

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

There are currently three motions pending before the Court:

- (1) Defendant Jennifer King Vassel's ("King Vassel") non-expedited motion for a HIPAA protective order, which would allow her access to the medical records of N.B., the minor patient whose psychiatric treatment forms the basis of this case (Docket #118);
- (2) Relator Toby Watson's ("Watson") expedited motion for a HIPAA protective order that would allow him to collect King Vassel's medical records from a records custodian (Docket #124); and
- (3) Watson's expedited motion to compel King Vassel to provide answers and supplemental information regarding Watson's discovery requests (Docket #127).

The Court has reviewed each of those motions, and now addresses them as follows.

1. KING VASSEL MOTION FOR HIPAA PROTECTIVE ORDER

King Vassel has moved for entry of a HIPAA protective order that would allow her to access the medical records of N.B., the minor patient for

whom King Vassel allegedly wrote off-label prescriptions constituting false claims, in order to ascertain whether other of his treating doctors also wrote similar prescriptions. (Docket #118, #119). Watson opposes this request as being irrelevant. (Docket #133).

The Court agrees with Watson. This case centers around whether King Vassel wrote prescriptions for N.B., which constitute false claims. It has nothing to do with what other treatment N.B. might have received outside of King Vassel's care.

The only way in which the Court could imagine the information being relevant is if the evidence submitted by Watson in support of his allegations is so vague as to leave open a question of whether another doctor wrote prescriptions on N.B.'s behalf that Watson is trying to impute to King Vassel. But, Watson bears the burden of proof in that regard, and if his submissions are so vague as to not carry his burden to show that King Vassel is responsible for writing the prescriptions in question, then Watson's claim will fail. The Court also presumes that King Vassel has her own treatment records regarding N.B. that she will be able to rely on to rebut an incorrect assertion from Watson that a prescription should be attributed to her when, in fact, it should not. Simply put, the Court cannot envision any material matter on which the requested information would bear that could possibly be relevant to this case. *U.S. ex rel. Camillo v. Ancilla Systems, Inc.*, 233 F.R.D. 520, 522 (S. D. Ill. 2005) (citing *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978)). King Vassel's request must, therefore, be denied.

2. WATSON MOTION FOR HIPAA PROTECTIVE ORDER

Watson also requests entry of a HIPAA order. The Court previously granted another of Watson's motions for a HIPAA order, finding that

Watson should be allowed access to the records of King Vassel, Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health, to determine whether King Vassel wrote any allegedly off-label prescriptions constituting false claims for any minors aside from N.B. Watson seeks this second protective order in order to clarify that he is entitled to receive King Vassel's records, which are in the hand of a records custodian, rather than in King Vassel's own possession. (Docket #124). King Vassel objects that Watson "is requesting records from unnamed medical records custodians to analyze numerous volumes covering an eight year span of time." (Docket #130, at 1).

The Court agrees with Watson. His proposed HIPAA order may seem broad, but it is confined to seeking discovery "only from custodians of records of patients of Defendant Jennifer King-Vassel...to whom Dr. King wrote prescriptions when they were under the age of 18, from March 3, 2005, to date." (Docket #124, Ex. 1, at ¶ 3). In other words, the proposal is confined to precisely the type of discovery the Court allowed in its previous order. The only difference is that the entity required to produce those documents is a records custodian, instead of King Vassel, herself. This difference is necessary as a result of King Vassel's own representation that "Dr. King is not a records custodian for any such patients and thus does not have custody or control of medical records for such patients." In other words, because King Vassel cannot provide the discovery, Watson must look elsewhere to receive it, and is entitled to an order allowing him to do so.

Again, the Court makes clear that this order does not settle any law that will be applied at trial. King Vassel's brief opposing Watson's motion for a HIPAA order rehashes her arguments regarding whether off-label

prescriptions are *per se* false claims. (Docket #130, at 2). That is irrelevant to the question. As the Court made clear in its prior order, Watson is entitled to receive this information because additional off-label prescriptions may constitute false claims. The court left open the question of whether Wisconsin can or does take steps to allow reimbursement for off-label prescriptions, which the Court noted is an open question. Without more evidence and argument—which the Court anticipates will likely come in the form of motions *in limine* prior to trial, once the parties’ discovery efforts are nearing an end—the Court is not prepared to rule on that issue at this juncture. But it will not cut Watson’s case off at the knees at this point, either. And, despite the perceived difficulties Watson may have in obtaining the records he seeks (Docket #130, at 3–4), that is a logistical issue that the parties, and particularly Watson himself, must make efforts to resolve. The Court is not holding that the providers of these materials need to engage in the factual analysis of whether the prescriptions were written for a use that falls outside of the FDCA or compendia, as further discussed below, but instead need to turn over records that are potentially relevant to claims that Watson asserts. The Court will issue an amended version of the prior HIPAA order it issued to Watson incorporating the language “for uses that Relator...claims are not supported by the” compendia. This change should make clear that the producing parties do not bear the burden of determining whether King Vassel’s prescriptions were written for non-compendia purposes, but instead whether they were written for a purpose that Watson contends is not supported by the compendia. As discussed more fully below, it is Watson’s burden to establish the fact that prescriptions were written for purposes that

are not supported by the compendia. The responsibility *is not* King Vassel's or the producing parties.

With these provisos, the Court will grant Watson's requested protective order and will also issue an amended version of the prior HIPAA order. It is the parties' responsibility to ensure that the producing parties comply with the Court's protective orders, and, in keeping with that responsibility, they should serve a copy of this order and the amended protective order on any producing party who has already been served to make clear those producing parties' responsibilities. Likewise, a copy of this order should be included with any requests for production to records custodians under the Court's newly-issued HIPAA order that allows for production of documents in the hands of records custodians.

3. WATSON MOTION TO COMPEL

The last motion which the Court now addresses is also the most difficult. Watson asks that the Court order King Vassel to: (1) provide "complete non-evasive responses" to his discovery requests; and (2) supplement her initial disclosures "with respect to her defense that prescriptions presented to Medicaid that were not issued for a medically accepted indication...are not false claims." (Docket #128, at 1). There are two groups of discovery requests and interrogatories at issue, which the Court will reference as Group 1 and Group 2. Group 1's discovery requests and interrogatories all seek an admission and further information that would establish that the prescriptions King Vassel wrote to N.B. are off-label prescriptions not issued for a use approved under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* (Docket #128, at 3-4). Group 2's requests and interrogatories seek slightly more detailed information

regarding whether the prescriptions at issue were written for a use supported by one of the drug compendia. (Docket #128, at 4–6). King Vassel refused to respond to either of these groups of requests and interrogatories, objecting to form and foundation and further stating that the prescriptions were consistent with the formularies. (See King Vassel Resp. to Req. for Adm. 1 & 2, Interrog. 1 & 2, Req. for Prod. 1 & 2).

To begin, the Court must reiterate the statutory scheme that this issue is a part of. Medicaid may only be used to provide reimbursement for “covered outpatient drugs.” 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). 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).

Accordingly, to prove his claim that King Vassel wrote prescriptions constituting false claims, Watson must establish that the prescriptions King Vassel wrote were not for purposes approved by the FDCA nor supported by a compendia. As discussed above, Watson is seeking to have King Vassel admit that both of those facts (essentially elements of Watson’s claim) are true. In essence, he is seeking to have King Vassel prove up part of his case for him.

The Court agrees with Watson that King Vassel should likely have responded to Group 1’s responses and interrogatories differently. Group 1

dealt with whether the prescriptions at issue were written for FDCA-approved purposes. In the Seventh Circuit's opinion remanding this case for further proceedings, the Seventh Circuit wrote that "[t]he prescriptions at issue are 'off-label' and so the parties agree that the drugs were not prescribed for an indication covered under the FDCA." *United States v. King-Vassel*, 728 F.3d 707, 715 (7th Cir. 2013). Thus, it is clear that this fact is foreclosed from further dispute, and King Vassel should have acknowledged so in her responses.

However, the Court can understand her reluctance to do so. Watson's request for admission called for King Vassel to admit not only that the prescriptions were issued for a use that is not approved by the FDCA, but further that the use was "off-label." The Seventh Circuit, of course, used basically the same phrasing, concluding that the prescriptions are off-label and not prescribed for an indication covered under the FDCA. An admission that the prescriptions are off-label, though, may be slightly more damning than an admission that the prescriptions are not covered under the FDCA. Throughout this case, the parties have used the term "off-label" in varying ways. Under their usage, it can encompass not only uses that fall outside FDCA approval, but also uses that are not supported by the compendia. Thus, if King Vassel has some reluctance to outright admit that the prescriptions were "off-label," for fear of that admission being taken to be broad than what the Seventh Circuit has provided, the Court is sympathetic to the reluctance. Moreover, as King Vassel points out in her response brief, the FDCA does not restrict the use of prescription drugs. (Docket #134, at 4-5). In fact, once a drug is approved, doctors are free to prescribe the drug for any use. (*Id.*). Thus, King Vassel is also correct that Watson's proposed

discovery requests in Group 1 are deficient insofar as they seek information that simply does not exist, relating to FDCA-approved uses. Nonetheless, it remains clear that, for purposes of this case, it has been conclusively decided that the prescriptions at issue were not written for indications covered under the FDCA.

Accordingly, the Court will grant Watson's motion to compel insofar as it must direct King Vassel to respond to Group 1's requests and interrogatories in a manner that is consistent with the Court's discussion and the Seventh Circuit's opinion. King Vassel need not admit that the prescriptions were written for off-label purposes to the extent that the term "off-label" is intended to mean anything other than non-FDCA-approved uses, nor is she required to admit that the "uses" were not approved by the FDCA.

On the other hand, the Court views Watson's motion to compel much differently with respect to Group 2. Group 2 deals with the question of whether the prescriptions at issue were written for uses supported by one or more compendia. As mentioned above, the Court essentially views this as an element of Watson's case: to establish that King Vassel wrote a false claim, Watson must show that the prescription was written for a use that is not approved by the FDCA and that is not supported by one or more compendia.

In contrast to the FDCA question, the Seventh Circuit did not make any final pronouncements on this issue. Instead, the Seventh Circuit left the question open, and seemed to make clear that Watson had the burden to prove this fact—whether it be through use of an expert or not. *See King-Vassel*, 728 F.3d at 717. In fact, that was a major portion of the Seventh Circuit's analysis and Watson's argument thereto. *Id.*, at 716–17. He argued

that he did not need an expert to prove that the prescriptions at issue were supported by the compendia, and the Seventh Circuit agreed. *Id.*, at 717. But, the Seventh Circuit did not say that its decision absolved Watson of his burden to prove that portion of his claim with or without use of an expert. *Id.*

Watson now attempts to shirk that duty—which the Court understands may very well be a burdensome one—by placing the onus upon King Vassel to *tell him* whether or not the prescriptions at issue were written for a use supported by a compendia. That is not her task. All she is required to do is to provide Watson with the relevant discovery materials. From there, it is Watson’s duty to examine the compendia as compared to the record and determine for himself whether there is evidence that would support his false claim contentions. After that, it will be his job to prove the same to the jury. Watson complains that King Vassel’s responses are “evasive,” but it is his complaint that rings hollow for, in the Court’s view, Watson is the one attempting evasion of his burden as the relator in this case.

For these reasons, the Court is obliged to deny Watson’s motion to compel insofar as it relates to Group 2’s requests and interrogatories, because those items seek information regarding whether the prescriptions were written for uses that are not supported by the compendia, when in fact that is a question that remains open and must be proven at trial for Watson to succeed on his claims.

Finally, the Court must address the final subject of Watson’s motion to compel: his assertion that King Vassel must update her initial disclosures to reflect her new defense that the prescriptions at issue were written for a use that is consistent with Wisconsin’s formulary. The Court has left open for

review and further evidence gathering the issue of whether states are permitted to draft their own formularies that provide reimbursement for prescriptions that were not prescribed for uses provided in the FDCA or the compendia, and whether the prescriptions written by King Vassel may fall under Wisconsin's formulary. (Docket #116, at 3–5). The Court has noted that this information may establish that either: (1) the prescriptions—even if written for non-FDCA-approved or compendia-supported reasons—are not false claims; or (2) King Vassel lacked the requisite knowledge that the prescriptions were for impermissible reasons. (Docket #116, at 3–5). The Court previously noted that it was leaving this question open for further evidence-gathering and arguments by the parties, and that remains the case. However, to the extent that King Vassel intends to rely on these arguments as a defense, Watson is certainly right that King Vassel must make the required Rule 26 disclosures. Fed. R. Civ. P. 26(a)(1)(A)(i) & (ii), 26(e). The Court will, therefore, grant Watson's motion in this regard.

4. CONCLUSION

For the reasons discussed, the Court is obliged to: (1) deny King Vassel's motion for a HIPAA protective order; (2) grant Watson's motion for a HIPAA protective order, which the Court will issue separately; (3) amend its prior protective order (Docket #117) to make clear that the order does not require producing parties to engage in the analysis of whether prescriptions were written for non-compendia uses, and the Court will separately issue an amended protective order consistent with this; and (4) grant in part and deny in part Watson's motion to compel.

Accordingly,

IT IS ORDERED that King Vassel's motion for a HIPAA protective order (Docket #118) be and the same is hereby DENIED;

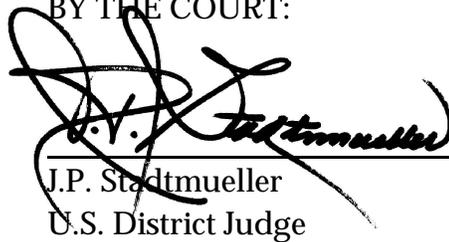
IT IS FURTHER ORDERED that Watson's motion for a HIPAA protective order (Docket #124) be and the same is hereby GRANTED;

IT IS FURTHER ORDERED that the Court's previous protective order (Docket #117) be and the same is hereby AMENDED as more fully discussed above; and

IT IS FURTHER ORDERED that Watson's motion to compel (Docket #127) be and the same is hereby GRANTED in part and DENIED in part, as more fully discussed above.

Dated at Milwaukee, Wisconsin, this 5th day of November, 2013.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge

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

PROTECTIVE ORDER

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R. § 164.512(e)(1), promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, §264, 110 Stat. 1936 (HIPAA), the Court finds good cause for the issuance of a qualified protective order. Accordingly,

IT IS HEREBY ORDERED that:

1. The parties (and their attorneys) to the above-captioned matter are hereby authorized to receive, subpoena, and transmit “protected health information” pertaining to minor patients of defendant, Jennifer King Vassel (“King Vassel”), who submitted for Medicaid reimbursement prescriptions from King Vassel for uses that Relator Toby Watson (“Watson”) claims are not supported by the American Hospital Formulary Service Drug Information (AHFS); the United States Pharmacopeia–Drug Information or its successor publications (US Pharmacopeia); or the DRUGDEX Information System (DRUGDEX).

2. For the purposes of this order, subject to the restrictions contained in paragraph 1, above, protected health information shall have the same scope and definition as set forth in 45 C.F.R. §§ 160.103 and 160.501. Protected health information includes, but is not limited to, health information, including demographic information, relating to either: (a) the past, present or future physical or mental condition of an individual; (b) the provision of care to an individual; or (c) the payment for care provided to an individual, which identifies the individual or which reasonably could be expected to identify the individual. However, any records produced should be redacted so as: (1) not to reflect any patient's Social Security number; and, (2) to reflect *only* the patient's first and last initials (i.e. the patient's full name should not appear anywhere in the records).

3. For purposes of this litigation, Watson seeks discovery only from custodians of records of patients of King Vassel to whom King Vassel wrote prescriptions when they were under the age of 18, from March 3, 2005, to date. As those entities are all "covered entities" (as defined by 45 C.F.R. § 160.13), the Court has power to authorize them to disclose protected health information for purposes of this litigation. Thus, the above-named entities are hereby authorized, subject to the restrictions set forth in paragraphs 1. and 2., above, to disclose to the attorneys in this matter protected health information pertaining to minor patients (under 18 years old at the time of the prescriptions) who received Medicaid benefits since March 3, 2005, including under the Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and/or Wisconsin Forward Health, and who received prescriptions from King Vassel for uses that Watson claims are not supported by the AHFS, the US Pharmacopeia, or the DRUGDEX.

4. The parties and their attorneys shall be permitted to use or disclose the protected health information that they receive in this matter *only* for purposes of prosecuting or defending *this* action and any appeals of this case. To be clear, this means that the protected health information that the parties gather in this case *may be used only for this case and not any other*.

5. This includes, but is not necessarily limited to, disclosure to their attorneys, experts, consultants, court personnel, court reporters, copy services, trial consultants, and other entities or persons involved in the litigation. Prior to disclosing the protected health information to entities or persons involved in this litigation, counsel shall inform each such entity or person that the protected health information may not be used or disclosed for any purpose other than this litigation. Counsel shall take all other reasonable steps to ensure that entities or persons receiving the protected health information do not use or disclose such information for any purpose other than this litigation.

6. Within 45 days after the conclusion of the litigation including appeals, the parties, their attorneys, and any other person or entity in possession of protected health information received from counsel pursuant to paragraph 5 of this Order, shall return the protected health information to the covered entity or destroy any and all copies of protected health information.

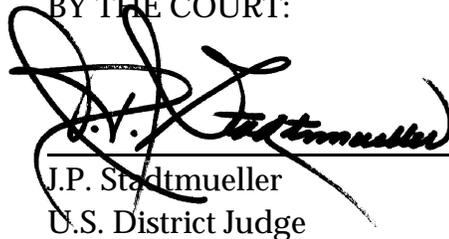
7. This Order does not control or limit the use of protected health information that comes into the possession of the parties or their attorneys from a source other than a “covered entity,” as that term is defined in 45 C.F.R. § 160.103.

8. Nothing in this Order authorizes the parties to obtain medical records or information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or other lawful process.

9. This order does not authorize either party to seal court filings or court proceedings. The Court will make a good cause determination for filing under seal if and when the parties seek to file protected health information or other materials under seal.

Dated at Milwaukee, Wisconsin, this 5th day of November, 2013.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA and
STATE OF WISCONSIN

Plaintiffs,

DR. TOBY TYLER WATSON,

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JENNIFER KING VASSEL,

Defendant.

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AMENDED
PROTECTIVE ORDER

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R. § 164.512(e)(1), promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, §264, 110 Stat. 1936 (HIPAA), the Court finds good cause for the issuance of this qualified protective order, which amends the Court's prior protective order, which issued on October 2, 2013 (Docket #117). Accordingly,

IT IS HEREBY ORDERED that:

1. The parties (and their attorneys) to the above-captioned matter are hereby authorized to receive, subpoena, and transmit "protected health information" pertaining to minor patients of defendant, Jennifer King Vassel ("King Vassel"), who submitted for Medicaid reimbursement prescriptions from King Vassel for uses that Relator Toby Watson ("Watson") claims are not supported by the American Hospital Formulary Service Drug Information (AHFS); the United States Pharmacopeia-Drug Information or

its successor publications (US Pharmacopeia); or the DRUGDEX Information System (DRUGDEX).

2. For the purposes of this order, subject to the restrictions contained in paragraph 1, above, protected health information shall have the same scope and definition as set forth in 45 C.F.R. §§ 160.103 and 160.501. Protected health information includes, but is not limited to, health information, including demographic information, relating to either: (a) the past, present or future physical or mental condition of an individual; (b) the provision of care to an individual; or (c) the payment for care provided to an individual, which identifies the individual or which reasonably could be expected to identify the individual. However, any records produced should be redacted so as: (1) not to reflect any patient's Social Security number; and, (2) to reflect *only* the patient's first and last initials (i.e. the patient's full name should not appear anywhere in the records).

3. For purposes of this litigation, Watson seeks discovery only from King Vassel, and Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health. As those entities are all "covered entities" (as defined by 45 C.F.R. § 160.13), the Court has power to authorize them to disclose protected health information for purposes of this litigation. Thus, the above-named entities are hereby authorized, subject to the restrictions set forth in paragraphs 1. and 2., above, to disclose to the attorneys in this matter protected health information pertaining to minor patients (under 18 years old at the time of the prescriptions) who received Medicaid benefits since March 3, 2005, including under the Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and/or Wisconsin Forward Health, and who received prescriptions from King Vassel

for uses that Watson claims are not supported by the AHFS, the US Pharmacopeia, or the DRUGDEX.

4. The parties and their attorneys shall be permitted to use or disclose the protected health information that they receive in this matter *only* for purposes of prosecuting or defending *this* action and any appeals of this case. To be clear, this means that the protected health information that the parties gather in this case *may be used only for this case and not any other*.

5. This includes, but is not necessarily limited to, disclosure to their attorneys, experts, consultants, court personnel, court reporters, copy services, trial consultants, and other entities or persons involved in the litigation. Prior to disclosing the protected health information to entities or persons involved in this litigation, counsel shall inform each such entity or person that the protected health information may not be used or disclosed for any purpose other than this litigation. Counsel shall take all other reasonable steps to ensure that entities or persons receiving the protected health information do not use or disclose such information for any purpose other than this litigation.

6. Within 45 days after the conclusion of the litigation including appeals, the parties, their attorneys, and any other person or entity in possession of protected health information received from counsel pursuant to paragraph 5 of this Order, shall return the protected health information to the covered entity or destroy any and all copies of protected health information.

7. This Order does not control or limit the use of protected health information that comes into the possession of the parties or their attorneys

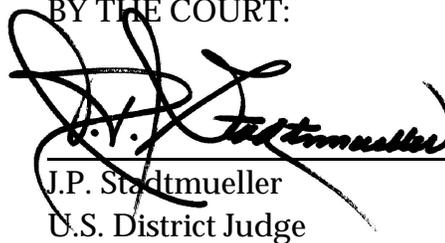
from a source other than a “covered entity,” as that term is defined in 45 C.F.R. § 160.103.

8. Nothing in this Order authorizes the parties to obtain medical records or information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or other lawful process.

9. This order does not authorize either party to seal court filings or court proceedings. The Court will make a good cause determination for filing under seal if and when the parties seek to file protected health information or other materials under seal.

Dated at Milwaukee, Wisconsin, this 5th day of November, 2013.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge