

**IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO**

MICHAEL J. HALASZ II, Administrator of the Estate of Joshua R. Stevens, etc.)	CASE NO. CV-13-812784
)	
Plaintiffs,)	JUDGE DICK AMBROSE
)	
-vs-)	
)	
ADVANCED PAIN MANAGEMENT CENTER, L.L.C., et al.)	<u>JUDGMENT ENTRY</u>
)	<u>AND OPINION</u>
)	
Defendants.)	

{¶1} This case involves claims by Plaintiff Brenda L. Halasz, Administrator of the Estate of Joshua R. Stevens (“Stevens’ Estate”), relating to the death of Joshua Stevens from a prescription drug overdose on April 5, 2012.¹ Plaintiff filed suit on August 26, 2013, against Advanced Pain Management Center, LLC (“APMC”), Dr. Joanne Poje (“Dr. Poje”), and various other entities² alleging medical negligence, pharmacy dispensing error negligence, and wrongful death.

¹ On June 18, 2014, Michael Halasz was substituted as the Plaintiff and administrator of Stevens’ estate.

² On June 26, 2014, Plaintiff filed a Third Amended Complaint adding additional parties. However, on December 22, 2014, Plaintiff voluntarily dismissed all claims against Ohio CVS Stores, LLC and CVS Rx Services, Inc. Therefore, claims remain pending against APMC, Dr. Poje, Joanne P. Tomasulo, M.D., Inc., Robert D. Mabe, Inc., DBA Ashville Apothecary, Inc., and Robert D. Mabe, Inc., DBA Circleville Apothecary.

{¶2} Plaintiff alleges that during five office visits from January 13 through April 2, 2012, Dr. Poje prescribed Joshua Stevens multiple narcotic medications. Defendants Robert D. Mabe, Inc., DBA Ashville Apothecary, Inc., and Robert D. Mabe, Inc., DBA Circleville Apothecary (the “Pharmacies”), among others, filled these prescriptions. Stevens died of a prescription drug overdose as a consequence of snorting crushed oxycodone tablets on April 5, 2012.

{¶3} On November 18, 2014 and February 16, 2015, Defendants filed motions to exclude evidence from the Ohio Automated Rx Reporting System (OARRS) during further discovery and trial. A hearing was held on February 24, 2015 on Defendants motions to exclude evidence regarding OARRS and Plaintiff’s challenge to the constitutionality of R.C. 4729.80(D) and 4729.86(B). The parties were given until March 6, 2015 to file any post-hearing briefs. The matter is now ripe for adjudication.

The Ohio Automated Rx Reporting System

{¶4} OARRS was created in response to R.C. 4729.75, which states that the “state board of pharmacy may establish and maintain a drug database * * * to monitor the misuse and diversion of controlled substances * * * and other dangerous drugs * * *.” To support their motions to exclude OARRS evidence, Defendants rely on R.C. 4729.80(D) and 4729.86(B), which govern the disclosure and dissemination of OARRS information.

{¶5} R.C. 4729.80(D) states the following: “A pharmacist or prescriber shall not be held liable in damages to any person in any civil action for injury, death, or loss to

person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database.”

{¶6} R.C. 4729.86(B) states the following: “A person shall not use information obtained pursuant to [OARRS] as evidence in any civil or administrative proceeding.”

{¶7} Defendants argue that Plaintiff is improperly relying on two expert medical reports which allege that Dr. Poje either: a) failed to obtain Stevens’ OARRS report, or b) incorrectly evaluated Stevens’ OARRS report. Defendants further argue that during Dr. Poje’s deposition, and the deposition of her colleague Dr. Chen, Plaintiff’s attorney improperly referenced OARRS documents. According to Defendants, this evidence violates a plain reading of the above-cited statutes.

{¶8} According to Plaintiff, Dr. Poje was required by law and medical standards of practice to obtain and assess an OARRS report prior to treating Stevens with “narcotic therapy.” See R.C. 4729.01(l)(4) (applying R.C. Chapter 4729 to physicians); Ohio Admin. Code 4731-11-11 and 4731-29-01(E)(6)(a)(vii); and expert reports from Gregory B. Collins, M.D., and John H. Nickels, M.D. Therefore, Plaintiff argues, Dr. Poje’s failure to obtain an OARRS report or improper assessment of an OARRS report necessarily falls below the standard of care in a medical malpractice claim.

