

**STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FILED	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	12/8/2014
File #	2014-09522

**IN RE: PETITION FOR EMERGENCY WAIVER
AND VARIANCE FROM RULE 61N-1.023(2),
FLORIDA ADMINISTRATIVE CODE,**

PARALLON BUSINESS SOLUTIONS, LLC,

PETITIONER.

VW 2014-384

**FINAL ORDER GRANTING IN PART AND DENYING IN PART PETITION FOR
VARIANCE/WAIVER**

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

PRELIMINARY STATEMENT

On October 27, 2014, Petitioner, Parallon Business Solutions, LLC, (hereafter, "Parallon" or "Petitioner"), filed a petition for emergency waiver and variance from the requirements of Rule 61N-1.023(2), Florida Administrative Code (hereafter, "F.A.C."). Notice of the petition was published in the October 30, 2014, issue of the Florida Administrative Register, Volume 40, Number 212.

FINDINGS OF FACT

1. Parallon's corporate offices are located at One Park Plaza, Nashville, Tennessee 37203.
2. Parallon owns and operates three prescription drug distribution centers that are permitted by the Department as restricted prescription drug distributors—health

care entity: Central Shared Services LLC, doing business as (d/b/a) West Florida Supply Chain Services located at 12901 Starkey Road, Suite 1000, Largo, FL 33773, holding permit number 50:284; Central Shared Services LLC, d/b/a North Florida Supply Chain Services, located at 8501-1 Westside Industrial Drive, Jacksonville, FL 32219, holding permit number 50:285; and Central Shared Services LLC, d/b/a East Florida Supply Chain Services, located at 10094 Premier Parkway, Miramar, FL 33025, holding permit number 50:283.

3. Establishments permitted as a restricted prescription drug distributor—health care entity that are doing business in this state are subject to the provisions of Chapter 499, Florida Statutes, the Florida Drug and Cosmetics Act, and are subject to the rules that are adopted under the Act.

4. Section 499.01(1)(g), Florida Statutes (2014), establishes the restricted prescription drug distributor permit for those persons located in this state who engage in the distribution of prescription drugs which distribution does not meet the definition of “wholesale distribution” under Section 499.003(53), Florida Statutes (2014), or any person in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return for destruction. The Department is authorized to adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. 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].

6. Rule 61N-1.023, Florida Statutes, implements Section 499.01, 499.012, 499.0121, and former section 499.014, Florida Statutes. These provisions relate to state-required permits, licensure requirements, storage and handling of prescription drugs, and with respect to former section 499.014, requirements for distributions of legend drugs by hospitals and health care entities. Section 499.002, Florida Statutes, sets forth the intended purposes for Part I, Chapter 499, Florida Statutes:

499.002 Purpose, administration, and enforcement of and exemption from this part.—

(1) This part is intended to:

(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and

regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

7. According to Parallon, the distribution centers, which are permitted as restricted prescription drug distributor-health care entity, purchase prescription drugs from authorized suppliers and distribute the drugs to approved facilities under common control with licensed pharmacies.

8. The Parallon distribution centers do not have pharmacy permits or licensed pharmacies onsite.

9. Parallon asserts that its distribution centers need to be able to receive prescription drugs back from the facilities to whom they transfer prescription drugs, in order to appropriately manage drug surpluses and shortages among the recipient facilities and provide timely dispensing of needed medications to patients.

10. Parallon further asserts that if Parallon is unable to accept prescription drugs back from one facility and distribute to another facility to account for inventory surpluses and shortages, the recipient facilities may be without sufficient prescription drug inventory when needed, thus impacting the health and welfare of patients who rely on the medications.

11. Parallon asserts that the distribution centers, by their very nature as prescription drug distribution centers, are authorized to acquire and possess prescription drugs.

12. According to Parallon, due to the common control requirement of Rule 61N-1.023, Florida Administrative Code, all drugs transferred back to the distribution centers would remain inside the system of commonly-controlled facilities, safeguarding the integrity of the drugs and protecting the public welfare.

13. Petitioner asserts that Rule 61N-1.023(2), F.A.C., was developed for a prior business model that contemplated hospitals with onsite pharmacies as distributors. Petitioner states that the rule has not been updated to account for industry changes that now use warehouses, which lack onsite pharmacies, for distributors.

14. According to Petitioner, the literal application of Rule 61N-1.023(2), F.A.C., as employed by the Department, results in a substantial hardship, violates principles of fairness, and impedes furtherance of the purposes of Chapter 499, Florida Statutes.

15. Petitioner states that the purposes of the statutes underlying Rule 61N-1.023(2), F.A.C., can be achieved by means other than strict compliance with the rule.

16. Parallon asserts that it has incurred considerable construction costs in updating its infrastructure to proceed with the proposed drug distribution model. According to Parallon, construction necessary to allow Parallon to proceed with the proposed drug distribution model is projected to be finished on November 8, 2014.

17. Parallon anticipates being able to activate this business model and begin accepting drug deliveries on December 9, 2014. After that date, Parallon asserts, without a waiver and variance Parallon will be exposed to tangible and immediate costs from lost revenue, contingency arrangements, inefficient drug distribution, and business uncertainty.

18. Parallon requests that the Department issue a final order granting Parallon a waiver and variance from Rule 61N-1.023(2), F.A.C., as follows:

A. A waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs; and

B. A variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits.

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 Emergency Petition for Waiver/Variance.

21. Section 120.542(2), Florida Statutes, 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. Thus, the statute would prohibit the Parallon

health care entities from transferring prescription drugs to entities other than hospitals or other health care entities under common control with the distribution centers, which entities also have a pharmacy permit that authorizes the acquisition and possession of prescription drugs.

23. 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 denied. This denial is based on the fact that if the prohibition was removed, Parallon would then be free to distribute drugs that have been purchased and held by a health care entity to any entity it chooses to distribute to, regardless of whether that entity is under common control with the Parallon distribution centers and regardless of whether such entities have pharmacy permits that authorize the acquisition and possession of prescription drugs. This would be a clear violation of the requirements of the statute.

24. As indicated in Section 120.542 above, an agency may not grant a variance or waiver to a statute. Since granting the waiver as requested by Petitioner in paragraph 16A above would be the equivalent to granting a waiver from the provisions of Section 499.005(21), Florida Statutes (2014), the request is denied.

25. Petitioner is correct that the Department has previously interpreted Rule 61N-1.023(2), Florida Statutes, to allow transfers from an entity permitted as a restricted prescription drug distributor-health care entity to a facility under common control that has a pharmacy permit that authorizes the acquisition and possession of prescription drugs, but prohibits the return of any of the transferred drugs to the distribution centers.

because such centers do not have pharmacy permits that authorize the acquisition and possession of prescription drugs. However, Petitioner is also correct that the purposes of the statute would be served if the distribution centers were allowed a variance from the rule to receive back from the pharmacies the drugs that the centers transferred to them. This is so because the purpose of the provision—to ensure that prescription drugs are distributed to entities that are authorized to receive and possess them, would be satisfied by allowing a permitted entity to receive back from entities under common control those drugs that it had transferred to the facilities.

26. Such returns of any surplus drugs back to the distribution centers would enhance the centers' ability to control and ensure appropriate quantities of prescription drugs are available to reach the intended recipients—patients.

27. Florida Law requires an establishment to maintain records of prescription drugs to protect the public health, safety, and welfare and Petitioner must comply with these requirements. See Section 499.0121, Florida Statutes and Rule 61N-1.012, F.A.C.

28. Petitioner is correct that the Rule 61N-1.023(2) was based on a business model of a hospital distributing to pharmacies under its control, and the pharmacies being able to distribute the drugs back to the hospital through the hospital pharmacy. However, Petitioner is also correct that the fact that the distribution centers hold permits as restricted prescription drug distributors—health care entity means the distribution centers are authorized to purchase and receive prescription drugs. Thus, the purposes of the statute—to protect the public health by ensuring that prescription drugs are

distributed to entities that are authorized to receive and possess them, would be satisfied.

29. Section 120.542, Florida Statutes (2013), places the burden on Petitioner to demonstrate that the underlying purpose of the statute will be or has been achieved by some other means.

30. Petitioner has met the burden of demonstrating that allowing the distribution centers to receive prescription drugs back from the facilities to which the centers transferred the drugs, achieves the purpose of the statute.

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

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

33. Based on the foregoing, Petitioner's request for a variance and waiver as set forth in paragraph 18A and 18B above, is denied in part and granted in part, as follows:


A. Petitioner's request for a waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs, IS DENIED, for the reasons set forth above; and

B. Petitioner's request for a variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits, IS GRANTED for the reasons set forth herein above.

