UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

MARIA TINAL PLAINTIFF

v. CIVIL ACTION NO. 3:11-CV-596-S

NORTON HEALTHCARE, INC. DEFENDANT

ORDER

This order is the second order in a series of orders entered by the Magistrate Judge to address a discovery dispute between the Plaintiff, Maria Tinal (Tinal), and her former employer, Norton Healthcare, Inc. (Norton). Tinal, a pharmacist, was employed by Norton at Suburban Hospital for nearly a decade until her discharge from employment in September of 2010. She claims that Norton unlawfully discharged her in violation of the Americans with Disabilities Act (ADA) following her return to work in February of 2009, after brain surgery to remove a tumor. Norton maintains it discharged Tinal for a series of errors she made related to dispensing medication that caused her to accrue sufficient disciplinary points to require her discharge under Norton's progressive discipline policy.

After Tinal filed suit against Norton in state court, it removed her lawsuit to federal court where the parties soon became embroiled in a discovery dispute over certain document requests made by Tinal in April of 2013. This dispute led Tinal to file a motion to compel discovery.[1] After the parties fully briefed their dispute,[2] the Magistrate Judge addressed their concerns by an order entered on January 24, 2014.[3]

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[1] DN 29, Pl's Mot. to Compel.
[2] DN 30, Def's Resp. in Opp; DN 33, Pl's Reply; DN 34, Pl's Mot. for Hearing; DN 35, Resp. to Mot. for Hearing; DN 36, Reply to Resp.
[3] DN 37, Order granting in part mot. for disc.

That order did not entirely end the dispute. An important issue remained unresolved about the application of a statutory privilege that Norton attempted to assert in response to Tinal's requests for production no. 10, 12, 13 and 17. These requests seek the following records:

Request No. 10: All records regarding Root Cause Analysis concerning any and acts of Maria Arnold in the period from Jan. 1, 2009, through Dec. 31, 2010. This shall include all documents viewed, compiled, received, collected, or gathered in connection with Root Cause Analysis, and all documents generated concerning or in connection with the Root Cause Analysis.

Request No. 12: All records concerning all errors of pharmacists at Suburban Hospital, occurring from Jan. 1, 2008, through Dec. 31, 2010, including but not limited to errors discernible in defendant's Meditech system or it Care Link system.

Request No. 13: All records concerning patient harm or adverse consequences associated with any errors of or attributed to Maria Tinal in the period from Jan. 1, 2009, through Dec. 31, 2010.

Request No. 17: All documentation concerning any error by plaintiff resulting in a patient getting too much Oxycodone in 2010, including without limitation records regarding any patient harm or adverse consequences.

(DN 29, Mot. to Compel, Ex. C, Def's First Sup. Resp., pp. 7-8).

Norton in response to each document request asserted the statutory privilege for patient safety work product created by the Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 U.S.C. §299b-21, *et seq.*[4] Tinal contended that the patient safety work product privilege defined in 42 U.S.C. §299b-22 does not apply to her employment discrimination case given the legislative history of the PSQIA and the well-established policy in favor of complete discovery in federal civil rights and discrimination cases.[5] Tinal also argued that because Norton had declined, despite her requests, to provide her with a privilege log as required by Rule 26(b)(5)(A) it had waived its claims of statutory privilege.

[4] Pub.L.No. 109-41; 119 Stat. 424-34 (2005).
[5] DN 33, Reply, pp. 8-15.

The Magistrate Judge considered the statutory definition of patient safety work product set out in 42 U.S.C. §299b-21(7) and the statutory provisions of the patient safety work product privilege contained in 42 U.S.C. §299b-22, but did not resolve the broader question of whether these provisions could be appropriately applied to prevent the discovery of otherwise relevant documents in a federal civil rights lawsuit.[6] Instead, a preliminary question over the proper assertion of the privilege under Rule 26(b)(5)(A) became the focus of the original order.

The Magistrate Judge concluded that Norton first must provide Tinal with an adequate privilege log under Rule 26(b)(5)(A) before the substantive dispute over the nature and scope of the statutory privilege itself could be resolved. The Court accordingly ordered Norton "to produce a thorough, detailed privilege log that includes each of the documents that it now withholds based on the patient safety work product privilege created by the Act."[7] The order in a footnote set forth the specific contents required in Norton's privilege log; one of which included "a general description of the contents [of the privileged documents] sufficient to permit the Plaintiff to meaningfully evaluate the claim of privilege…."[8] The order further directed Norton to provide for *in camera* review all of the documents on which it claimed the privilege created by the PSQIA.[9]

On Feb. 21, 2014 Norton filed under seal a copy of its privilege log along with the 84 numbered documents being withheld.[10] The privilege log included no description of the specific factual contents of any of the documents.[11] Instead, the section of the log labeled "Description of Document" for each entry of the first 77 documents contained the following language:

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[6] DN 37, Order, pp. 16-23.
[7] DN 37, Order, p. 22.
[8] Id., p. 22, n. 33.
[9] Id., p. 23.
[10] DN 38, Notice of Filing; DN 39, Def's Privilege Log, Vol. I; DN 40, Def's Privilege Log, Vol. II (DNs 39 and 40 filed under seal).
[11] DN 39, Privilege Log, Vol. I; DN 40, Privilege Log, Vol. II) (filed under seal).