{¶9} Plaintiff additionally argues that, prior to filling Stevens’ prescriptions, the Pharmacies were required by law to “review the patient profile for the purpose of identifying * * * [a]buse/misuse.” Ohio Admin. Code 4729-5-20(A)(7). See, also, R.C. 4729.01(A) and (B) (applying R.C. Chapter 4729 to pharmacies). Part of this review

“may include requesting and reviewing an OARRS report * * *.” Ohio Admin. Code 4729-5-20(B). According to Plaintiff, the Pharmacies’ failure to perform a proper prospective drug utilization review fell below the standard of care. (See expert report from Karen M. Ryle, M.S., RPh).

{¶10} Defendants argue, however, that the plain reading of R.C. 4729.80(D) prevents a pharmacist or doctor from being held liable in a civil action based on whether they “did or did not seek or obtain information from the database,” and R.C. 4729.86(B) prevents OARRS information from being used as evidence in any civil proceeding.

{¶11} Plaintiff maintains that these two statutory provisions are unconstitutional on their face and as applied to the instant case for three reasons: they violate the Equal Protection, Due Process, and Separation of Powers clauses of the Ohio Constitution. Defendants, on the other hand, first argue that Plaintiff failed to properly challenge the constitutionality of the OARRS statutes, thus depriving the Court of jurisdiction to hear the issue. In the alternative, Defendants argue that the statutes withstand constitutional scrutiny.

Jurisdiction to hear Constitutional issue

{¶12} Defendants argue that “Plaintiff failed to properly serve the Complaint upon the Attorney General at the outset of this case in clear violation of the mandates of R.C. 2721.12 and the law set forth by the Ohio Supreme Court in *Cicco v. Stockmaster*, 89 Ohio St.3d 95, 97 (2000).” However, R.C. 2721.12 and *Cicco* apply to declaratory judgment actions. *Cleveland Bar Ass’n v. Picklo*, 96 Ohio St.3d 195, 2002-Ohio-3995.

The case at hand is not an action for declaratory judgment; therefore, this Court's jurisdiction is intact. See, *Grover v. Bartsch*, 170 Ohio App.3d 188, 2006-Ohio-6115, ¶29 ("Where the constitutionality of a statute is challenged as part of a civil action for damages, a trial court has jurisdiction to address the statute's constitutionality").

Analysis of R.C. 4729.80(D) and 4729.86(B)

{¶13} The statutory purpose of OARRS is "to monitor the misuse and diversion of controlled substances * * *." R.C. 4729.75. According to the OARRS website, www.ohiopmp.gov, OARRS was created "in 2006 as a tool to assist healthcare professionals in providing better treatment for patients with medical needs while quickly identifying drug seeking behaviors. An OARRS [report] can assist in assuring that a patient is getting the appropriate drug therapy and is taking their medication as prescribed."

Constitutional Provisions

{¶14} Section 1, Article II of the Ohio Constitution grants the legislature the power to enact laws that do not conflict with the Ohio and United States Constitutions. Included within this authority is the task of making public policy decisions "necessary to further the common good." *Stetter v. R.J. Corman Derailment Servs., LLC*, 125 Ohio St.3d 280, 2010-Ohio-1029, ¶36. In turn, the courts "are charged with evaluating the constitutionality of their choices." *Id.*, at ¶35. In *Arbino v. Johnson & Johnson*, 116 Ohio St.3d 468, 2007-Ohio-6948, ¶25, the Ohio Supreme Court held that "[b]efore a court may declare unconstitutional an enactment of the legislative branch, 'it must appear

beyond a reasonable doubt that the legislation and constitutional provisions are clearly incompatible.” (Citation omitted.)

Equal Protection Analysis

{¶15} Section 2, Article I of the Ohio Constitution, which is the equivalent of the federal Equal Protection Clause, states that: “All political power is inherent in the people. Government is instituted for their equal protection and benefit.” “The first step in an equal-protection analysis is determining the proper standard of review. When legislation infringes upon a fundamental constitutional right or the rights of a suspect class, strict scrutiny applies. If neither a fundamental right nor a suspect class is involved, a rational-basis test is used.” *Arbino*, at ¶64. (Citations omitted.)

{¶16} The parties in the case at hand agree that the rational-basis test is appropriate. “The rational-basis test involves a two-step analysis. [Courts] must first identify a valid state interest. Second, [courts] must determine whether the method or means by which the state has chosen to advance that interest is rational.” *McCrone v. Bank One Corp.*, 107 Ohio St.3d 272, 2005-Ohio-6505, ¶9.

