

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:16-cv-72

DISABILITY RIGHTS NORTH)	
CAROLINA,)	
)	
Plaintiff,)	
)	
v.)	
)	COMPLAINT
RICHARD BRAJER, in his official)	
capacity as Secretary of the North)	
Carolina Department of Health and)	
Human Services,)	
)	
Defendant.)	
)	
)	
)	

INTRODUCTION

1. Plaintiff, Disability Rights North Carolina (“DRNC”), is the Protection and Advocacy System (“P&A”) for individuals with disabilities in North Carolina. DRNC advocates for and protects the civil rights of individuals with disabilities in this State through, among other means, investigating allegations of abuse or neglect. In the course of such investigations, DRNC is authorized to access records of individuals with disabilities. Defendant Richard Brajer, Secretary of the North Carolina Department of Health and Human Services (“DHHS”), has denied DRNC access to records to which it is legally entitled. By this action, DRNC seeks an order from this Court requiring Defendant to provide the requested information so that DRNC may discharge its statutory

duties and investigate the alleged abuse and neglect of an individual with a developmental disability.

JURISDICTION AND VENUE

2. DRNC brings this action for declaratory and injunctive relief for violation of the Developmental Disabilities Assistance and Bill of Rights Act (“the DD Act”), 42 U.S.C. §§ 15001 et seq.

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3), which grant this Court original jurisdiction in all actions authorized by 42 U.S.C. § 1983 to redress the deprivation under color of State law of any rights, privileges, or immunities guaranteed by the United States Constitution and Acts of Congress. Declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202.

4. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(b)(1). A substantial part of the events or omissions giving rise to Plaintiff’s claims occurred here and Defendant Brajer may be found here.

PARTIES

5. Plaintiff DRNC is the duly-designated P&A for individuals with disabilities in North Carolina. 42 U.S.C. § 10801(b); 42 U.S.C. § 15001(b)(2). DRNC, a non-profit corporation independent of state government, is incorporated in North Carolina and maintains its principal place of business in Raleigh, North Carolina.

6. DRNC receives federal funds pursuant to the DD Act and is thereby obligated to provide protection and advocacy services for individuals with developmental disabilities. Under the DD Act, DRNC is also authorized to investigate suspected incidents of abuse

and neglect and to pursue administrative, legal and other remedies on behalf of individuals with developmental disabilities. In order to carry out its investigative functions, DRNC is granted the authority to have access to individuals with disabilities in the locations where they receive services, and to have access to their medical and other records under certain conditions. 42 U.S.C. § 15043(I); 45 C.F.R. § 1386.25(a).

7. DRNC is a “person” authorized to seek legal and equitable relief against entities that deprive it of rights granted to it under federal law.

8. Defendant Brajer is the Secretary of the North Carolina DHHS. DHHS is the State agency responsible for providing public mental health, developmental disability and substance abuse services for individuals who have disabilities. N.C. Gen. Stat. § 122C-112.1. As part of that responsibility, DHHS oversees fourteen State-operated healthcare facilities, including Black Mountain Neuro-Medical Treatment Center in Black Mountain, North Carolina. § 122C-111.

9. Defendant Brajer is charged with overall responsibility for the administration of DHHS. Defendant has policy-making authority over the fourteen State-operated healthcare facilities. All of Defendant’s complained-of actions were taken under color of state law for purposes of 42 U.S.C. § 1983. He is sued in his official capacity.

FACTUAL ALLEGATIONS

10. Black Mountain Neuro-Medical Treatment Center (“BMNTC”) is a State-operated healthcare facility that provides services to individuals affected by developmental disabilities and by Alzheimer’s Disease.

11. On September 14, 2015, DRNC received a complaint regarding an individual with a developmental disability, hereinafter referred to as “the resident.” According to the complaint, the resident frequently disrobes and walks around in the nude in common areas of the unit, where other residents are exposed to this behavior. Additionally, the resident allegedly urinates and defecates on the floor of both the common areas and his/her bedroom, creating health and safety hazards for all residents. According to a second complaint received on the same date, BMNTC staff found the resident on the floor and subsequently determined that the resident had a fractured hip. A staff member disclosed his/her belief that the resident had urinated on the floor and slipped in the urine, causing the fall and fractured hip.