> Report of a medication event. The report is submitted electronically. It contains a number of data fields that may be entered over time. The data fields include patient demographics, certain provider details, narratives and clinical analysis of the event, and process checks for use in determining the necessity, scope or pathways of future reviews. Each report contains the unique data relative to the event for which the report was created, but the form for each report is virtually the same except for an occasional update. **The unique information with each report is not generally described within this privilege log because the factual relevancy of the event is not an element for the Patient Safety Work Product privilege**.

(DNs 39, 40, Privilege Logs, Vol. I and II)(emphasis added).

Tinal filed a supplement to her motion to compel to address the adequacy of the privilege log.[12] In her supplement, Tinal objects that the log "omits virtually all information that would be of use to the Plaintiff, or would comply with the requirements of the Court's Jan. 24, 2014 order and Rule 26(d)(5)(A(ii) to describe documents withheld under a claim of privilege in a manner allowing assessment of the claim of privilege."[13] Tinal concludes that she therefor has no way to assess the relevance of the non-described information to her ADA and other claims.

The result is that she cannot meaningfully discuss the reasons why the policy of broad discovery in federal civil rights actions such as her own outweighs the underlying policy of the PSQIA-- an Act intended by Congress to address patient safety improvement in the context of potential claims of medical malpractice. Tinal accordingly asks the Court to assume that each of the 84 documents at issue contains relevant information to her claims so that the underlying purpose of the PSQIA will be satisfied by the redaction of identifying information and the

[12] DN 41, Pl's Supp. Brief.
[13] Id., p. 1.

imposition of a confidentiality provision.[14] With these protections in place, Tinal asks the Court to order Norton to produce the documents now being withheld.

Norton filed a response to Tinal's supplemental brief.[15] The response renews Norton's position that the documents sought are confidential and privileged under PSQIA.[16] Norton also insists that the privilege log is adequate for Tinal to analyze the privilege without revealing the protected information itself.[17] The patient safety work product privilege, Norton argues, unlike a common law privilege developed by the courts, is statutorily-created; therefor, its scope and application are governed entirely by the text of the statute, which defines patient safety work product at 42 U.S.C. §299b-21(7) and creates a broad statutory privilege for it under §229b-22(a).

Norton contends that the privilege language of §229b-22(a) is plain and unambiguous. Statutory construction by the Court consequently is unnecessary and inappropriate.[18] Norton adds that the PSQIA is not the first time that Congress has created a broad statutory privilege. Similar examples include statutory privileges created for highway safety data, census data and aviation accident reports.[19] Based on the relevant language of the PSQIA, Norton explains that so long as a healthcare provider such as Norton processed the information at issue as part of a patient safety evaluation system (PSES) for report to a patient safety organization (PSO) under §299b-21(7)(A), and the information itself falls within the designation of patient safety work

[14] Id., pp. 4-5. Section 299b-21(2) and (3) define "identifiable patient safety work product" and "nonidentifiable patient safety work product, respectively. *See* 42 U.S.C. § 299b-21(2),(3) (2014). Tinal asks that the documents be redacted so as to become nonidentifiable patient safety work product.
[15] DN 43, Def's Resp.
[16] 42 U.S.C. §299b21, *et seq*.
[17] DN 43, Resp. p. 2.
[18] DN 43, p. 3-4.
[19] DN 43, pp. 4-5 (citing the Highway Safety Act of 1966; 23 U.S.C. §409. *See Pierce County v. Gullian*, 537 U.S. 129, 147 (2003); *Baldrige v. Shapiro*, 455 U.S. 345, 362 (discussing the privilege arising under the Census Act)).

product as defined by §299b-21(7)(B), then the information is confidential and absolutely protected.

Both conditions in Norton's view are established on the face of its privilege log, which the Court may confirm by *in camera* review of the affected documents. Because all the documents satisfy the requirements of the Act, Norton concludes that Tinal's claim that she cannot evaluate the "relevancy of the privileged information" is misplaced because the issue is not relevancy. The clear language of the statute set out in §299b-22(a) and (b) states that the privilege for patient safety work product exists "notwithstanding any other provision of federal law." All Tinal's arguments based on relevancy, need, hardship or public policy accordingly miss the mark as "Congress leaves no room for such a policy…."[20] Finally, Norton attempts to bolster its position with several decisions of the Jefferson Circuit Court of Jefferson County, Kentucky, in which the state court has upheld the application of the patient safety work product privilege in litigation that involves claims of medical negligence.[21]

Tinal has moved the Court for leave to file a reply, which the Court shall grant by separate order.[22] Attached to the motion is Tinal's reply. Tinal contends that Norton "assumes away" the key issue - - how to balance the competing policies that underlie the PSQIA and federal civil rights statutes such as the ADA.[23] She reiterates that the PSQIA was born out of a concern to protect health care providers from having patient safety information such as "root cause analysis" used against them in medical malpractice lawsuits, which the present case is not.

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[20] DN 43, Resp. p. 15.
[21] DN 43, Supp. Resp., Ex. B, *Fancher v. Shields, et al*, Case No. 10-CI-4219 (Jeff. Cir. Ct. Aug. 16, 2011) (Shake, J.); *Johnson v. Norton Hosps. Inc.*, Case No. 12-CI-5252 (Jeff. Cir. Ct. Jan. 21, 2014) (McDonald-Burkman, J.); *Dezarn, et al. v. Norton Healthcare*, Case No. 11-CI-05222 (Jeff. Cir. Ct. Feb. 17, 2014) (Perry, J.).
[22] DN 47, Mot. for Leave.
[23] DN 47, p. 1.

The information Tinal seeks relates only to her claims of employment discrimination. She hopes to show that other Norton employees, pharmacists and pharmacy staff, made drug-related errors comparable to those that allegedly led to her discharge, but were not themselves terminated from employment. In other words, Tinal hopes to prove that not only were similarly-situated employees treated less harshly than she was, due to her disability, but also that the true cause or "root cause" of the errors Norton attributes to her were actually inadequate hospital procedures for dispensing medication, rather than her own error.

Norton allegedly has made it impossible for Tinal to evaluate the relevance and importance of the documents now being withheld. Tinal protests that what Norton asks the Court to do now is to adopt a "rote application of the PSQIA privilege…."[24] Such an approach in Tinal's opinion completely ignores the legislative purpose that led to the PSQIA in the first instance - - protection of health providers who collect patient safety data from liability exposure in medical malpractice litigation - -a purpose that is entirely divorced from the context of federal civil rights litigation.

Tinal further argues that the judicial decisions cited by Norton in its supplemental response do not support its cause. Rather, the cited case law reaffirms the basic principle that statutes which establish an evidentiary privilege are to be narrowly construed since privileges "impede the search for the truth." *Pierce County v. Guillen*, 537 U.S. 129, 144-45 (2003) (citing *Baldrige v. Shapiro*, 455 U.S. 345, 360 (1982)). She insists that the cited cases do not suggest that the text of a statutory privilege is to be read separate and apart from the legislative purpose for which it was created.[25] Finally, as for the three decisions of the Jefferson Circuit Court that apply the PSQIA, Tinal observes that all three were medical malpractice cases and therefore do

[24] DN 47, p. 2.
[25] Id., p. 3.

nothing to diminish her position that the patient safety work product privilege is intended to be applied only in such malpractice actions, rather than federal civil rights litigation, an area of the law in which the policy of broad discovery has been well established.

LEGAL ANALYSIS

We begin our consideration of the above arguments bearing in mind several well-established, if not determinative, principles. First, no question exists in the Court's mind that discovery in a federal civil rights action is intended to be broad in scope. *See Trevino v. Celanese Corp.*, 701 F.2d 397, 405-406 (5th Cir. 1983) ("The imposition of unnecessary limitations on discovery is especially frowned upon in Title VII cases.");*Rich v. Martin-Marietta Corp.*, 522 F.2d 333, 343 (10th Cir. 1975) ("It is plain that the scope of discovery through interrogatories and requests for production of documents is limited only by relevance and burdensomeness, and in an EEOC case the discovery scope is extensive"); *Heward v. Western Elec. Co.*, Case No. 83-2293, 1984 WL 15666 at *6 (10th Cir. 1984) ("[T]his court that stated that in alleged discrimination cases the discovery scope is extensive; so extensive, that 'if the information sought promises to be particularly cogent to the case, the defendant must be required to shoulder the burden [of production].") (citing *Rich v Martin Marietta Corp,* 522 F.2d at 343);

Second, the policy of broad discovery in federal discrimination litigation has frequently been relied on by the federal courts to trump judicially-created privileges such as the medical peer review privilege. Tinal has cited a number of decisions that reject the common law medical peer review privilege. *See Adkins v. Christie*, 488 F.3d 1324, 1328-29 (11th Cir. 2007), *cert. den'd*, 552 U.S. 1131 (2008) ("[T]he [medical peer review] privilege must be considered against the corresponding and overriding goal - - the discovery of evidence essential to determining

whether there has been discrimination in employment. Guided by the principles disfavoring privileges … we conclude that the medical peer review process does not warrant the extraordinary protection of an evidentiary privilege in federal civil rights case."); *Francis v. United States*, Case No. 09 CIV 4004 (GBD) (KNF), 2011 WL 2224509 at *4 (S.D.N.Y. May 31, 2011) ("Although there appears to be consensus among lower courts and in other circuits that no federal privilege protects medical peer review materials in civil rights or antitrust actions … no such consensus has developed in medical or dental malpractice actions.") (collecting cases). In fact, recently our sister district court for the Northern District of Ohio in *Allen v Cuyahoga County*, no. 1:12-CV-1659, 2014 WL 434558 at *5 (N.D. Ohio Feb. 4, 2014) stated the matter directly and more broadly: "The weight of authority in the Sixth Circuit and elsewhere is that no medical peer review privilege exists under federal common law." (citing *Adkins*, 488 F.3d at 1328-30; *K.D. ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 592 (D. Del. 2010) (balance of authority weighs against recognition of medical peer review privilege)).

Third, the Court also agrees with Tinal that the impetus for congressional enactment of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §299b-21, *et seq*. was to limit the medical malpractice exposure of healthcare providers who collect and report patient safety information to a PSO as part of a PSES by the legislative creation of a privilege for patient safety work product via 42 U.S.C. §299b-22. This conclusion is strongly supported by the 1999 report of the Institute of Medicine (IOM), *To Err is Human: Building a Safer Health System*.[26]

[26] National Academy Press 2000 (available at http://www.nap.edu/openbook.php?isbn=0309068371 (last visited Apr. 28, 2014).

Tinal correctly notes that *To Err is Human* is cited in the Federal Register as being a primary source for the PSQIA.[27] The IOM report itself refers to the "medical liability system" as being an obstacle to the efforts of medical providers to learn from their errors.[28] Chapter 6 of the IOM report repeatedly refers to medical malpractice lawsuits and negligence claims.[29] Neither the Senate report[30] nor the House report[31] for the PSQIA gives any indication that Congress had in mind the possibility that the patient safety work product privilege would ever be asserted in the context of a federal civil rights action. In fact, neither report makes mention of employment discrimination or federal civil rights law. Further, federal common law at the time of the passage of the PSQIA did recognize a consensus in the lower federal courts that no medical peer review privilege exists in federal civil rights or antitrust litigation. Tinal appropriately cites in her original reply a number of published federal decisions that recognize this consensus.[32]

The critical task for the Court, keeping in mind the above principles, is to determine first if the privilege for patient-safety work product applies outside the context of the medical malpractice arena. If the privilege does apply to other types of claims, then the Court must determine second whether Norton has asserted the privilege to documents that qualify under the terms of the relevant federal statutes and regulations that implement the PSQIA. Finally, if the privilege created by the PSQIA does apply to claims of employment discrimination, and the 84 documents contained in Norton's privilege log satisfy the statutory requirements of 42 U.S.C. §§299b-21 and 299b-22, we must determine whether the manner in which Norton has prepared its privilege log affects the outcome of our analysis.

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[27] See 73 Fed. Reg. 8112, 8113 (Feb. 12, 2008) ("Much of the impetus for this legislation can be traced to the publication of the landmark report, *To Err is Human*, by the Institute of Medicine in 1999."). *See also, KD v. United States*, 715 F. Supp.2d at 595.
[28] DN 33, Reply, p. 11, Ex. G "Executive Summary" p. 3.
[29] Id., Ex. H. *To Err is* Human, Chapter 6, pp. 113-115.
[30] S.R. No. 108-196 (2003) (available at 2003 WL 22725427).
[31] H.R. No. 108-28 (2003) (available at 2003 WL 881122).
[32] DN 33, Reply. pp. 14-16.

Norton in its supplemental response distinguishes the statutory patient safety work product privilege from the common law medical peer review privilege. Norton insists that because the PSQIA-based privilege is a creature of statute, rather than judge-made law, we must first focus exclusively on the language of the relevant statutes in our efforts to determine when and how the privilege is to be applied. The Court agrees that the language of the statute is critical. Congress has set forth critical requirements that define both when and how the patient safety work product privilege is to be applied.

The Patient Safety and Quality Improvement Act of 2005

The Act defines patient safety work product at 42 U.S.C. §299b-21(7)(a) to be

> any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements - -
>
> (i) which—
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities;
>
> and which could result in improved patient safety, healthcare quality, or healthcare outcomes; or
>
> (ii) which identify or constitute the deliberations for analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

43 U.S.C. §299b-21(7)(A)(2014).

Subsection (B) of §299b-21(7) clarifies that patient safety work product does not include a patient's medical record, billing and discharge information, or other original patient or

provider records;[33] nor does it include information that is collected, maintained or developed separate from a patient safety evaluation system.[34] Information such as a patient's medical records, billing or discharge information, as well as information that is collected and maintained separate from a patient safety evaluation system, is fully discoverable and admissible in criminal, civil or administrative proceedings.[35]

A "patient safety evaluation system" is statutorily defined by §299b-21(6) to include "the collection, management, or analysis of information for reporting to or by a patient safety organization."[36] A "patient safety organization" is itself defined by §299b-21(4) to be "a private or public entity or component thereof that is listed by the Secretary pursuant to §299b-24(d) of Title 42."[37] The term "patient safety activities" found in the definition of patient safety work product is defined by §299b-21(5) to include:

(A) efforts to improve patient safety and the quality of healthcare;
(B) the collection and analysis of patient safety work product;
(C) the development and dissemination of information on improving patient safety;
(D) the use of patient safety work product for the purpose of encouraging a culture of safety and minimizing patient risk;
(E) the maintenance of procedures to preserve confidentiality with respect to patient safety work product;
(F) the provision of appropriate security measures for patient safety work product;
(G) the utilization of qualified staff;
(H) the activities related to the operation of a patient safety evaluation system and providing feedback to participants in such system.[38]

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[33] 42 U.S.C. §299b-21(7)(B)(i)(2014).
[34] 42 U.S.C. §299b-21(7)(B)(ii)(2014).
[35] 42 U.S.C. §299b-21(7)(B)(iii)(I)-(III)(2014). It is therefore possible that information contained in the 84 documents provided for *in camera* review, if determined to be privileged, remains discoverable to the extent that Norton maintains that information outside of the PSES. One potential example that comes to mind would be a disciplinary entry in an employee's personal records based on an adverse patient safety-related event. No such discovery issue is currently before the Court, which includes the cited example by way of explanation to highlight that information otherwise subject to the privilege may remain discoverable under certain circumstances statutorily described in §299b-21(7)(B).
[36] 42 U.S.C. §299b-21(6)(2014).
[37] 42 U.S.C. §299b-21(4)(2014).
[38] 42 U.S.C. §299b-21(5)(A)-(H) (2014).

