

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA and
STATE OF WISCONSIN

Plaintiffs,

DR. TOBY TYLER WATSON,

Relator,

v.

JENNIFER KING VASSEL,

Defendant.

Case No. 11-CV-236-JPS

ORDER

This matter is now before the Court on two motions filed by the relator, Toby Tyler Watson (“Watson”). His first is a motion *in limine*, in which he seeks to limit testimony and argument to whether the prescriptions issued by the defendant, Jennifer King Vassel (“King Vassel”), were issued for off-label uses not otherwise supported by a medical text. (Docket #102). In this regard, he requests that the Court further prevent the plaintiff from introducing evidence on the prevalence of such off-label prescriptions. (Docket #103, at 1). In his second motion, Watson requests that the Court issue a HIPAA protective order allowing him to gather medical information from other of King Vassel’s clients to determine whether she issued prescriptions for off-label uses to other Medicaid-recipient clients. (Docket #104). The Court now addresses those motions.

1. MOTION *IN LIMINE*

Watson’s motion *in limine* is extremely important to the resolution of this litigation. If the Court grants the motion, then Watson’s path to victory

will be much easier. Essentially, to grant Watson's motion *in limine*, the Court would have to hold that a false claim is made any time a prescription is written for a use that is not approved by the Food, Drug, and Cosmetic Act ("FDCA"), or supported by a drug compendia. While establishing support or lack thereof through use of a compendia may be very difficult for lay parties, it would be much easier to do than the alternative. That alternative, urged upon the Court by King Vassel, is to leave the question open. That would allow King Vassel to introduce evidence regarding the State of Wisconsin's process for approving drugs that it will reimburse. In turn, King Vassel could use that evidence to support a position that the prescriptions she wrote may have been for uses approved by the State of Wisconsin, even though they are not approved by the FDCA or supported by a compendia, thus making them non-fraudulent claims.

This is, in fact, a very complex issue to resolve, and the Court finds it appropriate to first address the underlying law before it can resolve the issue. Watson alleges that King Vassel violated the False Claims Act, 31 U.S.C. § 3729, by writing prescriptions to a minor, N.B., for uses that are not medically accepted. Medicaid may only be used to provide reimbursement for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). But the definition of such covered drugs explicitly excludes any drug that is "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A "medically accepted indication" is limited to a purpose that is either approved by the FDCA or "supported by" one of three medical compendia (the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the

DRUGDEX Information System). 42 U.S.C. §§ 1396r-8(g)(1)(B)(i), 1396r-8(k)(6).

In other words, walking this statutory scheme backwards to a logical conclusion,

if King Vassel prescribed a medication to N.B. for a use that is neither approved by the FDCA nor supported by a medical compendia,

then such a prescription was not for a medically accepted indication,

further meaning that the prescription is not for a covered outpatient drug, and

accordingly establishing that the prescription written by King-Vassel was a false claim if submitted to Medicaid for reimbursement.

That is the plain reading of the statutory scheme, and many courts apply the scheme in precisely that cut-and-dry fashion without even considering that there is an alternative. *See, e.g., U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 754 (S.D. Tex. 2010); *U.S. ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 409 (D. Mass. 2010); *United States v. Ortho-McNeil Pharm., Inc.*, 03-CV-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007). Those courts interpreting this statutory scheme hold that there is no wiggle room: if a prescription was written for a non-FDCA-approved or non-compendia-supported use, then it is a false claim.

There is, however, another alternative: that states have the power to determine whether they wish to cover prescriptions for uses that are not approved by the FDCA and are not supported by the compendia (or that, perhaps, they lack that power, but nonetheless do so anyway). For example, the court in *U.S. ex rel. King v. Solvay S.A.* noted that “[g]enerally, state Medicaid programs only reimburse for drugs that are included on their

formularies.” 823 F. Supp. 2d 472, 485 (S.D. Tex. 2011) *order vacated in part on other grounds upon reconsideration*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). This acknowledges, as has King Vassel (Docket #109, at 3), the existence of state-by-state formularies or systems, which control each state’s reimbursement decisions. Some courts have even gone further to explicitly find that states retain the control to determine whether they wish to reimburse for such prescriptions that fall outside of both the FDCA and compendia. *U.S. ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 294 (D. Mass. 2012) (“The statute appears to give states the ability to choose whether they will cover off-label, non-compendium prescriptions. “). *See also U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255, at *2-*3 (D. Mass. Aug. 22, 2003) (discussing without deciding defendant’s contention that the statutory scheme allows for states to decide that they will cover such prescriptions); *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1327 (S.D. Fla. 2006) (noting that “[w]hile the Medicaid Act requires a state paying for outpatient prescription drugs to reimburse for ‘medically accepted indications,’ the Act does *permit* states to limit coverage under certain circumstances.... Under § 1396r-8(d)(1)(B), a state *may* exclude a drug from coverage, that is, deny reimbursement, under four circumstances: if the prescribed use is not for a medically accepted indication (i.e., either FDA approved or supported by citation in a compendium)...”).

Perhaps Wisconsin is one of those states. Or, perhaps Wisconsin does not have the power to determine whether it will reimburse for non-FDCA, non-compendia prescriptions, but nonetheless has represented to physicians that it will reimburse the prescriptions, anyway.