12. Based on the complaints DRNC received, DRNC initiated an investigation into the possible abuse and/or neglect of the resident, and others on the same unit, pursuant to its federal authority under the DD Act.

13. On November 20, 2015, DRNC notified BMNTC, in writing, that it was investigating the allegation concerning the abuse and/or neglect of the resident. As part of that investigation, DRNC requested, in writing, a variety of documents, including incident reports regarding the resident and any internal management investigation records. The letter provided detail concerning the statutory basis for the request. The letter also requested access to these records within three business days, as required by the DD Act. 42 U.S.C. § 15043(a)(2)(J)(i). The letter is attached as Exhibit 1.

14. DRNC’s receipt of the records was delayed for a few weeks due to a variety of factors, including excessive redactions and a misunderstanding of the statutory basis for

the request. On December 10, 2015, DRNC received a set of records. According to the Assistant Attorney General representing BMNTC, these records included all documents DRNC requested other than those that are confidential and privileged pursuant to the Patient Safety and Quality Improvement Act (“PSQIA”), 42 U.S.C. §§ 299b-21 et seq.

15. Upon review of the records, DRNC determined that BMNTC did not provide the incident reports regarding the resident or any internal management investigation records. Both types of documents are prepared by the facility in the course of regular business, prior to and following the passage of the PSQIA, when an injury to a resident occurs.

16. On December 14, 2015, DRNC made an oral request for a list of the types of records that BMNTC declined to produce pursuant to the PSQIA. DRNC submitted a written request for the same on December 16, 2015. The request is attached as Exhibit 2.

17. On December 17, 2015, the Assistant Attorney General representing BMNTC responded to this request by stating, “The information that has not been produced meets the definition of Patient Safety work product as that term is defined in DOSHF [sic] [Division of State-Operated Healthcare Facilities, an office of DHHS] policy and the federal Patient Safety and Quality Improvement Act and its accompanying federal regulations. BMNTC has provided you with all information concerning this incident other than that which is confidential and privileged pursuant to the Patient Safety and Quality Improvement Act.” BMNTC counsel copied the Assistant General Counsel for DHHS on the response. The response is attached as Exhibit 3.

18. On December 17, DRNC made a written request of both the Assistant Attorney General representing BMNTC and the Assistant General Counsel for DHHS, seeking an

expanded explanation as to the types of documents (e.g. incident reports, management reports, etc.) that were being withheld by BMNTC. The request is attached as Exhibit 4.

19. As of the date of this Complaint, Defendant has failed to provide DRNC with the incident reports and management investigation documents it requested, and failed to provide DRNC with any further statement of the types of documents DHHS has declined to produce pursuant to the PSQIA.

DRNC's Authority to Access Records

20. The DD Act and its implementing regulations give DRNC, as North Carolina's designated P&A, the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or there is probable cause to believe the incidents occurred. 42 U.S.C. § 15043(a)(2)(B); 45 C.F.R. § 1386.25(a)(2)-(5).

21. The DD Act and its implementing regulations give DRNC the authority to access all individual records of:

any individual with a developmental disability, in a situation in which –

- a. the individual, by reason of such individual's mental or physical condition, is unable to authorize the system to have such access;
- b. the individual does not have a legal guardian, conservator, or other legal representative, or the legal guardian of the individual is the State; and

- c. a complaint has been received by the system about the individual with regard to the status or treatment of the individual or, as a result of monitoring or other activities, there is probable cause to believe that such individual has been subject to abuse or neglect.

42 U.S.C. § 15043(a)(2)(I)(ii); 45 C.F.R. § 1386.25(a)(2).

22. The resident who is the subject of DRNC's investigation is an individual with a developmental disability. His/her guardian, the Burke County Department of Social Services, is a division of the State of North Carolina. DRNC has received a complaint regarding alleged abuse and/or neglect of the resident. Therefore, DRNC is entitled to access the resident's individual records pursuant to the authority granted by the DD Act.