A "provider" for the purpose of the Act is defined by §299b-21(8) to include an individual or entity licensed or authorized under state law to provide healthcare services, such as for example a hospital, nursing facility, rehabilitation facility, home health agency, hospice program, pharmacy, physician or healthcare practitioner's office and the medical professionals employed at such facilities.[39] No dispute exists that Norton is a provider under the Act or that it maintains a patient safety evaluation system (PSES) that reports patient safety information to a listed patient safety organization (PSO). What is at issue is whether such status by operation of the PSQIA affords any privilege to the requested documents outside the context of a medical malpractice action.

By operation of 42 U.S.C. §299(b)-22, patient safety work product is to be considered both privileged and confidential. Specifically, the statute provides:

> (a) Privilege
>
> Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be - -
>
> (1) Subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> (2) Subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> (3) Subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;
>
> (4) Admitted as evidence in any federal, State, or local government civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

[39] 42 U.S.C. §299b-21(8)(A)(i), (ii) (2014).

> (5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under States law.
>
> (b) Confidentiality of patient safety work product
>
> Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

42 U.S.C. §299(b)-22(a),(b) (2014).

Subsection (c)(1) of §299b-22 creates an exception to both the privilege and confidentiality provisions of subsections (a) and (b), respectively, when a court following in camera review determines that the patient safety work product at issue contains evidence of a crime that is material to a criminal proceeding and is not reasonably available from any other source.[40] An exception also is created under subsection (c)(1) and the equitable relief provisions of §299b-22(f)(4) to permit an aggrieved individual to bring suit who is discharged, passed over for promotion or otherwise denied benefits based on his or her report in good faith of information to a patient safety organization, or to a provider with intent that it be reported to a patient safety organization.[41] Finally, an exception to both the privilege and confidentiality provisions of the statute exists when each provider identified in identifiable work product authorizes that it be disclosed.[42]

Subsection (c)(2) creates exceptions to the confidentiality provisions of §299b-22(b). Eight alphabetically designated exceptions are set forth in this subsection. None of the

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[40] 42 U.S.C. §299b-22(c)(1)(A)(2014).

[41] 42 U.S.C. §299b-22(c)(1) (B)(2014). Tinel does not allege in her complaint that her discharge by Norton was the result of her efforts to provide patient safety information to a PSO or to her provider for report to a PSO. Such an allegation would potentially raise questions of whether otherwise confidential and privileged patient safety work product would be subject to the equitable relief provisions of §299-22b(f)(4)(A), which expressly empowers an individual subject to an adverse employment action for having reported patient safety information to bring a civil action to obtain appropriate equitable relief (reinstatement, back pay and restoration of benefits).

[42] 42 U.S.C. §299b-22 (c)(1)(C)(2014).

exceptions, however, applies to the circumstances of the present case. We accordingly do not set them forth in this decision. A final exception from the privilege provision of subsection (a) is created by subsection (c)(3) of §299b-22, which provides that the privilege shall not apply to, nor shall it prohibit, voluntarily disclosed, nonidentifiable patient safety work product.[43]

The Rules of Statutory Analysis

Our task now is to examine the above language in the context of the full Act so as to give effect to congressional intent. *See United States v. Amer. Trucking Assoc.*, 310 U.S. 534, 542 (1940) ("In the interpretation of statutes, the function of the courts is easily stated. It is to construe the language so as to give effect to the intent of Congress."). The first step in such statutory interpretation is always taken by examining the language of the statute in an effort to divine its plain meaning if possible. *See United States v. Parrett*, 530 F.3d 422, 429 (6th Cir. 2008) (citing *United States v. Wagner*, 382 F.3d 598, 606-07 (6th Cir. 2004)).

As the U.S. Supreme Court has explained, "There is, of course, no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes. Often these words are sufficient in and of themselves to determine the purpose of the legislation." *Amer. Trucking Assoc.*, 310 U.S. at 543. *See also, Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 739 (1989) ("The starting point for our interpretation of a statute is always its language.") (citing *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980)). Only when the plain meaning cannot be

[43] 42 U.S.C. § 299b-22(c)(3)(2014). Two types of patient safety work product are created by the Act. Identifiable patient safety work product and nonidentifiable patient safety work product. Identifiable patient safety work product is presented in a form that allows the identification of the involved health care provider and the individual who reported the information. *See* 42 U.S.C. §299b-21(2)(2014). Nonidentifiable patient safety work product is defined by §299b-21(3) to be "patient safety work product that is not identifiable patient safety work product." *See* 42 U.S.C. §299b-21(3)(2014).

determined from the language of the statute read in its context, or such plain meaning would lead to either absurd or futile results, does the court continue to the second step of the 3-step process for statutory interpretation. *See Dept. of Housing and Urban Dev. v. Rucker*, 535 US. 125, 134-35 (2002) ("To avoid a law's plain meaning in the absence of ambiguity 'would trench upon the legislative powers vested in Congress by Art. I, §1, of the Constitution.'") (quoting *United States v. Albertini*, 472 U.S. 675, 680 (1985)). *Amer. Trucking Assoc*. 310 U.S. at 543 (court may look beyond the words to the purpose of the Act when their plain meaning would lead to absurd or futile results).

