

## WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

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IN THE MATTER OF DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MAIN STREET FAMILY PHARMACY,	:	
RESPONDENT.	:	<b>0002599</b>

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Division of Legal Services and Compliance<sup>1</sup> Case No. 13 PHM 029

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Main Street Family Pharmacy  
126 East Main Street.  
Newbern, TN 38059

Wisconsin Pharmacy Examining Board  
P.O. Box 8935  
Madison, WI 53708-8935

Division of Legal Services and Compliance  
Department of Safety and Professional Services  
P.O. Box 8935  
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent, Main Street Family Pharmacy, is licensed in the State of Wisconsin as a pharmacy, having license number 587-43, first issued on August 19, 2010 and current through May 31, 2014. Main Street Family Pharmacy's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 126 East Main Street, Newbern, Tennessee 38059.

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<sup>1</sup> The Division of Legal Services and Compliance was formerly known as the Division of Enforcement.

2. The Tennessee State Board of Pharmacy disciplined Respondent when, on December 6, 2011, Board investigators conducted an inspection of Respondent's facility and observed the following:

- a. The condition of the laminar flow hood at Respondent's facility was not compliant with Tennessee State Board of Pharmacy regulations;
- b. Eighty-nine outdated or deteriorated medications were found on the pharmacy shelves;
- c. Twenty of the outdated or deteriorated medications were recently used in drug compounding;
- d. Respondent's facility had shipped eleven (11) compounded prescriptions directly to physicians' offices for use; however, none of those prescriptions were patient-specific as require by Board rules; and
- e. A nurse had been working as a pharmacy technician in Respondent's facility without proper registration for four (4) years and three (3) months.

3. On May 17, 2012, the Tennessee State Board of Pharmacy issued a letter of warning to Respondent's pharmacist-in-charge ("PIC") and assessed civil penalties in the amount of \$5,100.00 against Respondent's PIC.

4. On November 19, 2012 the Tennessee State Board of Pharmacy investigators conducted an on-site visit of Respondent pharmacy. Investigators discovered 109 medications on the shelves that were out-of-date. Further, investigators found eleven (11) prescriptions dispensed by Respondent that were not written on tamper-resistant paper, and also discovered eight (8) e-mailed, unsigned prescriptions that were dispensed by Respondent. The Division of Health Related Boards of the Tennessee Department of Health commenced disciplinary proceedings against Respondent.

5. On or about February 21, 2013, Respondent entered into a Consent Order with the Tennessee State Board of Pharmacy. Effective March 13, 2013 the Tennessee State Board of Pharmacy placed Respondent's Tennessee pharmacy license (Tennessee pharmacy license no. 895) and Respondent's Tennessee wholesaler/distributor license (Tennessee manufacture/wholesaler/distributor license no. 3190) on probation for a period of three years. The Tennessee State Board of Pharmacy assessed civil penalties of \$12,800.00 against each license held by the Respondent, totaling \$25,600.00.

6. A true and correct copy of the Tennessee State Board of Pharmacy Consent Order is attached to this document as Exhibit A. Exhibit A is incorporated into this document by reference.

7. Respondent neither admits nor denies the allegations but has elected to resolve this matter through negotiation. Respondent concedes that the facts set forth above are sufficient to justify the Conclusions of Law and Order below.

8. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

### CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10, and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Main Street Family Pharmacy engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17) by being subject to disciplinary action by another state licensing authority.

3. As a result of the above violations, Main Street Family Pharmacy is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b).

### ORDER

1. The attached Stipulation is accepted.

2. The Board accepts the VOLUNTARY SURRENDER of the pharmacy license issued to Respondent Main Street Family Pharmacy (license no. 587-43).

3. Respondent may petition the Board for reinstatement, however, the Board retains sole discretion of whether or not to grant Respondent a pharmacy license in the future and to impose terms, conditions or limitations as the Board deems necessary to avoid unacceptable risk of harm to health care consumers or the general public.

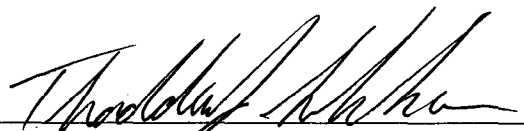
4. Respondent shall, no later than ten days after the date of this Order, surrender any and all indicia of licensure to the Department Monitor at the address below:

Department Monitor  
Division of Legal Services and Compliance  
Department of Safety and Professional Services  
P.O. Box 8935, Madison, WI 53708-8935  
Telephone (608) 267-3817; Fax (608) 266-2264  
DSPSMonitoring@wisconsin.gov

5. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:

  
A Member of the Board

9/11/13  
Date

BEFORE THE TENNESSEE STATE BOARD OF PHARMACY

IN THE MATTER OF: )

MAIN STREET FAMILY PHARMACY, LLC )

LICENSES 3190 (M/W/D), 895 (PHARMACY) ) Case No. L12-PHR-RBS-2013000051

126 EAST MAIN STREET )

NEWBERN, TN 38059 )

CONSENT ORDER

The Division of Health Related Boards of the Tennessee Department of Health ("State"), by and through the Office of General Counsel, and Respondent, Main Street Family Pharmacy, LLC ("Respondent"), respectfully move the Tennessee Board of Pharmacy ("Board") for approval of this Consent Order affecting Respondent's pharmacy license in the State of Tennessee.

I. Authority and Jurisdiction

The Board regulates and supervises pharmacies, pharmacists, pharmacy technicians, and pharmaceutical manufacturers, wholesalers, and distributors licensed to practice pursuant to the Tennessee Pharmacy Practice Act ("Practice Act"), Tennessee Code Annotated Section (Tenn. Code Ann. § 63-10-101, *et seq.*, including the discipline of licensees, as well as those who are required to be licensed, who violate the Practice Act and the Rules promulgated by the Board. Official Compilation of Rules and Regulations of the State of Tennessee ("Tenn. Comp. R. & Regs.") 1140-01-01, *et seq.* The Board enforces the Practice Act to promote and protect the health, safety and welfare of the public; accordingly, it is the policy of the Board to require strict compliance with the law and to apply the law to preserve the quality of pharmacy care provided in Tennessee.

II. Stipulations of Fact

1. At all times relevant hereto, Respondent was located at 126 East Main Street, Newbern.

Exhibit A

Tennessee, 38059.

2. On November 11, 1985, the Board granted Respondent pharmacy license number 895, permitting it to operate as a pharmacy in Tennessee.
3. On February 8, 2010, the Board granted Respondent manufacturer/wholesaler/distributor license number 3180, permitting it to operate as a manufacturer, wholesaler or distributor in the state of Tennessee.
4. On December 6, 2011 Board investigators conducted an inspection of Respondent's facility and observed the following violations of Tennessee pharmacy laws:
  - (a) The condition of the laminar flow hood at Respondent's facility was not compliant with Board regulations;
  - (b) 89 outdated or deteriorated medications were found on the pharmacy shelves;
  - (c) 20 of these outdated or deteriorated medications were used in drug compounding;
  - (d) Respondent's facility had shipped 11 compounded prescriptions directly to physicians' offices for use; however, none of those prescriptions were patient-specific as required by board rules; and
  - (e) A nurse had been working as a pharmacy technician in Respondent's facility without proper registration for 4 years and 3 months.
5. On May 17, 2012, facts concerning the above-referenced violations were presented to the Board. The Board approved the recommendation that Respondent's pharmacist-in-charge ("PIC") be assessed civil penalties for the violation pertaining to the unregistered pharmacy technician, and the Board voted to issue a letter of warning to Respondent's PIC for the above violations pertaining to compounding and the condition of the laminar flow hood.

6. Respondent's PIC thereafter entered into a consent order with the Board for the payment of a \$5,100.00 civil penalty for the unregistered technician. This order was ratified by the Board on July 27, 2012.
7. On November 19, 2012, Board investigators conducted an on-site visit of Respondent to confirm Respondent's compliance with sterile and non-sterile compounding statutes and rules.
8. During this inspection, Board investigators discovered 109 medications on the shelves that were out-of-date or deteriorated.
9. Of the 109 out-of-date or deteriorated medications, Board investigators observed that 107 were compounded drugs or drug powder materials. Of these, eighteen (18) vials of estradiol pellets were out-of-date or deteriorated, fifty-six (56) powder and/or cream mixtures were out-of-date or deteriorated, and six (6) powder and/or cream mixtures had no expiration date, lot, or batch numbers indicated on their containers. In addition, nineteen (19) bottles of out-of-date or deteriorated medication were found in the facility's refrigerator and freezer and eight (8) out-of-date or deteriorated vials of an injectable compound, Methione/Inositol/Choline B Complex with Lidocaine, were found later during this inspection.
10. Board investigators found eleven (11) prescriptions dispensed by Respondent that were not written on tamper-resistant paper, and also discovered eight (8) e-mailed, unsigned prescriptions which were dispensed by Respondent.
11. Tenn. Comp. R & Regs. 1140-09-.05(7) requires licensed manufacturers to "establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices..."

12. Tenn. Comp. R & Regs. 1140-09-.05(7)(d) states that licensed manufacturers must establish, maintain, and adhere to:

"A procedure to ensure that any outdated prescription drugs and devices shall be segregated from other prescription drugs and devices and either returned to the manufacturer or wholesaler or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of outdated prescription drugs and devices."
13. Tenn. Comp. R & Regs. 1140-03-.03(1) requires that all medical and prescription orders be signed by the prescriber.
14. Tenn. Comp. R & Regs. 1140-03-.04(2)(2)(iv) requires any electronic prescription order to have the "prescribing practitioner's electronic signature or other secure method of validation."
15. Tenn. Code Ann. § 53-10-401(a) requires that "[all] prescriptions written or printed by practitioners authorized to write prescriptions in this state [be] written on tamper-resistant prescription paper...".
16. Tenn. Comp. R & Regs. No. 1140-09-.05(9) requires licensed manufacturers to "operate in compliance with federal, state, and local laws and regulations."
17. Tenn. Comp. R & Regs. No. 1140-01-.02 provides that "[any] person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-505(6)."

### III. Stipulated Grounds for Discipline

18. The State of Tennessee Board of Pharmacy has the authority to revoke, suspend, or impose other lawful disciplinary action, including a civil penalty for any violation of any laws relating to drugs or to the practice of pharmacy and/or the Board's rules pursuant to



Tenn. Code Ann. §63-10-305, and Tenn. Comp. R. & Regs. 1140-1-.08 [CIVIL PENALTIES].

19. The Stipulations of Fact are sufficient to establish that Respondent has violated the following statutes or rules which are part of the Act, Tenn. Code Ann. § 63-10-101, *et seq.*, Tenn. Comp. R. & Regs., 1140-01-.01 *et seq.*, for which disciplinary action by the Board is authorized.

20. The facts stipulated in paragraphs 8 and 9 constitute grounds for which the Board may discipline a Respondent's license to operate a manufacturer/wholesaler/distributor pursuant to the following Tenn. Comp. R. & Regs. 1140-09-.05 [MINIMUM REQUIREMENTS FOR OPERATION] which states, in part:

(7)(d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.

21. The facts stipulated in paragraph 10 constitute grounds for which the Board may discipline a Respondent's license to operate a pharmacy pursuant to the following Tenn. Comp. R. & Regs. 1140-03-.03 [MEDICAL AND PRESCRIPTION ORDERS] which states, in part:

(1) To the extent that a medical order contains an order for the compounding, dispensing or administration of a prescription drug or device or related material, the medical order shall be treated as a prescription order. Written medical and prescription orders must be signed by the prescriber. Verbal medical and prescription orders must be immediately reduced to writing (by hand or other means), dated and initialed by the authorized individual accepting the medical and prescription orders.

