

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

FILED	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	1/28/2015
File #	2015-00812

IN RE: PETITION FOR WAIVER
BAPTIST HOSPITAL, INC.,

PETITIONER.

VW 2014-419

FINAL ORDER GRANTING WAIVER FROM REQUIREMENTS OF RULE 61N-1.023(2), FLORIDA ADMINISTRATIVE CODE

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department"), issues this final order granting the Petition for Waiver, in accordance with Section 120.542, Florida Statutes (2014).

PRELIMINARY STATEMENT

On October 31, 2014, Petitioner, Baptist Hospital, Inc. (hereafter, "Baptist" or "Petitioner"), filed a petition for waiver of Rule 61N-1.023(2), Florida Administrative Code (hereafter, "F.A.C.") with the Department. Notice of the petition was published in the November 18, 2014, issue of the Florida Administrative Register, Volume 40, Number 224.

FINDINGS OF FACT

1. Petitioner is a 492-bed acute care hospital located at 1000 West Moreno Street, Pensacola, Florida 32501. Baptist is a wholly owned subsidiary of Baptist Health Care Corporation. Baptist is licensed by the Department as a restricted prescription drug distributor—health care entity, having been issued permit number 50:159. Petitioner also holds a license as a hospital and is registered with the Drug Enforcement Administration (hereafter, "DEA").

2. On or about August 22, 2014, the Department conducted a routine compliance inspection of Petitioner during which the Department asked questions about Baptist's delivery of medications to certain medical offices in which the physician is a full-time employee of a group practice that is a wholly owned subsidiary of either Baptist Hospital or Baptist Health Care Corporation (hereafter, "Physician Office Locations").

3. Baptist's pharmaceutical wholesaler is McKesson. The Physician Office Locations place prescription drug orders directly with McKesson or through Petitioner's inpatient pharmacy, which then forwards the order to McKesson.

4. The orders from the Physician Office Locations are placed under a separate McKesson account and are designated on the invoice as "Baptist Hospital, Inc./MG, Customer #0972041." Each invoice indicates the specific ordering physician's name along with the specific designation that it is under the Physician Office Locations' accounts. The orders are for a very limited quantity and for a limited drug formulary.

5. McKesson delivers the order to Petitioner, and Petitioner delivers the medications and the corresponding invoice to the Physician Office Locations. Petitioner maintains a copy of the invoice for audit purposes.

6. Petitioner does not touch the delivered prescription medication; Petitioner merely acts as a courier between McKesson and the Physician Office Locations.

7. Through this process, Petitioner delivers medications to approximately 28 Physician Office Locations.

8. Petitioner's parent company, Baptist Health Care Corporation, wholly owns and operates Petitioner as well as a sister entity of Petitioner, Baptist Health

Ventures, Inc. Therefore, both are commonly controlled by Baptist Health Care Corporation.

9. The 28 Physician Office Locations currently receiving prescription medications through Petitioner fall into one of two categories under Baptist Health Care Corporation: 1) The Physician Office Location is wholly owned and operated by Petitioner, Baptist Hospital, Inc.; or 2) the Physician Office Location is wholly owned and operated by its sister entity, Baptist Health Ventures, Inc.

10. Petitioner asserts that requiring the 28 Physician Office Locations to acquire pharmacy permits would create substantial hardship economically and legally, and would be unfair.

11. Petitioner asserts that the Department advised Petitioner that the type of pharmacy permit that Petitioner would need under the requirements of Rule 61N-1.023(2), F.A.C., is the Type B Modified Class II Institutional Pharmacy permit.

12. Petitioner requests that the waiver apply both retrospectively and prospectively for those Physician Office Locations under common ownership with Baptist Health Care Corporation as described herein. Petitioner asserts that it is adding new Physician Office Locations on a regular basis. The described processes for delivering prescription medication would remain unchanged for each subsequent Physician Office Location added.

