



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

*Lawrence J. Hogan, Jr. Governor – Boyd K. Rutherford, Lt. Governor – Dennis R. Schrader,
Secretary*

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Mitra Gavgani, Board President – Deena Speights-Napata, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7016 0750 0001 0747 6133

June 13, 2017

Cystic Fibrosis, Inc.
6931 Arlington Road
Bethesda, Maryland 20814
Attn: Patrick Baker, R.Ph.

Re: Permit No. PW0369
Case No. PI-17-184
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Pharmacist Baker:

On December 02, 2016, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Cystic Fibrosis, Inc. (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated that the Pharmacy was not compliant with laws relating to pharmacy technician registration.

Specifically, the Board inspector observed a pharmacy technician performing delegated pharmacy acts with an expired technician registration. The Board's records indicate that the technician's registration has since been renewed.

I. FINDINGS AND CONCLUSION

The Board adopts as findings the deficiencies as stated in the Board's inspection report, dated December 02, 2016, and attached hereto as Exhibit A.

Based upon deficiencies at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(b)(1) and 12-6B-01.

410-764-4755 • Fax 410-384-4128 ext. 500 • Toll Free 800-542-4964

DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258

Web Site: www.dhmh.maryland.gov/pharmacy

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and on the attached Exhibit A.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal disciplinary proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 *et seq.*, and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Vanessa Thomas Gray, Compliance Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, **no later than thirty (30) days of the date of this Notice.**

Please be advised that at the hearing the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both. If the Pharmacy requests a hearing but fail to appear, the Board may nevertheless hear

and determine the matter in its absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty **within thirty (30) days** of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, MD 21203-2051

NOTE: Please include the case number, PI-17-184, on your check or money order to insure proper assignment to your case.

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final formal action with respect to the December 02, 2016 inspection, and shall be a public document in accordance with the Maryland Public Information Act, General Provisions Article § 4-333.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Compliance Investigator, at 410/764-2493.

Sincerely,



Deena Speights-Napata
Executive Director

cc: Linda Bethman, AAG, Board Counsel

Attachment

12/5/2016 ee
mem OK Memo pending
case pending,



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
Lawrence J. Hagan, Jr., Governor - Boyd K. Rutherford, Lt. Governor -
Van T. Mitchell, Secretary

Exhibit

A

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2999
Mitra Gaugani, Board President - Deena Speights-Napata, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name Cystic Fibrosis Services Inc.
Street Address 6931 Arlington Road Suite #400 Bethesda MD 20814
Business Telephone Number 800 541-4959 Business Fax Number 800 263-0251
Inspection Date: 12/02/2016 Arrival Time: 8:15am Departure Time: 1pm
Type of Inspection: Annual Follow-up Previous Date: 09/15/2015
Name of Inspector: Nancy Richard Thomas Evans

1. GENERAL INFORMATION

Yes No The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.

Pharmacy Hours M-F: 8am - 7pm Sat: Closed Sun: Closed

Yes No All permits, licenses, and registrations are posted conspicuously. HO § 12-311, HO § 12-408(b) and HO § 12-6B-08

PW0369

Maryland Pharmacy Permit Number PW0368 Expiration Date: 05/31/2018
CDS Registration Number N/A Expiration Date: N/A
DEA Registration Number N/A Expiration Date: N/A

Yes No The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

Yes No The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23

Yes No The pharmacy fills original prescriptions received via the internet.

Yes No The pharmacy fills original prescriptions via e-prescribing.

Yes No The pharmacist fills mail order prescriptions.

If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07

Comments: _____
Pharmacy receives e prescribing (sure script) but all prescriptions are dispensed in Frisco Texas.

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws
 Patrick Baker

| Pharmacist Employees | License # | Exp Date |
|----------------------|-----------|------------|
| Patrick Baker | 21666 | 03/31/2017 |
| Deborah P Hanson | 20937 | 07/31/2018 |
| Mahlet W Aklile | 22041 | 03/31/2017 |
| Roli Pessu | 23414 | 06/30/2017 |
| | | |
| | | |
| | | |
| | | |
| Doris Videla | T16016 | 08/31/2018 |
| Angela Taylor | T13143 | 11/30/2018 |
| Sataria Bey | T12468 | 09/30/2018 |
| Lisa Nanton | T02607 | 11/30/2017 |

| Registered Technicians | Registration # | Exp Date |
|-------------------------|----------------|------------|
| Parisia Geter | T04139 | 05/31/2018 |
| Jasmine A Johnson | T08594 | 05/31/2018 |
| Mia Garrett | T16041 | 08/31/2018 |
| Brayan Molina (working) | T09156 | 11/30/2018 |
| Shalia D Steele | T11467 | 12/31/2017 |
| Ashley A Williams | T08620 | 05/31/2018 |
| Tappi Small | T13135 | 02/28/2017 |
| Andrea D Smith | T07051 | 04/30/2017 |
| Louis Gray | T13066 | 07/31/2017 |
| Kantame L Landjerque | T03425 | 04/30/2018 |
| Rayonna Belle | T13316 | 10/31/2018 |
| Tylea N Pressley | T09193 | 02/28/2017 |
| Jimna Kou | T00582 | 08/31/2017 |
| Collins T Ngwa | T08180 | 02/28/2018 |
| Layna Stewman | T13140 | 02/28/2017 |
| Stacy N Cushnir | T01352 | 06/30/2018 |
| Akosua K Kumi | T13053 | 01/31/2017 |
| Tiese Alexander | T14080 | 11/30/2017 |
| Silvia Rivera | T13134 | 04/30/2017 |
| Tiffany N Tyler | T07920 | 11/30/2017 |

| Unlicensed Personnel (non-registered) | Title | Duties |
|---------------------------------------|-------|--------|
| See attached list of unlicensed | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

3. PERSONNEL TRAINING

Yes No N/A There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05

Yes No N/A All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

- Yes No N/A Maintaining records
- Yes No N/A Patient confidentiality
- Yes No N/A Sanitation, hygiene, infection control
- Yes No N/A Biohazard precautions
- Yes No N/A Patient safety and medication errors COMAR 10.34.26.03

Comments: _____
None. _____

- Yes No The pharmacy wholesale distributes to another pharmacy (COMAR 10.34.37)
- Yes No The pharmacy wholesale distributes to a wholesale distributor (COMAR 10.34.37)
- Yes No N/A The wholesale distribution business exceeds 5% of the pharmacy annual sales (COMAR 10.34.37)

Comments: _____
Does not Wholesale Distribute to another Pharmacy or to a Wholesale Distributor per Pharmacist Patrick Baker. _____

4. SECURITY COMAR 10.34.05

Yes No The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

Comments: _____
N/A This is not a dispensing Pharmacy. _____

Yes No The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Yes No The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)

Comments: _____
This is not a dispensing Pharmacy.

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

- Yes No Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
- Yes No The pharmacy provides a compounding service (non-sterile procedures).
Yes No If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02
- Yes No The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
- Yes No The pharmacy has hot and cold running water.
- Yes No The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
- Yes No The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B

Temperature N/A

Yes No The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature 72F

Yes No N/A If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.

Temperature N/A

Yes No The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)

Yes No The pharmacy has online resources. HO § 12-403(b)(15)

Comments: _____
No prescriptions are filled at this location.

6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505

- Yes No The name and address of the pharmacy; HG § 21-221(a)(1)
- Yes No The serial number of the prescription; HG § 21-221(a)(2)
- Yes No The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3)
- Yes No The name of the prescriber; HG § 21-221(a)(4)
- Yes No The name of the patient; HG § 21-221(a)(5)(i)
- Yes No The name and strength of the drug or devices; HO § 12-505(c)
- Yes No The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(ii)
- Yes No The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)
- Yes No The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)
- Yes No The expiration date is indicated; HO § 12-505(b)(2)

Yes No The pharmacist and data-entry technician initials are on prescriptions. COMAR 10.34.08.01

Yes No Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments:

No prescriptions are filled at this location.

7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.02

Yes No The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

Yes No There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

Comments:

Preventing medication error training and QA is done through LTMP. (Learning and Talent Manage Portal)

Yes No All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)

Yes No The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

Comments:

Does not process, fill or store any controlled substances.

11. AUTOMATED MEDICATION SYSTEMS Yes No (if No, go to #12)

Yes No N/A The facility uses an automated device(s) as defined in COMAR 10.34.28.02.

Policies and procedures exist for (check all that apply): COMAR 10.34.28.04A

- | | | | | |
|------------------------------|-----------------------------|------------------------------|-------------------------------------|--|
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Operation of the system |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Training of personnel using the system |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Operations during system downtime |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Control of access to the device |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Accounting for medication added and removed from the system. |

Yes No N/A Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06

N/A

Adequate records are maintained for at least two years addressing the following (check all that apply).
COMAR 10.34.28.11

- | | | | | |
|------------------------------|-----------------------------|------------------------------|-------------------------------------|---|
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Maintenance records. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | System failure reports. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Accuracy audits. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Quality Assurance Reports. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Reports on system access and changes in access. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Training records. |

Yes No N/A Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B

Yes No N/A The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments:

No Automation Systems.

12. OUTSOURCING

Yes No (if No, go to #13)

Yes No N/A

The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02

Yes No N/A

The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02

Yes No N/A

The facility serves as a secondary pharmacy. COMAR 10.34.04.02

Yes No N/A

The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.

If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E

Comments:

No Outsourcing.

Yes No N/A

The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)

If the pharmacy outsources a prescription order:

Yes No N/A

The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D

Yes No N/A

Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06

Yes No N/A

Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

Yes No N/A

That the prescription order was prepared by a secondary pharmacy.

Yes No N/A

The name of the secondary pharmacy.

Yes No N/A

The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.

Yes No N/A

The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.

Yes No N/A

The date on which the prescription order was transmitted to the secondary pharmacy.

Yes No N/A

The date on which the medication was sent to the primary pharmacy.

Yes No N/A

The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F

Yes No N/A

The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes: COMAR 10.34.04.07 (Check all that apply)

- Yes No N/A That the prescription order was transmitted from another pharmacy.
- Yes No N/A The name and information identifying the specific location of the primary pharmacy.
- Yes No N/A The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- Yes No N/A The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- Yes No N/A The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
- Yes No N/A The date on which the prescription order was received at the secondary pharmacy.
- Yes No N/A The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

13. Recommended Best Practices

- Yes No A perpetual inventory is maintained for Schedule II controlled substances.
- Yes No There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- Yes No The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
- Yes No The pharmacy maintains records of all recalls. See www.recalls.gov

INSPECTOR'S COMMENTS:

Reviewed entire inspection report Pharmacist Patrick Baker. This is a Specialty Pharmacy for Walgreens and Cystic Fibrosis Foundation. Orders are processed at this location and filled at Walgreens in Frisco Texas. All prescriptions are electronic, verbal mailed or faxed. Very few Hard Copies. All prescriptions are electronically stored. Pharmacy is VIPP, URAC and ACHC accredited. Process's prescription orders for around 4,500 patients. Process's #400 prescriptions daily. Employee's are Insurance Verifiers, Patient Care Coordinators (licensed Techs) Technicians, Patient Financial Services, Pharmacist and Management. Uses Windshield for daily operational services and QA. Please send to Nancy Richard @ 410 384-4137 or email to Nancy.Richard@maryland.gov the procedure for Patients notification for reporting medication errors by 12/09/2016. Brayan Molina a technician license was non renewed as of 11/30/2016 when verified during the inspection. Was performing technician duties. Entering Prescriptions into Script Med Enterprise.

Inspector Signature

Nancy Richard *Pat Baker*

Pharmacist Name ((Print): Patrick Baker

Date: 12/02/2016

Signature:

PS RB

Received a copy of this inspection report:

PS RB

Date and Pharmacist Signature

FINAL 09/02/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: Cyclic Fibrosis Services Inc.
Permit#: PW0369
Date: 12/02/2016
Pharmacist Signature: Patrick Baker *P.B. Baker*

Rx#: _____ N/A
Date Filled: _____ N/A

| DRUG | NDC Number | ON HAND INVENTORY | PERPETUAL INVENTORY |
|------|------------|-------------------|---------------------|
| N/A | N/A | | |
| N/A | N/A | | |
| N/A | N/A | | |
| N/A | N/A | | |

COMMENTS:

No Controls.

SCHEDULE II AUDIT

Drug N/A
Date of last Inspection/Biennial N/A

| | | |
|-------------------------------------|---|----------------------|
| Amount at last inspection/biennial | 0 | (A) |
| Purchased since inspection/biennial | 0 | (B) |
| Total inventory | 0 | (C) = A + B |
| Quantity dispensed | 0 | (D) |
| Expected inventory | 0 | (E) = C - D |
| Quantity on Hand | 0 | (F) |
| Discrepancy | 0 | (G) = (F-E) or (E-F) |
| | | Excess Shortage |

INVOICE REVIEW

CII:

No Invoices.

CIII - CV:

No Invoices.