Done and ordered this 8th day of December, 2014, at Tallahassee, Leon
County, Florida.

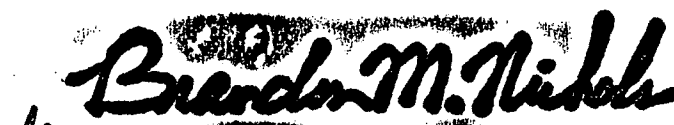
KEN LAWSON, Secretary
Department of Business & Professional
Regulation

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 Gabriel V. Warren, Esquire, Rutledge Escenia, P.A., 119
South Monroe Street, Suite 202, Tallahassee, Florida 32302, this 8th day of
December, 2014.


Brendon M. Nicks
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
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES AND COSMETICS

FILED	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	10/27/2014
File #	

In re: Parallon Business Solutions, LLC's
Petition for Waiver and Variance before the
Florida Department of Business and
Professional Regulation

VW 2014-384

PETITION FOR EMERGENCY WAIVER AND VARIANCE FROM RULE 61N-1.023(2)

Pursuant to section 120.542, Florida Statutes, and Florida Administrative Code Rule 28-104.004, Parallon Business Solutions, LLC ("Parallon"), by and through its undersigned counsel, petitions the State of Florida, Department of Business and Professional Regulation ("DBPR" or "Department") for a permanent emergency waiver and variance from Florida Administrative Code Rule 61N-1.023(2). In support of this Petition, Parallon states:

Identity of Petitioner

1. Parallon is formally known as Parallon Business Solutions, LLC, and its corporate offices are located at One Park Plaza, Nashville, Tennessee 37203. For purposes of this proceeding, Parallon's address and contact is that of its undersigned counsel.

2. Parallon owns and operates three (3) prescription drug distribution centers that are licensed by the Department as Restricted Rx Drug Distributors—Health Care Entity. These distribution centers do business under the names West Florida Supply Chain Services, North Florida Supply Chain Services, and East Florida Supply Chain Services. The distribution centers purchase prescription drugs from authorized suppliers and distribute these drugs to approved facilities under common control with licensed pharmacies. As a restricted prescription drug distributor, Parallon is subject to regulation under Chapter 499, Part I, Florida Statutes, and Florida Administrative Code Chapter 61N-1.

RECEIVED

OCT 27 2014

DBPR Agency Clerk

Applicable Rule

3. Rule 61N-1.023(2) authorizes the Department to issue restricted prescription drug distributor permits to health care entities that meet certain criteria.

4. Rule 61N-1.023(2) states in relevant part:

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.

5. The Department construes the language of Rule 61N-1.023(2) as prohibiting the transfer of prescription drugs to facilities that are not licensed with pharmacy permits, such as the distribution centers. Parallon seeks a waiver and variance from the rule as construed.

Statute Implemented

6. Rule 61N-1.023(2) states that it implements sections 499.01, 499.012, 499.0121, and 499.014, Florida Statutes.¹ These sections generally describe the various drug distribution permits authorized by statute, including the application and operating requirements associated with those permits.

7. The primary purposes of these sections and the rest of Chapter 499, Part I, Florida Statutes, as stated in section 499.002, Florida Statutes, are to:

(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of,

¹ Section 499.014, Florida Statutes, was renumbered as section 499.01(2)(g), Florida Statutes.

the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

8. The waiver and variance sought by Parallon fully serve the purposes of these statutes.

Type of Action Requested

9. Parallon requests a permanent waiver and variance from the limitation in Rule 61N-1.023(2) that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. Parallon requests that it be permitted to transfer prescription drugs from the receiving facilities under common control back to its distribution centers, which are not licensed with pharmacy permits.

Facts Demonstrating a Substantial Hardship

10. Parallon distribution centers are currently precluded by Rule 61N-1.023(2) from accepting drug transfers back from the facilities to which they distribute because the distribution centers do not possess pharmacy permits. The distribution centers need to be able to accept the transfer of prescription drugs back from these facilities in order to appropriately manage drug surpluses and shortages among the recipient facilities and provide timely dispensing of needed medication to patients.