23. The DD Act defines an individual record to include "a report prepared or received by any staff at any location at which services, supports, or other assistance is provided to individuals with developmental disabilities [or] a report prepared by an agency or staff person charged with investigating reports of incidents of abuse or neglect, injury, or death occurring at such location, that describes such incidents and the steps taken to investigate such incidents." 42 U.S.C. § 15043(c)(1)-(2).

24. The implementing regulations to the DD Act, which were revised and became effective on August 26, 2015, define individual records to include "reports prepared by a Federal, State or local governmental agency, or a private organization charged with investigating incidents of abuse or neglect, injury or death." These include

the incidents of abuse, neglect, injury and/or death; the steps taken to investigate the incidents; reports and records,

including personnel records, prepared or maintained by the service provider in connection with such reports of incidents; or supporting information that was relied upon in creating a report including all information and records that describe persons who were interviewed, physical and documentary evidence that was reviewed, and the related investigative findings.

45 C.F.R. § 1386.25(b)(2).

25. The regulations further explain that individual records to which the P&A is entitled access include “reports prepared by a Federal, State or local governmental agency, or a private organization charged with investigating incidents of abuse or neglect, injury or death. The organizations whose reports are subject to this requirement include, but are not limited to... developmental disabilities systems... or by medical care evaluation or peer review committees, regardless of whether they are protected by federal or state law.” Id.

26. As Secretary of DHHS, Defendant Brajer shall “administer and enforce rules that are conditions of participation for federal or State financial aid.” N.C. Gen. Stat. § 122C-112.1(a)(18). This includes the regulation which requires BMNTC, as a long-term care facility, to document and investigate incidents of abuse or neglect. 42 C.F.R. § 483.13(c)(2)-(3).

27. DHHS policy requires BMNTC and other facilities to undertake investigations into allegations of abuse or neglect. DHHS policy SOHF 136-AL(2), “Protecting

Patients/Residents from Rights Infringements.” Therefore, any reports or documents generated during BMNTC’s investigation of incidents regarding the resident are considered individual records to which DRNC is entitled under the authority of the DD Act.

PSQIA and Patient Safety Work Product

28. Congress passed the PSQIA in response to a 1999 report from the Institute of Medicine, which urged Congress to “pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for the purpose of improving safety and quality.” S. Rep. No. 108-196, at 2 (2003).

29. The PSQIA created a mechanism to permit health care facilities to utilize external, federally-certified review bodies, known as Patient Safety Organizations (“PSO”), to analyze incidents and events involving patient safety and to develop methods of improving the provision of patient care. Information submitted to or developed by a PSO enjoys protection under the PSQIA, permitting health care facilities and their employees to participate candidly in the review process.

30. The PSQIA grants the protection of privilege and confidentiality to certain types of documents that are collected or developed as part of a patient safety evaluation system, or “the collection, management, or analysis of information for reporting to or by a PSO.” 42 U.S.C. § 299b-21(6); 42 C.F.R. § 3.20.

31. These protections are extended only to a particular category of information and documents known as Patient Safety Work Product (“PSWP”). The PSQIA defines PSWP as

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

42 U.S.C. § 299b-21(7)(A); 42 C.F.R. § 3.20.

32. The PSQIA specifically excludes certain types of information from being categorized as PSWP. PSWP does not include information such as “a patient’s medical record, billing and discharge information, or any other original patient or provider records.” 42 U.S.C. § 299b-21(7)(B)(i); 42 C.F.R. § 3.20. Nor is “information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system” considered PSWP. “Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.” 42 U.S.C. § 299b-21(7)(B)(ii); 42 C.F.R. § 3.20.

33. Under the PSQIA, PSWP is privileged and cannot be subject to a subpoena from any Federal, State, local, or Tribal government; is not “subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding;” is not subject to a Freedom of Information Act request; and may not be admitted as evidence in any civil, criminal or administrative proceeding or in a professional disciplinary proceeding. 42 C.F.R. § 3.204(a).

Application of PSQIA to the Requested Records

A. Incident Reports are not PSWP

34. The incident reports constitute the type of information that is specifically excluded from the definition of PSWP, i.e. “information that is collected, maintained, or developed separately, or exists separately from a patient safety evaluation system.” 42 U.S.C. § 299b-21(7)(B)(ii); 42 C.F.R. § 3.20.

35. The commentary to the regulations implementing the PSQIA clarifies that the U.S. Department of Health and Human Services did not intend for the PSQIA to prevent the P&A from accessing information to which it is otherwise entitled. The regulations note, “Information is not patient safety work product if it is collected to comply with external obligations such as: state incident reporting requirements... or provision of access to records by the Protection and Advocacy organizations as required by law.” 73 Fed. Reg. 70,732, 70,743 (2008).

36. Federal law requires long-term care facilities, such as BMNTC, to “have evidence that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to

the administrator of the facility and to other officials in accordance with State law through established procedures.” 42 C.F.R. § 483.13(c)(2).

37. DHHS policy requires that staff who “observe, discover or hear about suspected rights infringements (including abuse, neglect and exploitation) will report all incidents to the designated supervisory staff on duty and to an internal Advocate.” SOHF 136-AL(2) at (IV)(C)(1).

38. DHHS policy further requires such events to be documented in an incident report. SOHF 126-AL(1), “Patient Safety Evaluation System.” The policy defines an incident report as

a log report of patient safety events that shall include only and all of the following data field elements: date and time of the event; date when the event was reported; patient and resident name; patient or resident Medical Record Number (MRN); nature or event type (e.g. fall, medication related); severity of patient or resident harm resulting from the event; location where the event occurred; staff involved in the incident (excludes the Reporter’s name if the report is submitted anonymously); and brief facts of the event.

Id. at (IV)(G).

39. The requested incident reports are vehicles by which a facility, such as BMNTC, demonstrates compliance with DHHS policy and federal law. Such reports have been created and maintained for many years, long before the passage of the PSQIA. As such,

they are documents that are created and exist separately from the PSO system, and therefore do not constitute PSWP. As non-PSWP, the incident reports cannot be shielded under the PSQIA.

40. DHHS acknowledges that incident reports are non-PSWP. Policy SOHF 136-AL(2) contains a statement of purpose which does not mention the PSO system and does not contemplate that an incident report would be gathered for any reason other than to ensure that the State-operated facilities “respond in a consistent manner when there are allegations or suspicions of rights infringements (including abuse, neglect and exploitation).” *Id.* at (I). Policy SOHF 126-AL(1) explicitly affirms that an event or incident report “is considered Non-PSWP.” *Id.* at (V)(B)(1)(b)(1)(c). DHHS cannot simultaneously acknowledge that the incident reports are non-PSWP and seek to protect such records as PSWP under the PSQIA.

B. Management Investigations are not PSWP

41. Investigations conducted by BMNTC management into incidents involving the resident are specifically excluded from the definition of PSWP, as they are “collected, maintained, or developed separately from, or exists separately from a patient safety evaluation system.” 42 U.S.C. § 299b-21(7)(B)(ii); 42 C.F.R. § 3.20.

42. Federal law requires long-term care facilities, such as BMNTC, to “have evidence that all alleged violations [involving mistreatment, neglect or abuse] are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.” 42 C.F.R. § 483.13(c)(3).

43. DHHS policy requires facility management to collaborate with the internal advocacy department in conducting interviews and collecting supporting documents and evidence regarding an allegation of abuse, neglect or other rights infringement. SOHF 136-AL(2). Based upon that information, management and internal advocacy make independent determinations about the matter. Management is charged with making findings “as they relate to personnel and/or quality assurance aspects of the incident. Finding may include, but are not limited to: job performance issues; personal conduct issues; system issues; [and] Quality of Care related issues.” Id. at (IV)(F)(1)(b).

44. The management investigations are conducted to comply with DHHS policy and federal law. Such investigations have been created and maintained for many years, long before the passage of the PSQIA. As such, they are documents that are created and exist separately from the PSO system, and therefore do not constitute PSWP. As non-PSWP, the management investigations cannot be shielded under the PSQIA.

C. In the Alternative: the PSQIA Privilege Does Not Apply to the Incident

Reports or Management Investigations

45. Regardless of whether the records sought by DRNC meet the definition of PSWP, DRNC is entitled to obtain those records. The PSQIA essentially creates a federal peer review privilege, exempting PSWP from, inter alia, discovery in connection with a civil, criminal or administrative proceeding.

46. DRNC does not seek access to the incident reports or management investigations in connection with any civil, criminal or administrative proceeding. DRNC has requested the records in furtherance of its federally-mandated investigatory authority as the P&A.

Therefore, the PSQIA privilege does not apply to the records. See, e.g., Disability Rights N.C. v. Moses H. Cone Mem. Hosp. Operating Corp., 2013 U.S. Dist. LEXIS 129367, 10-12 (M.D.N.C. 2013). See also Disability Rights N.C. v. Frye Reg'l Med. Ctr., Inc., 2014 U.S. Dist. LEXIS 158306 (W.D.N.C. 2014).

47. The DD Act requires DRNC to “keep confidential all records and information” relating to clients and investigations. Access to the incident reports and management investigations therefore would not run afoul of the PSQIA’s confidentiality protections. 45 C.F.R. § 1386.28(b)(1). See Cone at 12.

*D. In the Alternative: If the PSQIA Privilege Does Apply, DRNC is
Entitled to Pierce the Privilege*

48. The DD Act entitles DRNC to access peer review records, as such records are within the definition of “individual records.” The regulations implementing the DD Act define individual records to include “reports prepared by a Federal, State or local governmental agency... charged with investigating incidents of abuse or neglect, injury or death. The organizations whose reports are subject to this requirement include, but are not limited to... medical care evaluation or peer review committees, *regardless of whether they are protected by federal or state law.*” 45 C.F.R. § 1386.25(b)(2) (emphasis added).

49. In passing the regulations to the DD Act, the Administration on Intellectual and Developmental Disabilities specifically noted this regulation “facilitates the P&As fulfilling their responsibilities under the DD Act, maximizes the most efficient use of

resources, and *is consistent with court decisions allowing P&As access to all records of an individual.*” 80 Fed. Reg. 44,802 (2015) (emphasis added).

50. As with the State peer review privilege at issue in Cone and Frye, the regulations expressly intend the P&A’s access authority to preempt any State or federal peer review privilege. Therefore, DRNC is entitled to access records that would otherwise be privileged under the PSQIA.

CAUSE OF ACTION

51. In denying DRNC access to the incident reports and management investigations as requested, Defendant Brajer has acted pursuant to the authority vested in him by State law.

52. By refusing DRNC’s written request for access to the incident reports and management investigations, Defendant Brajer has deprived DRNC of its statutory rights under the DD Act, U.S.C. §§ 15001 et seq., and the regulations promulgated pursuant to it, 45 C.F.R. §§ 1386.1 et seq.

53. Defendant’s violation of the DD Act irreparably harms DRNC by preventing it from carrying out its responsibilities under the Act.

54. Unless Defendant Brajer is enjoined to provide DRNC the access required by the DD Act, DRNC will continue to be irreparably harmed and will be unable to protect and advocate for persons with disabilities.

INJUNCTIVE RELIEF

55. Plaintiff adopts and restates the allegations set forth in paragraphs 1-54 of this Complaint.

56. As a proximate result of Defendant's violation of the DD Act, DRNC has suffered, and will continue to suffer, irreparable harm for which there is no remedy at law.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court grant the following relief:

1. Enter a declaratory judgment that Defendant's refusal to provide the requested records violates the DD Act;
2. Enter permanent injunctive relief requiring the Defendant to provide Disability Rights NC with access to the requested incident reports and management investigations;
3. Retain jurisdiction over this action to ensure Defendant's compliance with the mandates of the DD Act;
4. Award DRNC attorneys' fees and costs pursuant to 42 U.S.C. § 1988; and
5. Award such other, further or different relief as the Court deems equitable and just.

This 12th day of February 2016.

Respectfully submitted,

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