{¶17} Plaintiff’s equal protection argument centers around the legislature’s alleged disparate treatment of civil litigants and criminal litigants with respect to OARRS information. R.C. 4729.86(A)(1)(a) allows information from the OARRS database to be disseminated “[w]hen necessary in the investigation or prosecution of a possible or alleged criminal offense.” As stated, this same information is prohibited in civil litigation.

{¶18} The state interest is unambiguous: “to monitor the misuse and diversion of controlled substances * * *.” R.C. 4729.75. One of the ways in which the legislature chose to advance this interest was to treat patients who were prescribed narcotics illegally, which would subject the provider to criminal prosecution, differently from patients who were prescribed narcotics negligently, which would subject the provider to civil liability. However, the Ohio Supreme Court has stated that an “equal protection argument can be rejected because criminal defendants and civil litigants have vastly different stakes and concerns and are not similarly situated.” *State v. Lang*, 129 Ohio St.3d 512, 2011-Ohio-4215, ¶82.

{¶19} Therefore, the Court finds Plaintiff’s equal protection argument inapplicable as this case is more appropriate for a Due Process analysis. See, e.g., *Arbino*, at ¶¶105-106 (noting that the same rational-basis analysis can be used for claims of Equal Protection and Due Process violations).

Due Process Analysis

{¶20} “Substantive due process is defined to implicate a fair and accurate application of statutory and substantive constitutional rights,” and is governed by the Fifth and Fourteenth Amendments to the United States Constitution and Article 1, Section 16 of the Ohio Constitution. *Lorain Educ. Ass’n v. Lorain City School Dist. Bd. of Educ.*, 46 Ohio St.3d 12, 16 (1989). A legislative enactment that does not involve a “fundamental right” withstands a challenge on substantive due process grounds if it is “rationally related to a legitimate goal of government.” *City of Toledo v. Tellings*, 114 Ohio St.3d 278, 2007-Ohio-3724, ¶33. The Ohio Supreme Court has additionally held that “a

legislative enactment will be deemed valid on due process grounds * * * if it bears a real and substantial relation to the public health, safety, morals or general welfare of the public and if it is not unreasonable or arbitrary.” *Mayer v. Bristow*, 91 Ohio St.3d 3, 13 (2000).

{¶21} A careful reading of Defendants’ Briefs in Opposition to this constitutional challenge reveals that Defendants have failed to put forth any explanation as to how excluding OARRS information from civil proceedings is “rationally related” to a government interest.³ The Court also notes that the constitutionality of R.C. 4729.80(D) and 4729.86(B) is an issue of first impression in the State of Ohio. Therefore, the Court looks for guidance from other jurisdictions.

{¶22} In *Lewis v. Medical Board of California*, 226 Cal. App. 4th 933 (2014), the Court of Appeal of California, Second Appellate District, Division Three, issued an opinion answering the following: “whether the Medical Board of California (the Board) violated patients’ informational privacy rights in their controlled substances prescription records when the Board obtained that data from the Controlled Substance Utilization Review and Evaluation System (CURES) during a disciplinary investigation of their physician.”

{¶23} *Lewis* is similar to the case at hand, but does contain the following differences: First, *Lewis* involves an administrative proceeding rather than a civil proceeding. Second, in *Lewis*, the plaintiff/petitioner is the doctor, who is asserting his patients’ right

³ Dr. Poje argues that Plaintiffs failed to meet their burden of showing purposeful or intentional discrimination and a fundamental right that is being violated. The Pharmacies argue that “the criminal and civil justice systems differ on a fundamental level.”

to privacy, rather than the patient's estate asserting the patient's right to use the information. Nonetheless, the court's analysis in *Lewis* illuminates the constitutional issue in the case at hand.

{¶24} In *Lewis*, the Board investigated patient complaints against Lewis, who is a doctor, and as part of this investigation, "obtained CURES reports for Lewis's prescribing practices * * *." *Id.* at 939. The Board has authorization to obtain this information pursuant to CURES. See Cal. Health & Saf. Code 11165, former subd. (c) ("Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes * * *"). Furthermore, CURES data "shall not be disclosed * * * to any third party." *Id.*

{¶25} This is in contrast to OARRS, which prohibits the data from being used "in any civil or administrative proceeding." However, the purpose behind CURES is similar to the purpose behind OARRS: "to control the diversion and resultant abuse of controlled substances * * *." *Lewis*, at 938 (citing Cal. Health & Saf. Code 11165, former subd. (c)).

{¶26} On appeal, Lewis argued that CURES was unconstitutional because the Board "is permitted to conduct searches, without any showing of any kind – whether good cause, reasonable suspicion, or some other similar standard – and without warrant or subpoena – of the controlled substances prescription records of patients * * *." Lewis argued that this violated his patients' right to privacy and the Fourth Amendment. *Id.*, at 940-941.

{¶27} The *Lewis* Court reasoned that the proper analysis “requires balancing [Lewis’s] patients’ right to privacy in their controlled substances prescription records against the state’s interest in protecting the public health by regulating the abuse and diversion of controlled substances, and in protecting the public against incompetent, impaired, or negligent physicians.”

{¶28} The *Lewis* Court concluded that CURES did not violate either the patients’ right to privacy or their Fourth Amendment rights. “There are sufficient safeguards in the CURES statute and other regulatory duties to protect patients’ informational privacy and confidentiality from unwarranted public disclosure and unfettered access to CURES data.” *Id.*, at 955. In reaching this conclusion, the court noted, however, that there is a diminished expectation of privacy regarding information about prescription drugs, because they “are subject to regular scrutiny by law enforcement and regulatory agencies as part of the pervasive regulation of controlled substances.” *Id.*, at 948. With this framework as a backdrop, the Court turns to its analysis of the constitutionality of OARRS.

{¶29} Generally, a patient has a right to the privacy of his or her medical information. R.C. 2317.02(B). However, testimony regarding medical “communication” and “advice” may be compelled “[i]n any civil action * * * [i]f the patient or * * * legal representative of the patient gives express consent * * *.” R.C. 2317.02(B)(1)(a)(i). “Communication” in this sense means the following: “any information, in any manner, concerning any facts, opinions, or statements necessary to enable a physician * * * to diagnose, treat, prescribe, or act for a patient.” R.C. 2317.02(B)(5).

{¶30} The Ohio Supreme Court has recognized the importance of this right: “[I]t is for the patient – not some medical practitioner, lawyer, or court – to determine what the patient’s interests are with regard to personal confidential medical information. As the Supreme Court of California has observed in discussing the related concept of a right to privacy, such a right ‘is not so much one of total secrecy as it is of the right to *define* one’s circle of intimacy – to choose who shall see beneath the quotidian mask.’ If the right to confidentiality is to mean anything, an individual must be able to direct the disclosure of his or her own private information.” *Hageman v. Southwest Gen. Health Ctr.*, 119 Ohio St.3d 185, 2008-Ohio-3343, ¶13 (citations omitted).

{¶31} In the case at hand, Plaintiff, as Stevens’ representative, waived Stevens’ right to nondisclosure of his medical information by filing this civil lawsuit against his former health care providers for medical negligence and wrongful death. A plain reading of R.C. 4729.80(D) and 4729.86(B), as applied to the facts of this case, prohibits Plaintiff from exercising Stevens’ waiver of his right to non-disclosure of OARRS information. “The right to privacy of this information is not the defendants’ right to waive. The right belongs to the person to whom the record pertains.” *Marks v. Giles*, U.S. District Court for the Western District of Washington No. 07-5572RJB/JRC (2009).

{¶32} The legislature implemented criminal accountability for health care providers who violate OARRS, but specifically provided civil and administrative immunity to providers for the same violations. Plaintiff wishes to introduce Dr. Poje’s testimony that she checks OARRS at every office visit. According to Plaintiff, however, there is no evidence that Dr. Poje checked Stevens’ OARRS report before prescribing him

narcotics. Plaintiff further wishes to introduce expert testimony that Stevens' OARRS report for the timeframe at issue reveals a classic pattern of doctor shopping. "Had Dr. Poje * * * obtained an online OARRS report * * * it would have been obvious to her, just like it was obvious to Mr. Stevens' previous physicians, that Mr. Stevens' had a serious drug problem and should never have been prescribed narcotic pain medications. The OARRS report should have been done at the time of the first session or even before the first session. The pharmacy records * * * indicated 113 prescriptions for controlled drugs from 28 prescribers, filled at 16 different pharmacies over a sixteen month period. This pattern is far from the norm in treating patients with chronic or acute pain complaints, and should have immediately alerted Dr. Poje to the likelihood of medication dependency on the part of Mr. Stevens." Expert report of Gregory B. Collins, M.D., ¶9.

{¶33} The Court can find no rational relationship between the state's interest of monitoring the "misuse and diversion of controlled substances" and the cloak of statutory immunity from civil liability under R.C. 4729.80(D) for those who either fail to use or misuse the OARRS database. Indeed, the two concepts are so unrelated that the statute's immunity provision operates as the antithesis of the goal of curbing prescription drug abuse.

Separation of Powers

{¶34} A statute that violates the doctrine of separation of powers is unconstitutional. "The principle of separation of powers is embedded in the constitutional framework of our state government. * * * It is inherent in our theory of government that each of the three grand divisions of the government, must be protected from the encroachments of

the others, so far that its integrity and independence may be preserved. * * * " *State ex rel. Ohio Academy of Trial Lawyers v. Sheward*, 86 Ohio St.3d 451, 475, 1999-Ohio-123 (citations omitted).

{¶35} Section 5(B), Article IV of the Ohio Constitution states that “the Supreme Court shall prescribe rules governing practice and procedure in all courts of the state * * *. All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect.” The Ohio Rules of Evidence are included within the judiciary’s realm. *Id.*, at 491. “[I]f a rule created pursuant to Section 5(B), Article IV conflicts with a statute, the rule will control for procedural matters, and the statute will control for matters of substantive law.” *Proctor v. Kardassilaris*, 115 Ohio St.3d 71, 2007-Ohio-4838, ¶17.

{¶36} Evid.R. 402 states in pertinent part as follows: “All relevant evidence is admissible, except as otherwise provided by * * * statute not in conflict with a rule of the Supreme Court of Ohio * * *.” Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Evid.R. 401. However, relevant evidence “is not admissible if its probative value is substantially outweighed by the danger of unfair prejudice, of confusion of the issues, or of misleading the jury.” Evid.R. 403. It is the trial court’s function to determine the admissibility of evidence. Evid.R. 104(A).

{¶37} Generally, medical records are admissible if the related health condition is at issue in the case. See, generally, *Csonka-Cherney v. Arcelormittal Cleveland, Inc.*, 8th Dist. No. 100128, 2014-Ohio-836. See, also, Evid.R. 803(4) (allowing the admissibility

of medical records that are “reasonably pertinent to diagnosis or treatment” as an exception to the rule against hearsay); Evid.R. 803(6) (allowing the admissibility of records “kept in the course of a regularly conducted business activity” as an exception to the rule against hearsay).

{¶38} To succeed in a medical malpractice claim, “the plaintiff is required to produce evidence by expert testimony to demonstrate all of the following: (1) the acceptable medical standard of care; (2) the defendant’s breach of that standard; and (3) that plaintiff’s injuries were proximately caused by defendant’s breach.” *W. v. Cleveland Clinic Found.*, 8th Dist. No. 77183, (June 15, 2000). In the case at hand, Plaintiff’s expert witnesses are of the opinion that Dr. Poje’s and the Pharmacies’ failure to review, or improper review of, Stevens’ OARRS report fell below the standard of care in this case and that these breaches were a proximate cause of Stevens’ death. Certainly, Stevens’ OARRS report is relevant.

{¶39} R.C. 4729.86(B) prohibits OARRS information from being used “as evidence in any civil or administrative proceeding.” This presents the issue of whether the General Assembly has usurped a core judicial function by determining the admissibility of specific evidence in a civil or administrative proceeding. This Court finds that the General Assembly has so infringed on the Court’s function to determine the admissibility of evidence. For this reason, the Court finds that R.C. 4729.86(B) violates the doctrine of separation of powers and is therefore unconstitutional.

Conclusion

{¶40} The Court finds that R.C. 4729.80(D) and R.C. 4729.86(B), as applied to the facts of this case, are unconstitutional. R.C. 4729.80(D) is not rationally related to the State’s expressed interest in monitoring the misuse and diversion of controlled substances and by precluding a plaintiff’s ability to use his or her own OARRS information, the statute violates substantive Due Process rights. R.C. 4729.86(B) directly conflicts with the Rules of Evidence and the Court’s ability to govern procedures used in the courtroom. Because it affects only procedure and does not create, define or regulate the rights of the parties, it is an intrusion by the legislature into the function of the judiciary and violates separation of powers.

IT IS SO ORDERED.

Date: _____

Judge Dick Ambrose