

CANCELLED

Meeting Notice

**Missouri Board of Pharmacy
Conference Call
May 14, 2015 3:00 p.m.
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (5), (7), and (14), and under Section 324.001.8, RSMo.

The Board may go into closed session at any time during the meeting. If the meeting is closed the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the open portion of the telephone conference call, s/he should be present at the Missouri Board of Pharmacy, 3605 Missouri Blvd., Jefferson City, Missouri, at 3:00 p.m. on May 14, 2015.

Please see attached tentative agenda for this meeting.

TENTATIVE AGENDA
May 14, 2015 3:00 p.m.
Missouri Board of Pharmacy
Professional Registration
3605 Missouri Blvd
Jefferson City, MO 65109
Conference Call

OPEN SESSION

- 1 Call to Order
- 2 Roll Call
- 3 STLCOP List Additions
- 4 State FDA MOU Response
- 5 The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, RSMo. The Board will return to open session at the conclusion of discussion of closed session items.
- 6 Adjournment

MISSOURI BOARD OF PHARMACY
MAY 14, 2015
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SECTION C -- OPEN

#C1 STLCOP College of Pharmacy Additions to Lists

SECTION D -- OPEN

#D1 State FDA MOU Response

SECTION E -- OPEN

SECTION A – OPEN

THERE ARE NO ITEMS FOR THIS SECTION

SECTION B – OPEN HEARINGS

THERE ARE NO ITEMS FOR THIS SECTION

SECTION C – OPEN

#C1 STLCOP List Additions

- STLCOP Site Listing
- STLCOP Preceptor Listing

054-016955	IL	Katherine Shaw Bethea Hospital	403 E 1st Street	Dixon	IL	61021	none
054-016079	IL	Medicine Shoppe	1116 W. Main	Fairfield	IL	62837	none
054-014099	IL	Walgreens Pharmacy #5147	9150 Skokie Blvd	Skokie	IL	60077	none (corrected license #)
054-003749	IL	Walgreens Pharmacy#2721	9000 Greenwood Ave.	Niles	IL	60016	none
054-009638	IL	Wal-Mart Pharmacy #334	18600 Shipman Blacktop Rd.	Carlinville	IL	62626	none
054-015438	IL	Wal-Mart Pharmacy #5044	10000 Bartel Blvd.	Galena	IL	61036	none
2-09626	KS	Stormont Vail Health Care	1500 SW 10th Ave	Topeka	KS	66604	none
21613600	OH	Kroger N-522	300 South Hamilton Rd	Gahanna	OH	43230	none
021673800-03	OH	Walgreens Pharmacy #10051	8060 S. Mason Montg. Rd.	Mason	OH	45040	none
100-0464	SD	Sanford USD Medical Center	1305 West 18th Street	Sioux Falls	SD	57110	none
3949	TN	Walgreens	1451 New Hwy 96 West	Franklin	TN	37064	none
00004339	TN	Walgreens Pharmacy	1804 Charlotte Ave.	Nashville	TN	37203	none
3734	TN	Walgreens Pharmacy #6409	101 Franklin Road	Brentwood	TN	37027	none
26618	TX	Rolling Plains Memorial Hospital	200 East Arizona Ave	Sweetwater	TX	79556	none
24369	TX	Stonegate Pharmacy	2501 Williams Cannon Dr.	Austin	TX	78745	none
4260	TX	TIRR Memorial Hermann	1333 Moursund	Houston	TX	77030	none
0201000187	VA	Rite Aid Pharmacy #3686	10521 Lee Highway	Fairfax	VA	22030	yes
CF00003999	WA	Bartell Drugs #37	1404 3rd Ave.	Seattle	WA	98101	does not provide
Phar.CF00002146	WA	Olympic Pharmacy & Healthcare	4700 Point Fosdick Dr.	Gig Harbor	WA	98335	does not provide
CF00005114	WA	QFC Pharmacy #851	22828 100th Ave. W.	Edmonds	WA	98020	does not provide
Phar.CF00005113	WA	QFC Pharmacy #856	926 164th St. SE	Mill Creek	WA	98012	does not provide
7485-42	WI	Aurora Pharmacy #1012	5900 S. Lake Dr.	Cudahy	WI	53110	none
8200-42	WI	Walgreens Pharmacy #06885	300 State Highway 13	Wisconsin Dells	WI	53965	none

Special Site Permits

STLCOP Preceptor Listing

License Number	State Licensed	Last Name	First Name	Discipline?
LICENSED IN MISSOURI				
041558	MO	Allinson	Alice M.	none
043725	MO	Rone	Donald D.	none
045110	MO	Shaw	Wendy	none
2002029007	MO	Brooks	Bryan W.	none
2008028094	MO	Buchanan	Emily A	none
2008029248	MO	Hamlin	Franklin	none
2009016858	MO	Lucido	Anthony	none
2009020986	MO	Eldridge	Brandon G.	none
2011029640	MO	Tubbs	Ashley N.	none
2012020938	MO	Chilicoat	Ryan R.	none
2012022819	MO	Jandak	Daniel J.	none
2012024144	MO	Fienup	Madeline J.	none
2012025406	MO	Penny	Jan R.	none
2012025418	MO	Lotz	Tyson J.	none
2012027493	MO	Park	Kristina S.	none
2012042658	MO	Williams	David A.	none
2013020271	MO	Miller	Morgan M.	none
2013022765	MO	Flaim	Silvio E.	none
2013026480	MO	Madden	Patrick	none
2014028408	MO	Alvira	Edgardo	none
LICENSED OUTSIDE MISSOURI				
12519	AL	Britton	Redonda S.	AL does not provide discipline
57620	CA	Choi	Chris	none
60140	CA	Tran	Van Q.	none
PHA.0017170	CO	Thompson	Amiee L.	none
PS40082	FL	Bruno	Tara A.	none
PS25992	FL	Thomas	Kathleen P.	none
051-289415	IL	Baker	Rob C.	none
051-033521	IL	Bavda	Kijaykumar T.	none

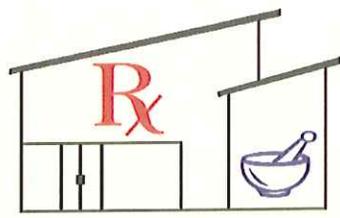
051-296696	IL	Bettinger	Danielle R.	none
051-287756	IL	Blue	Lori R.	none
051-290373	IL	Brown	Tara L.	none
051-291448	IL	Chung	Sean F.	none
051-296435	IL	Jochum	Elizabeth K.	none
051-286412	IL	Kamal	Majid	none
051-287503	IL	Kasting	Jill L.	none
051-033418	IL	Potts	Edwin R.	none
051-296301	IL	Reeder	Abigail L.	none
051-289327	IL	Runde	Robert	none
051-030583	IL	Schrey	Steve W.	none
26022529A	IN	Bryson	Emily L.	none
26024183A	IN	Hicks	Chris	none
1-13706	KS	Dunham	Jennifer L.	none
RPH.03223679	OH	Knight	Tricia	none
03323830	OH	Welsh	Terra C.	none
R5989	SD	Baye	Jordan F.	none
7990	TN	Daigle	Dwaine G.	none
39426	TX	Lake-Wallace	Sarah E.	none
27319	TX	Staggs	Grady Lynn	none
0202207348	VA	Prasad	Amrita	none
PH00039774	WA	Agnew	Robyn L.	none
PH60170851	WA	Harper	Melanie A.	none
PH60015291	WA	Hasslinger	Steven M.	none
PH00050018	WA	Yeung	Alfred Chi Hung	none
13131-40	WI	Dobbs	Diane M.	none
12593-40	WI	Knaus	Tammy	none
15479-40	WI	Lee	Melanie L.	none

SECTION D – OPEN

DISCUSSION AGENDA

#D1 **State FDA MOU Response**

- Solutions Pharmacy Response



Solutions Pharmacy

Compounding you can Trust

RECEIVED

MAY 04 2015

MISSOURI BOARD
OF PHARMACY

000658 MAY-4 15

April 28, 2015

Missouri State Board of Pharmacy:

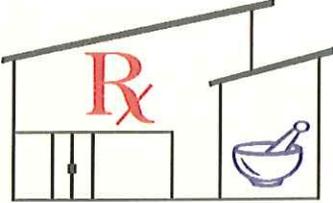
Solutions pharmacy desires to remain in good standing with each state board of pharmacy in the states we are licensed in. We want to inform you of a letter we sent to Grace Stuntz, Ms. Stuntz is Lamar Alexander's FDA representative on the Senate HELP Committee. Ms. Stuntz helped in creating the Drug Quality and Security Act (DQSA) and the Memorandum of Understanding (MOU) concerning compounding pharmacies. We posted the same letter on the FDA's general comment docket. Please read the attached copy of the letter we sent.

Sincerely,

Tom Beard, PharmD

Solutions Pharmacy

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Compounding you can Trust

As compounding pharmacy owners, we would like to reach out to the FDA in an attempt to point out some negative “unintended consequences” that would occur if the MOU was enforced in its current language. We are not stating that the Agency has intended, or is even aware of the many possible consequences. Several sections in the current language of the MOU and DQSA are potentially devastating to not only compounding pharmacies but the entire medical field, and potentially, to many U.S. citizens. Some sections are particularly alarming and seem to sway greatly from the original intents of Congress and the FDA since 1992. This bill attempts to make clear definitions and boundaries to identify who has jurisdiction and who is responsible for regulating certain medical entities.

In 1992, after the FDA released the Compounding Compliance Guidance (CPG), the Agency stated “*they did not intend to initiate enforcement actions against entities involved in traditional pharmacy compounding*”, but they did plan to do so in situations where a company’s activities resembled those of a drug manufacturer. In 1997 Congress added section 503a to the 1997 Food and Drug Modernization Act (FDAMA). On September 24th, 1997 Senator Kennedy said “*Congress’ intent in doing so was to bring the legal status of compounding in line with FDA’s longstanding enforcement policy of regulating **only drug manufacturing, not ordinary pharmacy compounding***”.

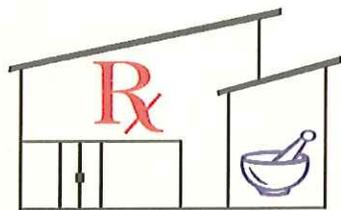
Since this time, the Agency has attempted to enforce this section of the FDAMA. Due to certain language in the original MOU that was found to be in violation of first amendment rights 2002 (Western States Medical Center vs Thompson), section 503a of the Act has remained dormant. The language RESTRICTED free speech provisions of the constitution regarding advertising provisions in the original MOU. This prompted a group of 7 compounding pharmacies to challenge the Agency’s unconstitutional restrictions. As the Agency knows, this particular group of compounding pharmacies were also prepared to challenge other language in the 1997 MOU, including the Agency’s attempt to restrict interstate prescription dispensing to a maximum of 5%-20%. The Supreme Court’s 9th District concluded that the language in the bill that was found to be in violation of 1st amendment rights, could not be severed from the rest of the MOU, therefore voiding the entire bill. We, as compounding pharmacy owners, ultimately wish the **Agency would use compounding pharmacies as a resource**, in the attempt to formulate practical legislation that would help ensure patient safety and not jeopardize patients’ access to what they and their physicians feel is the best CHOICE for medical treatment.

Compounding pharmacies dispense millions of patient specific prescriptions annually. The estimated 7,500 compounding pharmacies around the nation generate over 200 Billion dollars a year. As compounders, we feel that in many cases Americans are not aware of the crucial role compounding pharmacies play in the medical treatment. We feel it is necessary to inform the Agency of the massive amounts of patients, physicians, and the estimated revenue generated in order for them to understand the importance of getting the DQSA and MOU language changed to avoid lawsuits like those of 1997. We would also like to point out similar language that is possibly discriminatory and restrictive to the American people and the compounding industry in general. We will try to help the Agency better understand the reasons that compounding pharmacies, patients, and physicians are extremely concerned with the current DQSA and the MOU.

First, we feel that restricting the number of out of state prescriptions in no way improves overall patient safety and would negatively affect patient access to much needed medications. Compounding pharmacies are often licensed in several states, following all respective state boards, policies and procedures, as well as complying with USP 797. This shows an obvious need and desire for compounded medications that are not available in every state at every facility. If the facility is licensed in the state they are shipping to, following guidelines, and dispensing patient specific prescriptions, then there should be no reason to restrict interstate commerce. Any capped percentage placed on interstate distribution would be an arbitrary number.

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The FDA has often associated compounding pharmacies as facilities that *dispense* patient specific prescriptions. Both Congress and the FDA associate *distributing* with manufacturing and *dispensing* with “traditional compounding pharmacies” (2013 House Committee on Energy and Commerce Report: “The FDA’s Oversight of NECC and Ameridose: A History of Missed Opportunities?”)

<http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20130416Meningitis.pdf>
f. The FDA should be aware that it is unreasonable to ask the state boards to keep up with the numbers of all interstate prescriptions dispensed per each pharmacy in addition to every unit dispensed. How would a physician go about prescribing compounded medications if the facility they need and trust is located outside of their state? The physician would be forced to call the facility in order to get a projected percentage of the day’s out of state prescriptions and the estimated number of patients they might be able to fill for each physician. This process would be a waste of time for both physicians and pharmacists. If these issues are not addressed, nothing will be done in regards to making boundaries that are easily identifiable for the state boards or the Agency, and would make it more confusing in determining who has regulatory power and responsibility over each facility.

Secondly, office use compounding, in states that allow it, has become relied on by many health care professionals and patients and is necessary in many cases for the proper timely issuance of patient care. This was made very clear when 21 of the biggest medical organizations in the United States sent Congress a request to fix the language impeding office use in the current DQSA in November 2014.

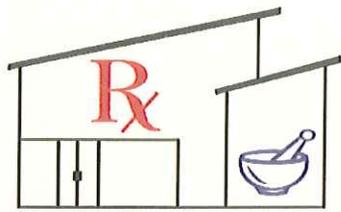
[http://c.ymcdn.com/sites/www.iacprx.org/resource/resmgr/DQSA/Coalition Letter to Congress.pdf](http://c.ymcdn.com/sites/www.iacprx.org/resource/resmgr/DQSA/Coalition%20Letter%20to%20Congress.pdf)

We are not aware of any response by the Agency or Congress in trying to address this problem that has done nothing to improve patient care and everything to restrict professional and patient access. In 2013, the DEA started enforcing a 1971 law relating to the “constructive transfer” of compounded medications. Compounding pharmacies have been forced to comply with dispensing sterile prescriptions to the patient or patient’s agent. Before this law was enforced after lying “dormant” for 40 years, compounding pharmacies dispensed the prescription to the prescribing practitioner’s office upon receipt of a valid prescription. This seems to be safer since the practitioner is trained in handling sterile medications. Many physicians were given permission by their patients, or were asked by their patients if they would become their “agent”, so that normal procedures could be followed. Many of these physicians and facilities were initially charged with some infraction of the law, but to our knowledge none of them have been convicted, and in most cases the charges have been dropped. However, this problem still remains. The DEA gave a verbal statement saying they intended to change the old law and definition of “constructive transfer” to include delivery to the patient, patient’s agent, or to the prescribing physician upon a valid prescription in instances where the specific medication was typically administered by the physician in the office. Rep Blackburn (TN) constructed legislation that would change this definition in 2014, but the bill has yet to be legally passed and enforced.

Finally, we would like to comment on the Agency's notion that compounding pharmacies could convert to a 503b outsourcing facility in order to solve any of these problems. Since 503b outsourcing facilities can only make products that appear on the FDA drug shortage list, this is not an option for compounders. This may help increase access to manufactured products, but would leave patients who CHOOSE compounded products without access to their medication. Compounding pharmacies believe in the patient/physician/pharmacist triad and would lose this important relationship if they were to try to convert to an outsourcing facility. The pure logistics of the large amount of money, building space, etc. makes it impractical to think compounding pharmacies around the nation could convert to a “mini manufacturer.” We are compounders, not manufacturers, and any “choice” that would make us discontinue compounding the medications our physicians and patients depend on is not a solution. Being a licensed FDA outsourcing facility that follows cGMP’s, has not been proven in anyway to be a safer overall practice than compounding pharmacies that follow USP 795 and 797.

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We have attempted to give the FDA a better understanding of the issues we see as potential blockades. These issues are key in getting resolved if the Agency hopes to truly improve patient care and to make clearer boundaries between that of a compounding pharmacy and a manufacturer. We would like the chance of working hand in hand with the Agency to help or advise them in changing the current wording of the DQSA and the MOU. If it is the goal of the Agency to implement section 503a of the FDAMA and to do so in a way that doesn't restrict or negatively affect patients, then we ask that they would consider the focal points we have tried to point out in the current format of the DQSA and the MOU.

Professionally Yours, Solutions Pharmacy

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SECTION E – OPEN

THERE ARE NO ITEMS FOR THIS SECTION