Step 2 of the legislative interpretation framework requires the Court to go beyond the natural meaning of the full text of a disputed statute to examine the common-law meaning of its statutory terms in an effort to resolve any ambiguity determined to be present. *See gen., Beaven v. U.S. Dept. of Justice*, 622 F.3d 540, 548 (6th Cir. 2010) (discussing the 3-step legislative-interpretation framework established by the Supreme Court); *Elgharib v. Napolitano*, 600 F.3d 597, 601 (6th Cir. 2010) (same). In the absence of such ambiguity, rules of statutory construction as an aid to ascertain the meaning of statutory terms not otherwise obscure or doubtful is not appropriate. *See Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923) (Rules of statutory construction "have no place, as this court has many times explained, except in the domain of ambiguity."). *See also, United States v. Denham*, 663 F. Supp.2d 561, 563 (E.D. Ky. 2009) ("If the meaning [of the statute] is plain, then the interpretation need go no further and has concluded.") (citing *United States v. Goins*, 516 F.3d 416, 420 (6th Cir. 2008)).

Third and finally, if the intent of Congress cannot be ascertained from the plain language of the statute or from common law definition of its otherwise ambiguous terms, then and only then, the courts may consider the statutory and legislative history for their guidance. *Beaven*,

622 F.3d at 548 (citing *Lockhart v. Napolitano*, 573 F.3d 251, 255 (6th Cir. 2009). *See also, Parrett*, 530 F.3d at 429 ("If the statutory language is not clear, we may examine the relevant legislative history.").

Here, we need go no further than step 1 of the 3-step legislative-interpretation process. The plain language of the privilege provision set forth in §299b-22(a) answers in full the question of whether Congress intended the patient safety work product privilege to apply outside the context of medical malpractice actions. With only limited the exception set forth in subsection (c) of §299b-22, those items that qualify as patient safety work product shall be privileged **"notwithstanding any other provision of the federal, state or local law**." 42 U.S.C. §299b-22(a)(emphasis added). Further, the qualifying patient safety work product by operation of §299b-22(a)(2) shall not **"be subject to discovery in connection with a federal, state, or local civil, criminal or administrative proceeding**…." 42 U.S.C. §299b-22(a)(2) (2014)(emphasis added).

Nowhere in the quoted language is there any limitation or exception for federal civil rights or employment discrimination cases. To the contrary, the statute speaks in plain, unequivocal terms that encompass all federal, state or local civil or criminal proceedings. The same type of plainly-worded, absolute prohibition is found in subsection (a)(4) of the statute which states clearly that patient safety work product shall not be **"admitted as evidence in any federal, state, or local governmental civil proceedings**…." 42 U.S.C. §299b-22(a)(4) (2014)(emphasis added). No ambiguity can be read into the quoted provisions of subsection (a) of the privilege statute.

The next portion of the statute, subsection (b), on confidentiality is likewise unambiguous in its plain language. Patient safety work product is to be treated as being confidential and is not

to be disclosed "notwithstanding any other provision of federal, state or local law" other than that found in subsection (c) of §299b-22, the subsection on exceptions. Subsection (c) of the statute does appear to provide several very limited exceptions to the otherwise absolute privilege and confidentiality provisions of subsections (a) and (b), respectively.

Under subsection (c) of §299b-22, as noted above, the provisions of subsections (a) and (b) of the statute do not apply to "disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an *in camera* determination that such patient safety work product contains evidence of a criminal act and … is material to the proceeding and not reasonably available from any other source." 42 U.S.C. §299b-22(c)(1)(A)(2014). In other words, Congress has determined in the context of a criminal proceeding that relevant patient safety work product may be non-privileged and non-confidential *if* the court after *in camera* review determines it to contain evidence of a criminal act that is both (1) material to the criminal proceeding and (2) not reasonably available from any other source. *Id*.

This exception of §299(b)-22(c)(1)(A) is the sole explicit exception for litigation, albeit criminal in nature. The exception obviously has no application in the context of the present action, a civil suit that alleges the violation of the ADA, among other claims. Noteworthy is the fact that Congress did not include in §299(b)-22(c) an exception for proceedings involving federal civil rights actions or employment discrimination claims. Indeed, Congress made no explicit reference whatsoever to civil claims at all in the exception provisions of subsection (c) outside the equitable remedies provisions of §299b-22(f)(4)(A) incorporated by reference into §299b-22(c)(1)(B). That reference by incorporation relates only to civil claims brought by employees of a provider who suffer an adverse employment action for their efforts to report patient safety information to a PSO. Only in this one, highly-limited context did Congress

provide an exception to the privilege and confidentiality protections for civil litigation in an employment context.[44]

In the absence of any explicit exception to the plain language of subsections (a) and (b) for federal civil rights actions, it is clear to the Court that the privilege created for patient safety work product is intended to apply across-the-board to all other types of claims. We certainly have no authority through the means of statutory construction to judicially create any exception that Congress did not provide for in the language of the statute. *See United States v. Johnson* 529 U.S. 53, 58 (2000) ("When Congress provides exceptions in a statute, it does not follow that the courts have authority to create others. The proper inference, and the one we adopt here, is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth."). *N.L.R.B. v Ky River Community Care, Inc.*, 532 U.S. 706, 711 (2001) ("The general rule of statutory construction that the burden of proving justification or exemption under a special exception to the prohibitions of a statute generally rests on the one who claims its benefits.") (quoting *FTC v. Morton Salt co.*, 334 US. 37, 44-45 (1948)). Because Tinal bore the burden to establish an exception to the privilege for federal civil rights claims, and because the plain language of subsections (a) and (b) of §299b-22 clearly establishes that Congress intended patient safety work product to be privileged and confidential in all federal, state and local civil, criminal and administrative proceedings, we are required by the above-cited authority, along