22. The facts stipulated in paragraph 10 constitute grounds for which the Board may discipline a Respondent's license to operate a pharmacy pursuant to the following Tenn.

Comp. R. & Regs. 1140-03-.04 [FACISIMILE OR ELECTRONIC MEDICAL AND PRESCRIPTION ORDERS] which states, in part:

(a) Prescription or medical orders transmitted electronically shall meet the following criteria:

....

2. The transmission shall include:

- (i) The telephone number of the authorized prescriber to allow verbal confirmation of the validity and accuracy of the order;
- (ii) The correct time and date of the transmission;
- (iii) The name of the pharmacy to which the order is being transmitted; and
- (iv) The prescribing practitioner's electronic signature or other secure method of validation. "Electronic Signature" is defined as the process that secures the user authentication (proof of claimed identity, such as by biometrics, fingerprints, retinal scans, hand written signature verification, etc.) at the time the signature is generated and creates the logical manifestation of a signature.

23. The facts stipulated in paragraph 10 constitute grounds for which the Board may discipline a Respondent's license to operate a pharmacy pursuant to Tenn. Code Ann. § 53-10-401(a) [TAMPER PROOF PRESCRIPTIONS] which states:

(a) All prescriptions written or printed by practitioners authorized to write prescriptions in this state shall be written on tamper-resistant prescription paper that meets the current centers for Medicare and Medicaid services guidance to state Medicaid directors regarding § 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, P.L. 110-28, and meets or exceeds specific TennCare requirements for tamper-resistant prescription paper.

24. The facts stipulated in paragraphs 7 through 17 constitute grounds for which the Board may discipline a Respondent's license to operate a manufacturer/wholesaler/distributor pursuant to the following Tenn. Comp. R. & Regs. 1140-09-.05 [MINIMUM REQUIREMENTS FOR OPERATION] which states, in part:

(9) Compliance with federal, state, and local law. Manufacturers and wholesalers shall operate in compliance with applicable federal, state, and local laws and regulations.

25. The facts stipulated in paragraphs 7 through 17 constitute grounds for which the Board may discipline a Respondent's license to operate a pharmacy and a

manufacturer/wholesaler/distributor pursuant to the following Tenn. Comp. R. & Regs. 1140-01-.02 [VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT] which states:

Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-505(6).

26. The facts stipulated in paragraphs 7 through 17 constitute grounds for which the Board may discipline a Respondent's license to operate a pharmacy and a manufacturer/wholesaler/distributor pursuant to Tenn. Code Ann. §§ 63-10-305(4), (5), and (8)

- (4) engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of this chapter or any other laws of the state or of the United States relating to drugs or to the practice of pharmacy;
- (5) being guilty of dishonorable, immoral, unethical or unprofessional conduct; [and]
- (8) failing to comply with duly promulgated rules of the board.

#### IV. Stipulated Disposition

27. Without admitting to the truth of the allegations herein or to any alleged failure to comply with a lawful order or duly promulgated rule in violation(s) of Tenn. Code Ann. § 63-10-305(8) and for the purpose of avoiding further administrative actions with respect to this cause, Respondent agrees to the following:

- (a) The Tennessee pharmacy license of Main Street Family Pharmacy, LLC, license number 895, is hereby placed on PROBATION for a period of three (3) years, effective the date of entry of this Consent Order.
- (b) The Tennessee manufacturer/wholesaler/distributor license of Main Street Family Pharmacy, LLC, license number 3190, is hereby placed on PROBATION for a

period of three (3) years, effective from the date of entry of this Consent Order.