In either situation, such information would be relevant to determining whether King Vassel had the required level of knowledge to be found liable for having submitted a false claim. 31 U.S.C. § 3729(a)(1); *United States ex rel. Fowler v. Caremark RX, LLC*, 496 F.3d 730, 740 (7th Cir. 2007) (noting the three elements of a False Claims Act claim: (1) presentation to a government officer; of (2) a false claim; with (3) knowledge of its falsity). The Court does not outright decide, at this point, that it will admit such evidence. Rather, the parties should engage in discovery on the topic, and, after they have identified the Wisconsin reimbursement process, they may submit such further arguments to the Court regarding the relevance of the discovered information. It may very well be that the Court decides that such information is not relevant and bars it from presentation at trial. But that is a fact-bound determination best reserved for another day.

Accordingly, the Court will deny Watson's motion *in limine* without prejudice subject to renewal, together with additional briefing, after the parties have had an opportunity to engage in further discovery.

2. MOTION FOR HIPAA PROTECTIVE ORDER

On the other hand, the Court must grant Watson's request for a HIPAA protective order that will allow him to gather additional evidence regarding King Vassel's patients. Watson's complaint includes claims against King Vassel for issuing off-label prescriptions to Medicaid and Medical Assistance recipient minors. Thus, the Court cannot confine Watson's discovery only to his claims against N.B. In other words, information regarding King Vassel's non-FDCA, non-compensia prescriptions to Medicaid-recipient minors is directly relevant to Watson's claims.

The Court's prior order denying a HIPAA protective order was very concerned with the lack of any strictures on the proposed order. In short, that order could hardly have been called a "protective order." The Court concluded that, as submitted, it allowed almost unfettered access to records regarding King Vassel's patients.

Watson's more recent proposal has largely cured those deficiencies. It calls for the disclosure of non-privileged protected health information that is limited to identifying minor participants in Wisconsin's public medical programs who received non-FDCA, non-compensia prescriptions from King Vassel. It requires destruction of any records after the conclusion of this case. And, most importantly, it also limits the parties' ability to use the information in any other case. The protective order states that disclosed information may be used only in a manner that is reasonably connected with this case.

The Court will adopt the general form of Watson's proposed order, but will replace much of the language therein to clarify its scope. To begin, the Court will replace much of Watson's proposed language with that found in the model order he submitted with his reply brief. (Docket #115, ex. 1). The Court will edit paragraph seven (and renumber it as paragraph eight) so that it is more precise, as the plaintiffs have expressed concern over that paragraph's meaning. It will also order that the disclosing parties redact the social security number of any disclosed patient. The disclosing parties will also be required to redact any disclosed patient's name so that only his or her first and last initial appear in the documentation. The Court understands that it is Watson's goal to identify additional patients to whom King Vassel may have prescribed off-label medications. Thus far, Watson has identified N.B.

solely by his initials, and the Court believes that the same level of detail should suffice for any additional disclosed patients. If Watson believes otherwise, he may file a motion with the Court requesting that those redaction requirements be lifted. The parties may then brief that issue. The Court notes, however, that it will be reluctant to lift the requirements without a showing of cause, because it wishes to protect the privacy of patients to the greatest degree possible. The Court will also add in paragraph nine from the model order submitted by Watson, because that paragraph, pertaining to sealing filings, is important to the procedure of this Court. (Docket #115, ex. 1). Finally, the Court will strengthen the language that limits use of these documents.

The Court takes Watson at his word that he will not abuse this discovery by treating it as a fishing expedition for new claims that would fall outside of this case or otherwise stepping outside of the bounds of the Court's HIPAA order. At this stage, that is all the Court can do. Watson is entitled to take this discovery. Watson's attorneys are bound by their professional responsibilities. And the Court has previously fined Watson for his own duplicitous activities. At some level, the Court must accept Watson and his counsel's representations that they will act ethically. Suffice it to say that, if Watson or his counsel abuse that trust and overstep the bounds of this HIPAA order, there will be extremely unpleasant consequences for them, whether those consequences be in the form of fines, disciplinary referrals, or some other variant. A word to the wise ought be sufficient.

With these provisos, the Court notes that it will grant Watson's motion for a HIPAA order, which it will issue separately from this order. However, the parties are advised that they should disclose both this order and the

separate HIPAA order when making records requests, as this order may serve to clarify some of the portions of the HIPAA order.

3. CONCLUSION

For the reasons discussed and as more fully described above, the Court will deny Watson's motion *in limine* and will grant his motion for a HIPAA order, but with modifications to his proposal. The Court will issue its HIPAA order separately.

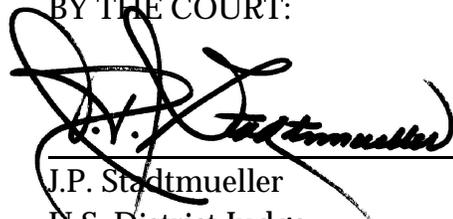
Accordingly,

IT IS ORDERED that Watson's motion *in limine* (Docket #102) be and the same is hereby DENIED; and

IT IS FURTHER ORDERED that Watson's motion for a HIPAA order (Docket #104) be and the same is hereby GRANTED with modifications.

Dated at Milwaukee, Wisconsin, this 2nd day of October, 2013.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge