

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-JPS

JENNIFER KING VASSEL,

Defendant.

**SECOND MOTION FOR ENTRY OF
HIPAA QUALIFIED PROTECTIVE ORDER**
(King-Vassel & Wisconsin)

Qui tam relator Dr. Toby Watson moves for the entry of a qualified protective order under 45 CFR §164.512(e) promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, §264, 110 Stat. 1936 (HIPAA) to:

1. engage in discovery against defendant King-Vassel, and
2. allow Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health pursuant to a discovery request or requests,

to disclose protected health information limited to identifying additional off-label prescriptions written by Dr. King-Vassel and presented to Medicaid for payment for uses that do not have support in 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), which are the statutorily incorporated "compendia" under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i) for determining off-label outpatient drug coverage under Medicaid and therefore false claims.

Dated this 15th day of September, 2013.

LAW PROJECT FOR PSYCHIATRIC
RIGHTS, INC.

s/ James B. Gottstein

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Case No. 11-CV-236-JPS

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**BRIEF IN SUPPORT OF
SECOND MOTION FOR ENTRY OF
HIPAA QUALIFIED PROTECTIVE ORDER**
(King-Vassel & Wisconsin)

Qui tam relator Dr. Toby Watson has moved for the entry of a qualified protective order under 45 CFR §164.512(e) promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, §264, 110 Stat. 1936 (HIPAA) to:

1. engage in discovery against defendant King-Vassel, and
2. allow Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health pursuant to a discovery request or request(s),

to disclose protected health information limited to identifying additional off-label prescriptions written by Dr. King-Vassel and presented to Medicaid for payment for uses that do not have support in 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), which are the statutorily incorporated "compendia" under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i) for determining off-label outpatient drug coverage under Medicaid.

A. Background and Purpose

This is a case against defendant, Jennifer King-Vassel, M.D.,¹ for causing the presentment of false claims to Medicaid for outpatient prescriptions of psychotropic drugs to Medicaid recipients that were not for a "medically accepted indication," which is statutorily defined as an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia:

A "false or fraudulent claim" occurs when Medicaid pays for drugs that are not used for an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia.²

If a prescription is not issued for an indication approved by the FDCA, it is called "off-label," and so another way to describe a prescription constituting a false claim is that it is off-label and not for a use supported by any of the compendia.

The Complaint in this matter, at ¶24, identifies some 49 prescriptions that it is alleged are not for a medically accepted indication. On July 15, 2012, at Docket No. 25, Dr. Watson moved for a qualified protective order authorizing "covered entities" to disclose protected health information pursuant to discovery requests and deposition subpoenas to uncover more such prescriptions. However, through Docket No. 39, this Court denied the motion, concerned that the requested protective order was too broad.

In particular, this Court was concerned that the expected discovery would have the potential to lead to the identification of a slew of patients, their physical and mental condition, the care they received, and the payment for their care, concluding:

For these reasons, without some further limiting principles and some

¹ Encompass Effective Mental Health Services, Inc., and CAPA Child and Adolescent Psychiatric Services were also originally defendants, but were voluntarily dismissed.

² Docket No. 59, p. 11. This was affirmed in the remand of this case in, *ex rel Watson v. King-Vassel*, 2013 WL 4532140, Slip Opinion in Case No. 12-3671, p. 16 (7th Cir. Aug 28, 2013).

overarching purpose identified by Dr. Watson, the Court is obliged to deny his motion. If he feels that a protective order is necessary to gain access to truly relevant documents during the discovery process, he may request such an order from the Court, but should be sure to limit the scope of such requested order.

Docket No. 39, p.3.

This is exactly what Dr. Watson is attempting to do through this Second Motion for Entry of HIPAA Qualified Protective Order. It is true that Dr. Watson is seeking to identify off-label prescriptions to patients besides N.B., constituting false claims because their use was not supported in any of the compendia. While such prescriptions must necessarily be linked to specific patients, this can be done without identifying the patients, themselves. Each Medicaid patient has a unique Member Identification Number, and Dr. Watson has no objection to Dr. King-Vassel redacting patients' names provided their Member Identification Number is used instead.

However, it might be of sufficient protection to this Court that Paragraph 5 of the proposed order provides:

(5) At the conclusion of the litigation any person or entity in possession of protected health information received pursuant to paragraph 6 of this order shall destroy any and all copies of such protected health information.

Dr. Watson complies with HIPAA's requirements in this motion and is certainly willing to accept other provisions to protect the privacy of patients, but it respectfully suggested he is entitled to discovery to identify additional false claims. As the Court said in *Johnson v. Jung*, 242 F.R.D. 481, 483 (N.D. Ill 2007)

[T]he Federal Rules of Civil Procedure provide for liberal discovery. *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002). Under Rule 26(b)(1), "[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party...."

Against this backdrop, of course, is F.R.C.P. 26(c)(1), which provides that a "court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment,

oppression, or undue burden or expense," and HIPAA's specific process and criteria for releasing protected health care information.

The original motion, Docket No. 25, sought a qualified protective order respecting all "covered entities," while this one is restricted to just two—the defendant, and Wisconsin's Medicaid programs, Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health, and specifically limited to discovery of off-label prescriptions for uses not supported by any compendia, i.e., prescriptions causing false claims. The Qualified Protective Order proposed by this motion will not prevent Dr. King from objecting to specific discovery requests or subpoenas, or seeking additional protection, or both, as provided in the Federal Rules of Civil Procedure.

A more detailed description of HIPAA's process for allowing discovery of protected health information follows.

B. HIPAA Provisions

Under 45 CFR 164.512 "covered entities" are authorized to disclose "protected health information" without

- (1) written authorization of the individual under 45 CFR 164.508, or
- (2) the individual being given the opportunity to agree or object under 45 CFR 164.510, in judicial or administrative proceedings in compliance with 45 CFR 164.512(e). As pertinent to this motion, 45 CFR 164.512(e) provides:

(e) Standard: Disclosures for judicial and administrative proceedings.

(1) Permitted disclosures. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

. . . (ii) In response to a subpoena, discovery request, or other lawful process . . . , if:

. . . (B) The covered entity receives satisfactory assurance, as described in

paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section. . . .

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

The proposed Qualified Protective Order filed herewith complies with the requirements of 45 CFR 164.512(e)(v) and in an attempt to address this Court's concerns, further limited to (a) identifying additional off-label prescriptions written by Dr. King-Vassel and presented to Medicaid for payment for uses that do not have support in any compendia, and (b) disclosure by defendant Dr. King-Vassel and Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health.

C. Conclusion

Dr. Toby Watson respectfully suggests that upon compliance with HIPAAs' requirements he is entitled to disclosure and discovery of additional off-label prescriptions for use on children

presented to Medicaid for payment that were not supported by any of the compendia and therefore constitute false claims. He has tried to limit the request in this second motion as much as possible in order to address this Court's concerns and does not object to other means of protecting patients' privacy to the extent possible, while still being able to prosecute this case.

For the foregoing reason, *relator*, Dr. Watson respectfully requests this Court **GRANT** his Second Motion For Entry Of HIPAA Qualified Protective Order.³

Dated this 15th day of September, 2013.

LAW PROJECT FOR PSYCHIATRIC
RIGHTS, INC.

s/ James B. Gottstein
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³ As provided in 45 CFR 164.512 (e)(1)(ii)(B), set forth above, disclosure and discovery of protected health information is allowed if "reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v)." Dr. Watson did not rely on this provision to conduct discovery prior to this Court's ruling on his previous motion for entry of HIPAA Qualified Protective Order, Docket No. 25, but in light of the compressed schedule in this case, intends to do so for this motion. The idea is that this is necessary for discovery to be completed within the time frame for the close of discovery requested in Docket No. 101, but that responses to discovery requests for protected health information against Dr. King-Vassel will not be required until after this Court has a chance to rule.

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Defendant.

Case No. 11-CV-236-JPS

**ORDER GRANTING HIPAA QUALIFIED
PROTECTIVE ORDER**

In order to provide for the orderly and proper discovery of protected health information under 45 CFR §164.512(e), promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub.L. No. 104-191, §264, 110 Stat. 1936 (HIPAA), and to ensure compliance therewith, pursuant to F.R.C.P §26(c),

IT IS HEREBY ORDERED:

(1) The parties (and their attorneys) to the above-captioned matter are hereby authorized to

(a) engage in discovery against defendant King-Vassel, and

(b) allow Wisconsin Medical Assistance Program, Wisconsin BadgerCare System,

and Wisconsin Forward Health pursuant to a discovery request or requests,

to disclose, receive and transmit non-privileged "protected health information" limited to identifying or seeking to identify off-label prescriptions written by Dr. King-Vassel and presented to Medicaid for payment for uses that do not have support in 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 CFR 160.103 and 160.501. Without limiting the generality of the foregoing, subject again, however, to the restrictions contained in paragraph (1), above, 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.

(3) Dr. King-Vassel, and Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health, are hereby authorized, subject to the restrictions set forth in paragraph (1), above, to disclose protected health information pertaining to children and youth (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 transmit to all attorneys in this matter.

(4) The parties and their attorneys may use the protected health information in any manner that is reasonably connected with the above-captioned litigation. This includes, but is not limited to, disclosure to the parties, their attorneys of record, the attorneys' firm (i.e., attorneys, support staff, agents, and consultants), experts, consultants, court personnel, court reporters, copy services, trial consultants, jurors, venire members, and other entities involved in the litigation process. Other uses of the protected health information are prohibited.

(5) At the conclusion of the litigation any person or entity in possession of protected health information received pursuant to paragraph 6 of this order shall destroy any and all copies of such protected health information.

(6) This order shall only control or limit the use of protected health information that comes into the possession of any party or any party's attorney from Dr. King-Vassel, Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health pursuant to this order through formal discovery requests, subpoenas, or depositions.

(7) Nothing in this order authorizes counsel to obtain medical records or information through means other than formal discovery requests, subpoena, or through depositions, pursuant to a patient authorization, or through attorney-client communications.

Dated at Milwaukee, Wisconsin, this _____ day of _____, 2013.

BY THE COURT:

J.P. Stadtmueller
U.S. District Judge