- (c) Pursuant to TENN. CODE ANN. § 63-10-307, Respondent shall undergo an inspection by the Tennessee Board of Pharmacy three times during the period of eighteen (18) months subsequent to the date of entry of this Consent Order. This inspection shall occur at least once every nine months.
- (d) Respondent shall pay civil penalties of twelve thousand, eight hundred dollars (\$12,800.00) assessed against each license held by Respondent, for a total civil penalty payment of twenty-five thousand six hundred dollars (\$25,600).
- (e) At the expiration of the three (3) year probationary period, Respondent shall become eligible to petition the Tennessee Board of Pharmacy for an "Order of Compliance" lifting the restrictions imposed by this Consent Order. As part of his petition for an "Order of Compliance," Respondent shall appear personally before the Tennessee Board of Pharmacy.
- (f) Respondent understands that this is a formal disciplinary action and will be reported to the Health Integrity and Protection Data Bank (H.I.P.D.B.) and/or similar agency.
- (g) Any and all costs shall be paid in full within ninety (90) days from the issuance of the Assessment of Costs. Payment shall be made by certified check, cashier's check, or money order, payable to the State of Tennessee, Department of Health. Any and all payments shall be forwarded to the Disciplinary Coordinator, The Division of Health Related Boards, Tennessee Department of Health, Heritage Place Metro Center, 227 French Landing, Suite 201 Nashville, Tennessee 37243. A notation shall be placed on said money order or such check that it is payable for the Costs of Main Street Family Pharmacy, LLC. Case No. 2013000051.

## V. Notice

28. The Respondent, by its signature to this Consent Order, waives the right to a contested case hearing and any and all rights to judicial review in this matter. Respondent agrees that presentation to and consideration of this Consent Order by the Board for ratification and all matters divulged during that process shall not constitute unfair disclosure such that the Board or any of its members shall be prejudiced to the extent that requires their disqualification from hearing this matter should this Order not be ratified. Likewise, all matters, admissions and statements disclosed or exchanged during the attempted ratification process shall not be used against the Respondent in any subsequent proceeding unless independently entered into evidence or introduced as admissions.
29. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of or to challenge or contest the validity of this Consent Order. Respondent understands that by signing this Consent Order, Respondent is allowing the Board to issue its order without further process. In the event that the Board rejects this Consent Order for any reason, it will be of no force or effect for either party.
30. Should this Consent Order not be accepted by the Board, it is agreed that the presentation and consideration of this Consent Order shall not unfairly or illegally prejudice the Board or any of its members from further participation in or resolution of these proceedings, including a formal disciplinary hearing.
31. Furthermore, Respondent acknowledges the understanding that it has a right to a hearing under the provisions of the Uniform Administrative Procedures Act, Tenn. Code Ann. Title 4, Chapter 5, but that they hereby waive that right in order to enter into this proposed Consent Order.
32. A violation of this Order shall constitute a separate violation of the Pharmacy Practice

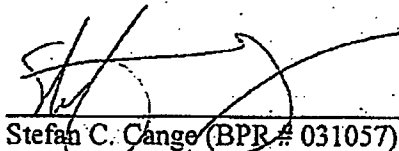
Act, TENN. CODE ANN. § 63-10-305(8), and constitutes grounds for further disciplinary action by the Board.

**APPROVED FOR ENTRY:**



Main Street Family Pharmacy, LLC  
Pharmacy License No. 895  
Manufacturer/Wholesaler/Distributor License No. 3190  
Respondent

2-21-13  
DATE



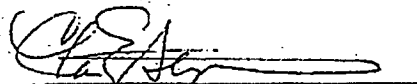
Stefan C. Cange (BPR # 031057)  
Assistant General Counsel  
Tennessee Department of Health  
Office of General Counsel  
220 Athens Way, Suite 210  
Nashville, Tennessee 37243  
(615) 741-1611

3/13/13  
DATE

**Approval by the Board**

Upon the agreement of the parties and the record as a whole, this **CONSENT ORDER** was approved as a **FINAL ORDER** by a majority of a quorum of the Tennessee Board of Pharmacy at a public meeting of the Board and signed this 13<sup>th</sup> day of MARCH, 2013.

ACCORDINGLY, IT IS ORDERED that the agreements of the parties will, and hereby do, become the Final Order of the Board.

  
Chairperson/Acting Chairperson  
Tennessee Board of Pharmacy