[44] Norton points out in footnote 11 at page 3 of its supplemental response (DN 43) that the term "exceptions" as used in the heading for subsection (c) of §299b-22 is arguably a misnomer as the immediately following language of subsection (d)(1) of the same statute indicates that the disclosure of patient safety work product under subsection (c) does not remove the privileged and confidential nature of the disclosed work product. The Court agrees that there is obvious tension between the provisions of subsections (c) and (d) of the statute, which appear to be ambiguous, if not outright contradictory, in this sole regard. Any such ambiguity, however, is irrelevant to our present analysis since Tinal does not qualify for an "exception" under subsection (c) regardless of what the implications might be if she did so qualify. We leave to another court for another day consideration of whether Congress can rationally create a nonexception exception to the patient safety work product privilege. It is clear that Congress by its plain language has *not* created an exception to the privilege for federal civil rights litigation. We need look no farther than that to resolve the parties' primary dispute.

with the plain language of the statute, to hold that the patient safety work product privilege applies to Tinal's ADA and other claims against Norton.

We have no authority to go behind the plain meaning of the statute even though its application in the present case places substantial obstacles in Tinal's efforts to discover the potential disparate treatment of other similarly situated Norton pharmacy employees. *See Violette v. P.A. Days, Inc.*, 427 F.3d 1015, 1017 (6th Cir. 2005) ("The judiciary is not 'licensed to attempt to soften the clear import of Congress's chosen words whenever a court believes those words lead to a harsh result.'") (quoting *United States v. Locke*, 471 U.S. 84, 95 (1985)).[45]

[45] To the extent that legislative history may be considered, the Court notes that such history is at least partially supportive of Norton's position when one considers the language and history of the Healthcare Quality Improvement Act of 1986 (HCQIA), 42 U.S.C. §§11101-11152 (2014). The HCQIA "provided qualified immunity for persons providing information to a professional review body regarding the competence or professional conduct of a physician." *Sevilla v. United States*, 852 F. Supp.2d 1075, 1064 (N.D. Ill. 2012) (citing 42 U.S.C. §11111(a)(1)). *See gen., Lee Medical, Inc. v. Beecher*, 312 S.W.3d 515, 534 (Tenn. Sup. Ct. 2010) ("The HCQIA granted immunity from monetary damages to medical peer review committees, but it did not specifically create a peer review privilege.") (citing *Virmani v. Novant Health, Inc.*, 259 F.3d 284, 291-92 (4th Cir. 2001)).

No broadly-worded privilege such as that found in the PSQIA was created by Congress in the HCQIA, which "carefully crafted a very specific privilege, applicable [only] to peer review material submitted to the Secretary pursuant to the dictates of the mandatory reporting provisions of that statute." *Nilivar v. Mercy Health System-Western Ohio*, 210 F.R.D. 597, 602 (S.D. Ohio 2002). *See Dieffenbach v. United States*, 715 F. Supp.2d 587, 594-95 (D. Del. 2010) ("[T]he prevailing analysis of the HCQIA is that 'Congress spoke loudly with its silence' in not enacting a broad privilege against discovery of peer review materials.") (quoting *Teasdale v. Marin Gen. Hosp.*, 138 F.R.D. 691, 694 (N.D. Cal. 1991).

Not only did Congress *not* create a broad privilege for medical peer review records in the HCQIA, it did create "an express exception to the immunity provision [providing qualified immunity for persons giving information to a professional review body regarding the competence of a physician] in the case of civil rights actions. *Sevilla*, 852 F. Supp.2d at 1064-65 (citing *Virmani*, 259 F.3d at 291-292). In other words, Congress expressly declined in the HCQIA to create a type of privilege found in the PSQIA *and* chose to create a specific exception to the immunity provisions of the HCQIA for civil rights actions.

No express exception for civil rights actions is to be found in the PSQIA, which unlike the HCQIA creates a broad privilege for patient safety work product that a provider reports to the PSO as part of a PSES. See 42 U.S.C. §299b-22(a), (b) (2014); *Lee Med. Inc.*, 312 S.W.3d at 535 ("The PSQIA creates a tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety organization.'); *Venosh v. Henzes*, Case No. 11CV-3058, 2013 WL 3725157 at *12 (Pa. Ct. Com. Pl. July 17, 2013) ("The PSQIA creates 'a federal medical peer review privilege' for 'patient safety work product.'") (citing *Francis v. United States*, 2011 WL 2224509 at *6 (S.D. N.Y. 2011)); *Dept. of Financial and Professional Reg. v. Walgreen Co.*, 970 N.E.2d 552, 557 (Ill. Ct. App. 2012) ("The Patient Safety Act 'announces a more general approval of the medical peer review process and adds more sweeping evidentiary protections for materials used therein.'") (quoting *K.D. ex rel. Dieffenbach*, 715 F.Supp.2d at 595). The Court cites this legislative history, and the court opinions that interpret it, not because either of them are determinative, but rather only to demonstrate that beyond the plain language of 42 U.S.C. §299b-22(a) and (b), the legislative genesis of the PSQIA and its predecessor HCQIA reinforce the Court's conclusions based on its review of the plain language of the statute.