13. Petitioner asserts that requesting the waiver is based on both principles of hardship and fairness. Petitioner argues that requiring Petitioner to obtain a Type B Modified Class II Institutional Pharmacy permit for 28 different locations would create a substantial hardship economically and legally. Petitioner further argues that applying for

these permits would incur a considerable amount of time, effort, and cost to apply for, collect detailed information about, pay for, and retain all information required for maintaining such permits as well as meeting all pharmacy committee and onsite pharmacy requirements for Type B Modified Class II Institutional Pharmacies listed in Rule 64B16-28.702, F.A.C.

14. As to fairness, Petitioner argues that under current law, physician offices are permitted to order and receive modest amounts of prescription medications directly from pharmaceutical distributors without a pharmacy permit; that Physician Office Locations are in fact physician offices ordering small amounts of medications that do not include controlled substances or expanded formularies; that the only difference is that Physician Office Locations' ordering is done through Petitioner's pharmacy wholesaler system and not directly with a pharmaceutical distributor; and that as such, it is unfair to require Physician Office Locations, which are obtaining the same quantity and limited types of medications as other physician offices, to apply for, pay for, and maintain such a permit simply because the medication is ordered through Petitioner's pharmacy wholesaler, McKesson.

15. Rule 61N- 1.023(2), F.A.C., provides:

(2) Restricted Rx Drug Distributor – Health Care Entity. This permit is required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in Section 499.012(1)(a)3., F.S.; or (2) members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under "common control" as defined in Section 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing

organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. This permit also authorizes a warehouse or purchasing depot of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with Section 240.241, F.S. All requirements of paragraph (6) of this rule related to the Restricted Rx Drug Distributor – Institutional Research permit must be complied with for transfers under this provision. [Emphasis added].

16. Petitioner requests a waiver from the requirements of the above-cited rule that each location to which Petitioner transfers prescription drugs have a pharmacy permit that authorizes the acquisition and possession of prescription drugs.

17. Petitioner asserts that the purposes of the underlying statute are to deter prescription drugs from leaving regulatory controls established in state law that serve to maintain the safety, integrity and efficacy of prescription drugs by requiring distributors to maintain proper documentation; ensure medications have not been adulterated; and guarantee that prescription medications have not been unlawfully introduced into the market.

18. Petitioner asserts that the purposes of the underlying statute would be satisfied since the Petitioner's processes requires each Physician Office Location to review the medication received with the invoice and promptly report any discrepancies, and that the inventory is also cross-referenced with Petitioner's invoice. Petitioner alleges that this protects the public by creating a double audit trail of the drugs thereby guarding against unlawful circulation of the drugs.

CONCLUSIONS OF LAW

19. The Department has jurisdiction to issue this final order pursuant to Section 120.542(8), Florida Statutes (2014).

20. Petitioner has standing to seek this Petition for Waiver.

21. Section 120.542(2), Florida Statutes (2014), provides:

(1) Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2), Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different

from the way it affects other similarly situated persons who are subject to the rule.

22. The Department has construed the language in Rule 61N-1.023(2), F.A.C., to prohibit the transfer of prescription drugs by a hospital or health care entity holding the restricted prescription drug distributor—health care entity permit, to facilities under common control that are not permitted with a pharmacy permit that allows them to acquire and possess prescription drugs. Section 499.005(21), Florida Statutes (2014), prohibits the wholesale distribution of a prescription drug that was purchased by a public or private hospital or other health care entity, or that was donated or supplied at a reduced rate to a charitable organization. Here, the statutory provision in Section 499.005(21), Florida Statutes (2014), is not implicated because Petitioner's transfers of the prescription drugs would be within its own commonly owned Physician Office Locations, and not outside to any other distributor that Petitioner might choose.

23. Section 120.542, Florida Statutes (2014), places the burden on Petitioner to demonstrate that the underlying purpose of the statute will be or has been achieved by some other means.

24. Petitioner has demonstrated that the purposes of the underlying statute, to protect the public health by ensuring that prescription drugs are safe, properly documented, and that the prescription drugs are only distributed to those persons who are lawfully able to possess them, are satisfied.

25. Petitioner has met the burden of demonstrating that substantial economic hardship would result if Rule 61N-1.023(2), F.A.C., was strictly applied to Petitioner,

such that each Physician Office Location would be required to obtain and maintain licensure under Chapter 465, Florida Statutes.

26. Petitioner has failed to meet the burden of demonstrating, in the alternative, that the literal application of the rule would affect Petitioner in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule. Physician's offices that are not wholly owned by licensed hospitals and/or the hospital's parent corporation are not similarly situated to the "Physician Office Locations" owned and operated by Petitioner.

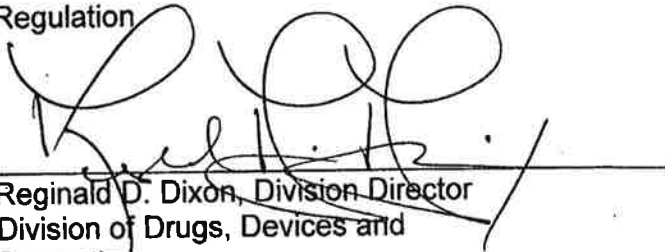
27. Granting the petition for waiver would not remove the safety provisions of the Rule and would sufficiently protect the public.

28. Based on the foregoing, Petitioner's request for a waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers are limited to those made to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs, is granted. Petitioner may transfer prescription drugs to the Physician Office Locations as described herein above.

29. This Order and the waiver granted herein operate prospectively from the date of filing.

Done and ordered this 27th day of January, 2015, at Tallahassee, Leon County,
Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation



BY:

Reginald D. Dixon, Division Director
Division of Drugs, Devices and
Cosmetics
1940 North Monroe Street, Suite 26A
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has
been furnished by U.S. mail to Jody E. Okrzesik, 171 "E" Street, Suite 320, Pensacola,
Florida 32501, this 28th day of January, 2015.

for: 
Agency Clerk

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

STATE OF FLORIDA
FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES, AND COSMETICS

FILED
Department of Business and Professional Regulation
Deputy Agency Clerk
CLERK Brandon Nichols
Date **10/31/2014**
File #

IN RE: PETITION FOR WAIVER
BAPTIST HOSPITAL, INC.

VW 2014-419

PETITION FOR WAIVER OF RULE 61N-1.023(2)

Petitioner, Baptist Hospital, Inc. ("Petitioner" or "Baptist Hospital"), pursuant to section 120.565 of Florida Statute and rule 28-104.002 of the Florida Administrative Code, petitions the Florida Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics Program ("Department") for a waiver from rule 61N-1.023(2) of the Florida Administrative Code ("Waiver"). In support of this Waiver, Petitioner states as follows:

1. Petitioner, Baptist Hospital, is a 492-bed acute care hospital located at 1000 West Moreno Street, Pensacola, Florida, 32501. It is a wholly owned subsidiary of Baptist Health Care Corporation. Petitioner is licensed by the Department as a Restricted Prescription Drug Distributor – Health Care Entity operating under permit number 50159. Petitioner is also licensed as a hospital by AHCA, as well as by the D.E.A. To the best knowledge of Petitioner, it has not been disciplined by the Department during its 63 years of operation.
2. For purposes of this Petition, all correspondence and communication should be provided to undersigned in-house counsel for Petitioner at the address, telephone number, and facsimile number provided below.
3. On August 22, 2014, Don Yerbey, Field Inspector for the Department, conducted a routine compliance inspection of Petitioner ("Inspection"). During the Inspection, Petitioner's pharmacists were questioned about its processes, including the Petitioner's delivery of medications to certain medical offices in which the physician is a full-time employee of a

RECEIVED

NOV 10 2014

DBPR Agency Clerk



RECEIVED

OCT 31 2014

Drugs, Devices and Cosmetics

group practice that is a wholly owned subsidiary of either Baptist Hospital or Baptist Health Care Corporation (“Physician Office Locations”).

4. After the Inspection, the Department requested that Petitioner’s representatives appear at the Department’s office in Tallahassee to further discuss and clarify Petitioner’s processes.
5. On September 4th, 2014 in Tallahassee, Petitioner’s representatives, David Gowarty, RPh., and Dave Crawford, RPh., met with the following Department representatives: Reginald Dixon, Director; Renee Ashbrook, Attorney, Chief of Compliance and Enforcement, and Don Yerbey, Field Inspector. Rule 61N-1.023(2) of the Florida Administrative Code was discussed that facilities receiving transfers of medications (such as the Physician Office Locations) under a Restricted Rx Drug Distributor license must be licensed with a “pharmacy permit that authorizes the acquisition and possession of prescription drugs.” The permit that would be required under this statute for the Physician Office Locations Offices would be a Type B Modified Class II Institutional Pharmacy.
6. In the meeting, Petitioner’s delivery process was further described as follows: Petitioner’s Pharmaceutical Wholesaler is McKesson. Physician Office Locations place prescription orders directly with McKesson or through Petitioner’s inpatient pharmacy, which then forwards the order to McKesson. The orders from the Physician Office Locations are placed under a separate McKesson account and are designated on the invoice as Baptist Hospital, Inc./MG, Customer #972041. Each invoice indicates the specific ordering physician’s name along with the specific designation that it is under the Physician Office Location accounts. The orders are for a very limited quantity and limited drug formulary. McKesson delivers the order to Petitioner, and Petitioner delivers the medications and the corresponding invoice to the Physician Office Locations. Petitioner retains a copy of the invoice for audit purposes. The delivered prescription medications are untouched by Petitioner; it simply acts as a courier between McKesson and the Physician. Through this process, the Petitioner delivers prescription drugs to approximately 28 Physician Office Locations.

7. Based on the rule and the information stated herein, Petitioner respectfully requests that this Waiver be granted to Petitioner.
8. Florida Administrative Code 61N-1.023 (2) outlines the permits and provisions applicable to Restricted Rx Drug Distributor – Health Care Entity. This provision states that a permit is required for a hospital or health care entity as defined in section 499.003(15) of Florida Statute “for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are under common control as provided in Section 499.012(1)(a)3., F.S.” It goes on to state that such transfers “are limited to a facility under common control . . . which must be licensed with a pharmacy permit that authorized the acquisition and possession of prescription drugs.” FLA. STAT. 499.003(15) (2010).
9. Pursuant to Florida Administrative Code 61N-1.023, Petitioner has and maintains a Restricted Rx. Drug Distributor – Health Care Entity permit. Petitioner has an unblemished history of substantial compliance with Florida laws governing prescription medications. Petitioner has fully cooperated with the Department and believes that it is in compliance with all Florida laws governing its operation, including those pertaining to its recordkeeping.
10. Petitioner’s parent company, Baptist Health Care Corporation, wholly owns and operates Petitioner as well as a sister entity of Petitioner, Baptist Health Ventures, Inc. Therefore, both are commonly controlled by Baptist Health Care Corporation.
11. The 28 Physician Office Locations currently receiving prescription medications through Petitioner falls into one of two categories under Baptist Health Care Corporation: a) the Physician Office Location is wholly owned and operated by Petitioner, Baptist Hospital, Inc. b) the Physician Office Location is wholly owned and operated by sister entity, Baptist Health Ventures, Inc. Therefore, all prescription medications being delivered to each Physician Office Location is a facility under the same common control.
12. A waiver or variance is appropriate where certain licensing requirements are too burdensome for an applicant. *Univ. of So. Fla ex. rel. Fla. Bd. of Regents v. Dep’t. of Children and*

Family Services, 787 So.2d 223, 224 (Fla. Dist. Ct. App., 2001). Moreover, section 120.542 (2) of the Florida Statutes provides that a state agency shall grant waivers of their own rules when a person subject to the rule demonstrates that he or she can achieve or has achieved the purpose of the underlying statute by other means and when application of the rule would “create a substantial hardship or would violate principles of fairness.” FLA. STAT. 120.542 (2) (2013). A substantial hardship is defined as “a demonstrated economic, technological, legal or other type of hardship to the person requesting the variance or waiver.” *Id.* The statute states that principles of fairness are violated when “the literal application of the rule affects a particular person in a manner significantly different from the way it affects other similarly situation persons who are subject to the rule.” *Id.*

13. Petitioner is requesting this Waiver based on both hardship and principles of fairness.

Requiring Petitioner (or each Physician Office Location) to obtain a Type B Modified Class II Institutional Pharmacy permit for 28 different locations would create a substantial hardship economically and legally. Applying for these permits would incur a considerable amount of time, effort and cost to apply for, collect detailed information about, pay for, and retain all information required for maintaining such permits as well as meeting all pharmacy committee and onsite pharmacist requirements for Type B Modified Class II Institutional Pharmacies listed in rule 64B16-28.702 of the Florida Administrative Code.

14. There is also a fairness aspect to this Waiver request. Under Florida law, physician offices are permitted to order and receive modest amounts of prescription medications directly from pharmaceutical distributors without a pharmacy permit. Physician Office Locations are in fact physician offices ordering small amounts of medications that do not include controlled substances or expanded formularies. The only difference is that the ordering is done through Petitioner’s Pharmacy Wholesaler system and not directly with a pharmaceutical distributor. As such, it is unfair to require Physician Office Locations, which are obtaining the same quantity and limited types of medications as other physician offices, to apply for, pay for, and

maintain such a permit simply because the medication is ordered through Petitioner's pharmacy wholesaler, McKesson. In fact, Petitioner's audit process is arguably more stringent than that of independent physicians who order medications directly from drug distributors because the invoicing and supply chain records is maintained not only by the Physician Office Location, but also by the Petitioner.

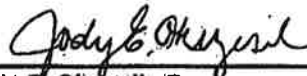
15. The purpose of the underlying statute is to deter prescription drugs from leaving the regulatory controls established in state law that serve to maintain the safety, integrity and efficacy of prescription drugs by requiring distributors to maintain proper documentation, ensure medications have not been adulterated, and guaranteeing that prescription medications are not unlawfully introduced into the market. *See, e.g., Bio-Med Plus, Inc. v. State, Dept. of Health*, 915 S.2d 669 (Fla. Dist. Ct. App., 2005).
16. Petitioner's processes meets the underlying purposes of the statute since Petitioner requires each Physician Office Location to review the medication received with the invoice and promptly report any discrepancies. This inventory is also cross referenced with Petitioner's invoice. This protects the public by creating a double audit trail of the drugs thereby guarding against unlawful circulation of the drugs.
17. The fact that Petitioner does not touch the drugs but is merely a courier for ordering the medications serves the statute's underlying purpose of ensuring medications are not adulterated prior to delivery. Furthermore, because the medications are delivered directly to Petitioner in sealed totes designated for each physicians' office as part of a large daily shipment, the medications are at less risk for being stored at improper temperatures while awaiting delivery to smaller physician offices. This more frequent delivery procedure ostensibly decreases the risk of inadvertent adulteration due to improper storage.
18. Petitioner requests this Waiver apply both retrospectively and prospectively for those Physician Office Locations that fall under common ownership with Baptist Health Care Corporation as described herein. Petitioner is adding new Physician Office Locations on a

regular basis. The described processes for delivering prescription medications would remain unchanged for each subsequent Physician Office Location added. All would be under common ownership of Petitioner or BHC. As such, the same criteria for this Waiver would apply to future Physician Office Locations.

19. For the reasons outlined above, the Department should grant Petitioner's request for a permanent Waiver of its requirement for each Physician Office Location to obtain a Type B Modified Class II Institutional Pharmacy permit since allowing such Waiver eliminates the hardship and unfairness of obtaining such permit, while still satisfying the underlying purpose of the rule.

WHEREFORE, Petitioner, Baptist Hospital, respectfully requests that pursuant to Section 120.565, the Department grant Petitioner's request for a waiver of any and all rules that the Department interprets as requiring Petitioner to obtain pharmacy licenses for Physician Office Locations that receives medications through Petitioner.

Respectfully Submitted,



Jody E. Okrzesik, Esq.
Florida Bar No. 0693091
Baptist Health Care Corporation
171 North "E" St., Suite 320
Pensacola, Florida 32501
Telephone: 850-469-7721
Facsimile: 850-434-4841
Email: jody.okrzesik@bhcpns.org

Cc: Joint Administrative Procedures Committee, Room 680, Pepper Building, 111 W. Madison St., Tallahassee, FL 32399-1400