UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT JENNIFER KING VASSEL'S BRIEF IN OPPOSITION TO THE PLAINTIFF'S MOTION IN LIMINE REGARDING FALSE CLAIMS

The plaintiff misstates the law governing Medicaid prescription drug reimbursement by failing to fully disclose the federal statute governing reimbursement. In his rush to, in effect, request summary judgment in this case, and before any discovery is completed as a result of the remand from the Seventh Circuit Court of Appeals, the plaintiff quickly filed this premature motion in limine in an attempt to foreclose one of the primary issues on which discovery would occur: whether Medicaid reimbursement is lawfully permitted on a basis beyond the compendia on which the plaintiff has focused.

As will be addressed below, Wisconsin and all other states utilize a process to determine reimbursement that is *not* limited to applying the compendia cited by the plaintiff, and therefore Dr. King must be permitted to introduce such relevant evidence to explain how reimbursement criteria are truly established. Defendant Jennifer King Vassel (Dr. King), by

her attorneys, Gutglass, Erickson, Bonville & Larson, S.C., respectfully submits the following brief in opposition to the plaintiff's motion in limine regarding false claims.

FACTUAL BACKGROUND

As support for the law cited below, the plaintiff acknowledged that off-label use of a prescription medication is "almost customary" and a recognized part of medical practice in Wisconsin and the country. *Affidavit of Bradley S. Foley*, *Exhibit A, Deposition of the Plaintiff*, pp. 51-52. The plaintiff also admitted that off-label use of prescription medication is actually more common and more widely utilized by physicians than the approved FDA purpose. ***Id.***, p. 52. Furthermore, Dr. King was paid to treat the patient regardless of whether she prescribed medications, and she received no benefit for writing prescriptions. (Document 30, p. 2.)

ARGUMENT

OFF-LABEL USE OF PRESCRIPTION MEDICATION CAN BE REIMBURSED BY MEDICAID.

As the Seventh Circuit aptly explained, "[i]n the case of prescription drugs, pharmacies pay pharmaceutical companies for drugs and then submit claims to the state Medicaid agency for reimbursement." ***Watson v. King-Vassel***, ___ F.3d ___, 2013 WL 4532140, *6 (7th Cir. 2013). States can choose to reimburse for off-label use of prescription medication. ***United States ex rel. Rost v. Pfizer, Inc.***, 253 F.R.D. 11, 16 (D. Mass. 2008). Rather than relying solely on the compendia to determine whether there is Medicaid coverage for prescription medications, Medicaid reimbursement law mandates that a panel of

physicians, pharmacists, and other professionals *consider* information including the compendia, but also other medical information that reflects medical practices such as medical literature.

This requires review of the Medicaid reimbursement process, as established in the statutes. First, an examination of what are permissible restrictions for coverage of prescription medications.

> (d) Limitations on coverage of drugs
> (1) **Permissible** restrictions. [. . .]
> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if –
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(g) of this section);
> (ii) the drug is contained in the list referred to in paragraph (2);
> [. . .] **or**
> (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

42 U.S.C. § 1396r-8(d) (emphasis added). Of significance, the limitations on coverage are not mandated, but are subject to the *discretion* of the State. The plaintiff has failed to present any evidence or law as to whether the State of Wisconsin has restricted coverage for the medications at issue in the case at bar. In addition, the plaintiff glosses over what statute or administrative rule excludes coverage for the off-label use of prescription medication. *See Plaintiff's brief,* p.2 (referring to 42 U.S.C. §§ 1396b(i)(10) and 1396r-8(a)(3)).

The formulary, as noted in sub(iv) above, may be established by a State if it meets certain requirements. 42 U.S.C. § 1396r-8(d)(4). Among other requirements, the formulary must be developed by the state's drug use review board. 42 U.S.C. § 1396r-8(d)(4)(A). The

establishment of a drug use review board is mandated by statute. 42 U.S.C. § 1396r-8(g)(3) ("Each State shall provide for the establishment of a drug use review board [. . .] either directly or through a contract with a private organization.")

The drug use review board reviews prescription medications to determine whether they are appropriate, medically necessary, and not likely to result in adverse medical results, using a number of sources and *not limited* to the compendia as contended by the plaintiff.