11. Parallon distribution centers need to be able to receive prescription drugs back from the facilities to which they distribute. If Parallon is unable to receive prescription drugs back from one facility and redistribute to another facility to account for inventory surpluses and shortages, then the recipient facilities may be without sufficient prescription drug inventory

when it is needed, thus impacting the health and welfare of the patients that rely on these medications. Surplus drug inventory results in waste and lost revenue, while drug shortages increase patient risk and greatly inflate costs to meet supply needs under pressing circumstances. Permitting the proposed activity comports with the spoke and wheel distribution model contemplated by the purposes of the statutes. It will also greatly improve efficiency in health care delivery and potentially lower costs.

12. Parallon distribution centers do not have pharmacy permits or licensed pharmacies onsite. However, the distribution centers are authorized to acquire and possess prescription drugs by their very nature as drug distribution centers. Due to the common control requirement of the Restricted Rx Drug Distributor—Health Care Entity permit, all drugs transferred back to the distribution centers would remain inside the system of commonly controlled facilities, safeguarding the integrity of the drugs and protecting the public welfare. Rule 61N-1.023(2) was developed for a prior business model that contemplated hospitals with onsite pharmacies as distributors. It has not been updated to account for industry changes that now use warehouses, which lack onsite pharmacies, as distributors.

13. The literal application of Rule 61N-1.023(2), as employed by DBPR, results in a substantial hardship, violates the principles of fairness, and impedes furtherance of the purposes of Chapter 499, Part I, Florida Statutes.

The Waiver and Variance Would Serve the Statutory Purposes

14. As previously indicated, the purposes of the statutes underlying Rule 61N-1.023(2), namely Chapter 499, Part I, Florida Statutes, can be achieved by means other than strict compliance with the rule.

15. Parallon will continue to comply with all other requirements placed on Restricted Rx Drug Distributor—Health Care Entity permit holders by Chapter 499, Part I, Florida Statutes, and related administrative regulations. Parallon will also continue to uphold its obligations to make prescription drugs available in a safe and timely manner for the ultimate health and welfare of Florida patients.

Emergency Circumstances

16. To date, Parallon has incurred considerable construction costs in updating its infrastructure to proceed with the proposed drug distribution model. Construction necessary to allow Parallon with the proposed drug distribution model is projected to be finished on November 8, 2014. Parallon anticipates being able to activate this business model and begin accepting drug deliveries on December 9, 2014. After that date, without a waiver and variance Parallon will be exposed to tangible and immediate costs from lost revenue, contingency arrangements, inefficient drug distribution, and business uncertainty.

17. As detailed above, Parallon will suffer immediate adverse effects in the form of lost revenue, incurred costs from contingency arrangements, and overall business uncertainty if the waiver and variance is not issued more expeditiously than the ordinary time frame of 90 days.

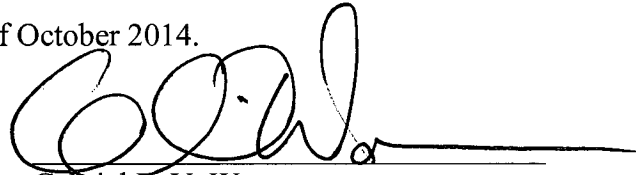
Conclusion

Parallon requests that the Department issue a Final Order granting Parallon a waiver and variance to Rule 61N-1.023(2) as follows:

18. A waiver from the limitation in Rule 61N-1.023(2) that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs; and

19. A variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits.

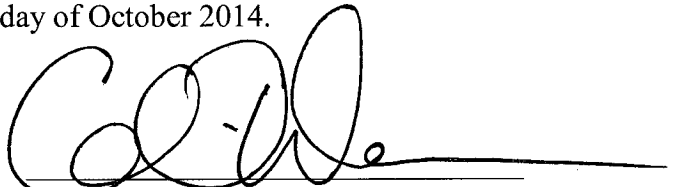
Respectfully submitted this 27th day of October 2014.



Gabriel F. V. Warren
FL Bar No. 84777
Rutledge Ecenia, P.A.
119 South Monroe Street, Suite 202
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Tel. 850-681-6788
Fax 850-681-6515
gwarren@rutledge-ecenia.com
Attorney for Parallon Business Solutions, LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the original of the foregoing document was filed via hand delivery with the Agency Clerk of the Department of Business and Professional Regulation at 1940 North Monroe Street, Suite 92, Tallahassee, Florida 32399-2202; via electronic mail to Reginald Dixon, Esq, reggie.dixon@myfloridalicense.com, and Kathryn Price, Esq., kathryn.price@myfloridalicense.com on this 27th day of October 2014.



Gabriel F. V. Warren