

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	CASE NO. 2013-80
Nonresident Pharmacy License of	)	
<b>MAIN STREET PHARMACY,</b>	)	<b>NOTICE OF HEARING AND</b>
License No. 3941	)	<b>STATEMENT OF CHARGES</b>
Respondent.	)	

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**COMES NOW** the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges against Main Street Family Pharmacy, 126 East Main St., Newbern, Tennessee 38059, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent's Iowa nonresident pharmacy license number 3941 is currently active and expires on December 31, 2013.

**A. TIME, PLACE, AND NATURE OF HEARING**

Hearing. A disciplinary contested case hearing shall be held on November 5, 2013, before the Board. The hearing shall be held during the afternoon session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8<sup>th</sup> Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 Iowa Administrative Code rule 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Cathelyn  
Assistant Attorney General  
Iowa Attorney General's Office  
2<sup>nd</sup> Floor, Hoover State Office Building  
Des Moines, Iowa 50319

Ms. Cathelyn can also be reached by phone at (515) 281-6690 or by e-mail at [laura.cathelyn@iowa.gov](mailto:laura.cathelyn@iowa.gov).

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case.

## **B. LEGAL AUTHORITY AND JURISDICTION**

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C (2013) and under 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

## **C. CHARGES**

### **Count I**

#### **FAILURE TO COMPLY WITH LAWS AND RULES OF THE HOME STATE**

Respondent is charged with failing to comply with the pharmacy laws and rules of Tennessee in violation of Iowa Code section 155A.13A(3) and 657 Iowa Administrative Code rules 8.3(1), 19.10 and 36.1(4)(*ad*).

### **Count II**

#### **FAILURE TO REPORT DISCIPLINARY ACTION IN OTHER JURISDICTIONS**

Respondent is charged with failing to report disciplinary action in other jurisdictions in violation of Iowa Code section 155A.13A(3) and 657 Iowa Administrative Code rules 19.10 and 36.1(4)(*k*).

## **D. FACTUAL CIRCUMSTANCES**

1. Respondent holds Iowa nonresident pharmacy license number 3941, which is currently active and expires on December 31, 2013.
2. On March 13, 2013, the Tennessee Board of Pharmacy approved a Consent Order for Respondent containing disciplinary action for several violations of Tennessee pharmacy and drug related rules and regulations, including those related to sterile compounding.

3. On April 30, 2013, the Board received correspondence from Respondent reporting the March 13, 2013 Consent Order.

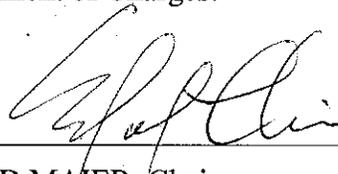
4. On May 28, 2013 the Respondent issued a voluntary, nationwide recall of all lots of sterile products compounded by the pharmacy with beyond-use dates of 11-20-13 or before. Five Iowa patients received compounded medications subject to the recall.

#### **E. SETTLEMENT**

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Cathelyn at (515) 281-6690.

#### **F. FINDING OF PROBABLE CAUSE**

On this 28th day of August, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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EDWARD MAIER, Chairperson  
Iowa Board of Pharmacy  
400 SW Eight Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Laura Cathelyn  
Assistant Attorney General  
Hoover Building, 2<sup>nd</sup> Floor  
Des Moines, IA 50319

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |   |   |
|---|---|
| <input type="checkbox"/> personal service                         | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number 91719999917031041368 <del>27</del> 34              | <input type="checkbox"/> other _____      |

on the 29<sup>th</sup> day of August, 2013.

I declare that the statements above are true to the best of my information, knowledge and belief.

  
Debbie S. Jorgenson

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	CASE NO. 2013-80
Nonresident Pharmacy License of	)	
	)	<b>SETTLEMENT AGREEMENT AND</b>
<b>MAIN STREET PHARMACY,</b>	)	<b>FINAL ORDER</b>
License No. 3941	)	
Respondent.	)	

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Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy (Board) and Main Street Pharmacy (Respondent) enter into the following Settlement Agreement to settle a disciplinary proceeding currently pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued Iowa nonresident pharmacy license number 3941, which is currently active and expires on December 31, 2013.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. A Statement of Charges was filed against Respondent on August 28, 2013.
4. On March 13, 2013, the Tennessee Board of Pharmacy approved a Consent Order for Respondent containing disciplinary action for several violations of Tennessee pharmacy and drug related rules and regulations, including those related to sterile compounding.
5. On April 30, 2013, the Board received correspondence from Respondent reporting the March 13, 2013 Consent Order.
6. On May 28, 2013, the Respondent issued a voluntary, nationwide recall of all lots of sterile products compounded by the pharmacy with beyond-use dates of 11-20-13 or before. Five Iowa patients received compounded medications subject to the recall.
7. Respondent has chosen not to contest the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for discipline.
8. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license to resolve this matter.
9. This voluntary surrender is considered a revocation under 657 Iowa Administrative Code rule 36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least three years from the date of Board approval of this Settlement Agreement. Reinstatement requests are governed by 657 Iowa Administrative Code rule 36.13.

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10. Respondent shall surrender its Iowa nonresident pharmacy license to the Board within ten (10) days of the Board's approval of this Settlement Agreement.
11. Respondent agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.
12. Should Respondent violate the terms of this Settlement Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.
13. This Settlement Agreement is the resolution of a contested case. By entering into this Settlement Agreement, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Final Order.
14. Respondent is freely and voluntarily entering into this Settlement Agreement.
15. The State's legal counsel may present this Settlement Agreement to the Board *ex parte*.
16. This Settlement Agreement is subject to approval by a majority of the full Board. If the Board fails to approve this Settlement Agreement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement, it shall be the full and final resolution of this matter.
17. This Settlement Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.
18. The Board's approval of this Settlement Agreement shall constitute a FINAL ORDER of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 27<sup>th</sup> day of September, 2013.

  
 Main Street Pharmacy    Main Street Family Pharmacy, LLC  
 Respondent  
 Christy R. Newbaker, PharmD

By this signature, Christy R. Newbaker, PharmD acknowledges s/he is the Owner / Pharmacist-In-Charge for Main Street Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Main Street Pharmacy.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 10th day of October, 2013.



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EDWARD MAIER, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Laura Cathelyn  
Assistant Attorney General  
Hoover Building, 2<sup>nd</sup> Floor  
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[laura.cathelyn@iowa.gov](mailto:laura.cathelyn@iowa.gov)

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