> (g) Drug Use Review
> (1) In general.
> (A) In order to meet the requirement of section 13896b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions
> (i) are appropriate,
> (ii) are medically necessary, and
> (iii) are not likely to result in adverse medical results. [. . . .]
> (B) The program shall assess data on drug use against predetermined standards, consistent with the following:
> (i) compendia which shall consist of the following:
> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System; **and**
> **(ii) the peer reviewed literature.**

42 U.S.C. § 1396r-8(g) (emphasis added).

The State of Wisconsin complied with this mandate and establish a Drug Utilization Board. According to the bylaws of the State of Wisconsin Drug Utilization Review Board,

> Pursuant to the Omnibus Budget Reconciliation Act of 1990

> (OBRA '90), federal rules require at 42 CFR § 456.716 that the state Medicaid agency establish a Drug Utilization Review (DUR) program. The DUR program is charged with developing procedures to assure drug use as appropriate, medically necessary and unlikely to result in adverse medical results.

Affidavit of Bradley S. Foley, Exhibit B, Bylaws of the Wisconsin Drug Utilization Board.

The members of the Drug Utilization Board are all health care professionals, *e.g.*, physicians, pharmacists, or nurses. ***Id.***, *Exhibit C, Wisconsin DUR Board Members.*

The drug use review program is described as follows:

> **(2) Description of program**
> Each drug use review program shall meet the following requirements for covered outpatient drugs:
>
> **(A) Prospective drug review.**
>
> (i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. *Each State shall use the compendia* ***and literature*** *referred to in paragraph (1)(B) as its source of standards for such review.*

42 U.S.C. § 1396r-8(g)(2) (emphasis added).

The drug use review program is required to apply certain standards, based on the compendia and medical literature, in order to improve the quality of care and conserve program funds.

> **(C) Application of standards**
>
> The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards **(using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment)** including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug–disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

42 U.S.C. § 1396r-8(g)(2)(C)(emphasis added).

The Drug Utilization Board's activities are required to include not only prospective drug review as noted above, but also retrospective drug use review with the compendia and medical literature standards, among other activities. 42 U.S.C. § 1396r-8 (g)(3)(C). In other words, the statutes provide that the compendia is *not* the sole basis for determining whether off-label use of prescription medication can be reimbursed by a state Medicaid program. Dr. King will present expert testimony regarding her off-label use of prescription medications and Wisconsin's formulary permitting reimbursement beyond the compendia. *Compare* ***Watson v. King-Vassel***, ___ F.3d ___, 2013 WL 4532140, *10 (7th Cir. 2013) ("The district court may very well be correct that Watson requires an expert to explain some number of the prescriptions he charges constitute false claims.")

Moreover, discovery needs to occur regarding whether the State Drug Utilization Review Board permitted reimbursement of the prescription medications at issue here. The

plaintiff's motion in limine is premature, without the disclosure of experts and further discovery occurring.

CONCLUSION

In short, determining whether Medicaid provides coverage for off-label use of prescription medication is not as simple as reviewing the compendia. Contrary to the plaintiff's contention, evidence regarding Wisconsin's formularies as developed by the state Drug Utilization Board is clearly more significant and clearly relevant to the issues raised in the complaint. Dr. King should not be precluded from presenting this fundamental and highly relevant evidence that reimbursement is not based solely on the compendia.

Based on the foregoing arguments, defendant Jennifer King Vassel respectfully requests that the Court deny the plaintiff's motion in limine.

Dated at Milwaukee, Wisconsin this 18th day of September, 2013.

GUTGLASS, ERICKSON,
BONVILLE & LARSON, S.C.

s/ Bradley S. Foley
Mark E. Larson (#1016423)
Bradley S. Foley (#1026871)
Attorneys for Defendant Jennifer King Vassel

P.O. ADDRESS:
735 North Water Street, Suite 1400
Milwaukee, Wisconsin 53202-4267
Telephone: (414) 273-1144
mark.larson@gebsc.om
bradley.foley@gebsc.com

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

AFFIDAVIT OF BRADLEY S. FOLEY IN SUPPORT OF DEFENDANT JENNIFER KING VASSEL'S BRIEF IN OPPOSITION TO THE PLAINTIFF'S MOTION IN LIMINE REGARDING FALSE CLAIMS

STATE OF WISCONSIN)
) ss.
COUNTY OF MILWAUKEE)

BRADLEY S. FOLEY, being duly sworn under oath, deposes and states as follows:

1. I am one of the attorneys representing defendant Jennifer King Vassel in the above-referenced action and am authorized to make this affidavit on her behalf.

2. Attached as Exhibit A is a true and accurate copy of selected portions of the May 4, 2012 deposition of the plaintiff.

2. Attached as Exhibit B is a true and accurate copy of the Bylaws of the State Of Wisconsin Drug Utilization Board.

3. Attached as Exhibit C is a true and accurate copy of the members of the Wisconsin Drug Utilization Board.

s/Bradley S. Foley
Bradley S. Foley

Subscribed and sworn to before me
this 18th day of September, 2013.

s/Carrie Wentland
Notary Public, State of Wisconsin
My Commission expires: 1/19/14

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

vs. Case No. 11-CV-236

JENNIFER KING VASSEL, CAPS
CHILD & ADOLESCENT PSYCHOLOGICAL
SERVICES, and ENCOMPASS EFFECTIVE
MENTAL HEALTH SERVICES, INC.,
Defendants.

Deposition of TOBY T. WATSON
Friday, May 4th, 2012

1:39 p.m.

at

GUTGLASS, ERICKSON, BONVILLE & LARSON, S.C.
735 North Water Street
Milwaukee, Wisconsin

Reported by Rosanne E. Pezze, RPR/CRR

Page 50

clinic, or was it prepared originally somewhere else?
A It was created on an old laptop. I don't have the laptop anymore, but it was created on that.
Q It was a laptop that was yours as opposed to the attorney's?
A Correct.
Q Did you notice that there was a four-year gap in the claims history?
A Not off the top of my head.
Q Do you have any information that there was payment for any medications prescribed by Dr. King from September of 2003 until the beginning of 2007?
A Say the question again.
Q Yeah. That there is -- let me ask it this way. Did you appreciate and are you aware --
A Okay.
Q -- that from September of 2003 and at least through the end of 2006, there's no indication that any prescriptions written by Dr. King were covered by this program?
A Got it.
Q Were you aware of that?
A I am looking at a document that shows right now that there were no medications from, correct, '03 until January 9th of '07.

Page 51

Q So if the complaint contains allegations that prescriptions written by Dr. King were submitted for payment by Medicaid programs for Nicholas Bingham, that would be inaccurate?
A Say it one more time. I'm sorry.
Q I'll give it one more try.
A I apologize.
Q Would you agree with me that to the extent that the complaint alleges that prescriptions written by Dr. King for Nicholas Bingham during the time frame between September of 2003 and until at least the end of 2006, had been submitted to Medicaid for reimbursement, that those allegations would in fact be inaccurate?
A I don't know. I only have the information that I gathered. I don't have if there was actually even more medication submitted by her or by somebody else. I wouldn't know.
Q Are you aware of any other claims information other than what's attached here to your initial disclosure to the court?
A I don't believe so.
Q I assume you're familiar with the concept of off-label prescribing?
A Correct.

Page 52

Q You would agree with me that that's recognized as, generally speaking, that off-label prescribing in and of itself is not unreasonable care by a physician?
A I wouldn't use the word unreasonable, but it is often done and almost customary.
Q It's done very often and, in fact, some off-label uses of prescription medication are actually more common and more widely utilized by physicians than the approved FDA purpose; is that true?
A Correct.
Q Because the way the law works in the United States is once the FDA approves a medication for use in the United States, physicians have the ability to prescribe that medication for other reasons?
A Correct.
Q And very reasonable, competent physicians use that for the benefit of their patients every day?
A Generally speaking, yes; but I would caution about not for the benefit of the patient often.
Q Well, there are medications that are very beneficial to patients that are only prescribed on an off-label basis?
A If we're talking about just the psychiatric medications, they are often given off-label, not always for the benefit of the patient, but it's often

Page 53

done. And you have to be careful how you define benefit. It may actually cause a symptom reduction of thought and/or behavior in the short term, but the long term there is no benefit then. So it's kind of a loaded question when you say benefit.
Q But one of the ways this happens is there are a group of patients who have heart disease, for example?
A Sure.
Q People learn, and it's reported through the medical literature and medical science then agrees to accept this as a proven fact that there are medications that were intended to aid a cardiac condition that has some other benefit, it reduces risks of some other ailment?
A Sure. Yeah, there's certain meds that can do that.
Q And that's off-label prescribing?
A Yes.
Q In this particular case, Dr. King, to the extent that she ever received any reimbursements of her services through Medicaid, that would be for seeing the patient, correct, or don't you know?
A I don't know.
Q All right. Do you know whether or not -- do you have any base of knowledge for whether or not she would have been reimbursed regardless of whether she

Scott Walker
Governor

Dennis G. Smith
Secretary

State of Wisconsin
Department of Health Services

DIVISION OF HEALTH CARE ACCESS AND ACCOUNTABILITY

1 WEST WILSON STREET
P O BOX 309
MADISON WI 53701-0309

Telephone: 608-266-8922
FAX: 608-266-1096
TTY: 888-692-1402
dhs.wisconsin.gov

BYLAWS OF DRUG UTILIZATION REVIEW BOARD

I. LEGAL AUTHORITY

Pursuant to the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), federal rules require at 42 CFR § 456.716 that the state Medicaid agency establish a Drug Utilization Review (DUR) program. The DUR program is charged with developing procedures to assure drug use as appropriate, medically necessary and unlikely to result in adverse medical results.

II. COMPOSITION AND MEMBERSHIP

At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. In addition, at least one member of the Board shall be a registered nurse with prescribing authority. All professional members shall be licensed to practice in the State of Wisconsin. DUR Board members must have recognized knowledge and expertise in at least one of the following:

- Clinically appropriate prescribing of covered outpatient drugs.
- Clinically appropriate dispensing and monitoring of covered outpatient drugs.
- Drug use review, evaluation, and intervention.
- Medical quality assurance.

The DUR Chief Pharmacist shall be staff to the Board as shall any members designated by the Division of Health Care Access & Accountability (DHCAA), Department of Health Services, State of Wisconsin.

DHCAA shall solicit recommendations for Board membership through a qualified DUR contractor who will contact the Wisconsin Medical Society, the Pharmacy Society of Wisconsin, the University of Wisconsin – School of Pharmacy and the Wisconsin Nurses Association for nominations. Members will be recommended to the DHCAA by the contracted DUR provider. Members will be appointed by the Administrator of the DHCAA. The Chair and Vice Chair of the Board will be appointed annually by the Administrator.

III. TERMS OF OFFICE

Board members will be appointed for a three year term and may be reappointed. Board members serve at the pleasure of the Administrator of DHCAA. Terms of office will be staggered.

IV. REPLACEMENT OF MEMBERS

If a vacancy is created by the resignation of a member, the DHCAA will solicit and appoint an individual to fill the unexpired term.
Absence from two consecutive meetings shall result in a letter from the Chair of the Board that further participation on the Board is in jeopardy. Absence from a third consecutive meeting will result in removal from the Board.

V. QUORUM

For purposes of voting, and other official action, a quorum shall be declared if at least 50 percent of the voting members are present.

VI. DUTIES AND RESPONSIBILITIES

A. Administrative

The DUR contractor will coordinate all necessary administrative functions including:

- Coordination of meetings;
- Record keeping including preparation of meeting agenda and minutes; and
- Payment of travel expenses.

B. Professional:

The DUR Board activities shall include but not be limited to the following:

- Review and make recommendations to the DHCAA based on federally predetermined standards for retrospective and prospective DUR;
- Approve ongoing educational interventions for physicians and pharmacists, targeted toward cost effective prescribing, therapy problems or individuals identified in the course of drug use reviews; and
- Oversee the operation of the DUR program.

VII. FREQUENCY OF MEETINGS

Meetings will be held at least four (4) times annually.

VIII. CONFIDENTIALITY AND IMMUNITY

All DUR Board members will be required to sign a statement of confidentiality in which the member agrees not to use, distribute, or disclose information regarding any member, provider or case reviewed by the DUR Board. The Board member must also agree that any information discussed at the DUR Board meeting will not be disclosed in a manner which could identify the views of the specific members of the DUR Board.

All DUR Board members are entitled to the same immunities from civil liability as a result of acts or omissions in rendering service as a member of the DUR Board as are enjoyed by state employees and officials for acts within the scope of their employment.

IX. CONFLICT OF INTEREST

A conflict of interest shall exist when the member has an existing or potential personal, professional or monetary interest, or when a member's spouse or child has an existing or potential monetary interest, in a matter under consideration by the DUR Board. A member shall disclose any potential conflict in writing at the time of their appointment to the Board and at the commencement of consideration of substantive matters before the Board, or at the point when conflict of interest becomes apparent to the member. In the event of a conflict of interest the Board member shall not participate in discussion or deliberation of the matter and shall abstain from any vote in the matter. Minutes of the meeting will reflect the conflict of interest and that abstention from voting had occurred. In the event there are questions as to whether a conflict of interest or potential conflict of interest exists in a case of an individual member, the question shall be decided by the Chair.

Members shall not represent themselves as officers or employees of the State of Wisconsin when acting as a DUR Board member.

Approved:

_____

Brett Davis
Medicaid Director

Date: _____

WISCONSIN DUR BOARD MEMBERS

- Robert Breslow, RPh
- Michael C. Brown, PharmD
- Ward Brown, MD
- Daniel Erickson, MD
- Robert Factor, MD, PhD
- Michael Ochowski, RPh
- Jacob Olson, RPh
- Lora Wiggins, MD
- Paul M. Cesarz, R.Ph
- Maria Brenny-Fitzpatrick RN MSN FNP-C, GNP-BC

The policy of the DUR Board as passed by the Board is that all inquiries with regard to their capacity as Board members be addressed to them in care of Monica Yeazel for forwarding to them.

Monica Yeazel, R.Ph. Monica.Yeazel@wisconsin.gov
(608) 205-4066