (citing *Army Times Publ'g Co. v. Dep't of Air Force*, 998 F.2d 1067, 1071 (D.C. Cir. 1993)).

³³ See *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. Ct. 2012) (administrative subpoena for incident reports); *Tinal v. Norton Healthcare, Inc.*, 2014 U.S. Dist. LEXIS 191995 (W.D. Ky. July 15, 2014) (employment discrimination); *Johnson v. Cook Cnty.*, 2015 U.S. Dist. LEXIS 115868 (N.D. Ill. 2015) (Section 1983 lawsuit for constitutional violation); *Taylor v. Hy-Vee, Inc.*, 2016 U.S. Dist. LEXIS 177764 (D. Kansas Dec. 22, 2016) (employment discrimination); and *Wantou v. Wal-Mart Stores, Inc.*, No. 5:17-cv-00018-RWS-CMC (E.D. Tex. May 14, 2018) (employment discrimination).