The Court now turns to the second question before it for review. That question is whether the 84 documents contained in the privilege log provided by Norton satisfy the statutory requirements for patient safety work product under the Act.[46] Review of the documents provided to the Court for *in camera* examination, along with the affidavits of Norton's Associate Vice-President and Assistant General Counsel, Thomas E. Powell,[47] confirm that the documents withheld by Norton satisfy the statutory prerequisites for the protection of the patient safety work product privilege in their entirety. Norton undisputedly is a healthcare provider as defined by 42 U.S.C. §299b-21(a), which instituted a reporting tracking process for patient safety information beginning in January 1, 2009, as part of a patient safety evaluation system as defined by 42 U.S.C. §299b-21(6). The documents included with the privilege log for the Court's review were reported by Norton to a listed PSO on various dates as part of its PSES. The various columns of information set forth in Norton's privilege log contain information sufficient to establish that the documents at issue satisfy the statutory definition of patient safety work product along with the implementing federal regulation contained in 42 C.F.R. Part 3. There is no indication from the Court's *in camera* review that any of the otherwise qualifying patient safety work product was voluntarily removed by Norton from its PSES prior to being reported to the PSO so as to lose its privilege status.[48] Also, none of the responsive documents provided to the Court along with the privilege log appears to include a patient medical record, billing or discharge information or other original patient or provider records not eligible for treatment as patient safety work product under 42 U.S.C. §299b-21(7)(B)(i).

The affidavit of Assistant Counsel Powell further advises that the patient safety information found in the contested documents does not exist separately from Norton's PSES nor

[46] DN 39, Norton Priv. Log, Vol I (sealed); DN 40, Norton Priv. Log, Vol. II (sealed).
[47] DN 30, Resp., Ex. A, Powell Aff. of Sept. 9, 2013; DN 38, Not. of Filing, Powell Aff. of Feb. 21, 2014.
[48] See 73 Fed.Reg. at 70733.

was it publicly disclosed or reported.[49] It therefore appears to the Court that the conditions for application of the statutory privilege for patient safety work product have been met as to all of the documents now being withheld based on a claim of such privilege. The Court accordingly concludes that, first, the patient safety work product privilege applies outside the context of malpractice litigation given the plain language of the statute, and second, the documents being withheld satisfy the statutory criteria to be considered privileged patient safety work product protected from discovery or admission at trial.

The only question that remains, the third and final one, is whether the privilege log itself satisfied the criteria of Rule 26(b)(5)(A)(ii) to "describe the nature of the documents … not produced or disclosed … in a manner that, without revealing information itself privileged … will enable other parties to assess the claim." Fed.R.Civ.P. 26(b)(5)(A)(ii)(2014). As noted, Tinal maintains that Norton has violated this provision of Rule 26(b)(5) by its reliance upon a generic description, "report of medication event" accompanied by a brief description of the report form itself to satisfy the "description of the document" category in its privilege log. Tinal correctly points out that Norton's reliance upon this generic description for withheld document nos. 1-77 prevents her from assessing the relevance of the withheld documents in relation to the elements of her ADA claims.

Nevertheless, the generic description is sufficiently informative to determine whether the statutory elements of the patient safety work product privilege are satisfied. Evaluation of relevance is not the issue at this point. Rather, the question is whether the withheld documents contain patient safety information gathered as part of a PSES and reported by the provider to its PSO without being previously removed from the PSES or otherwise disclosed apart from the PSES. The privilege log provided by Norton is sufficient to permit Tinal to evaluate whether the

[49] DN 30, Resp., Ex. A, Powell Aff., ¶¶12-13.

statutory elements are met. The fact that it provides her no opportunity for weighing the relevance of any particular document, while obviously disappointing to Tinal, is not determinative. Accordingly, no basis for the imposition of sanctions under Rule 37 is presented by the nature of the privilege log provided.

CONCLUSION

At the outset of its legal analysis the Court offered three basic observations: discovery in federal civil rights actions is broad in scope; the consensus among the lower federal courts is that the common law medical peer review privilege does not apply in federal civil rights and antitrust actions; and concerns about medical malpractice liability were instrumental in the adoption of the Patient Safety Quality Improvement Act of 2005. None of these propositions is in any way diminished by the Court's conclusions in this opinion concerning the scope of the patient safety work product privilege. The plain language of §299b-22(a) and (b) clearly indicates that Congress intended to give the privilege broad effect outside the context of medical malpractice actions with only the most narrow exceptions, none of which apply in the present case. To the extent that there is debate about the scope of the privilege, or the creation of further exceptions to it, such debate must be held in the halls of Congress. The plain language of the statute allows for no other conclusion; the documents at issue are privileged and are not subject to discovery. For these reasons, Tinal's motion to compel the production of documents in response to request nos. 10, 12, 13 and 17 is **DENIED**.

May 7, 2014

Dave Whalin, Magistrate Judge
United States District Court

Cc: Counsel of Record