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BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of: **INTEGRITY Rx SPECIALTY PHARMACY** Holder of Permit No. Y005956 In the State of Arizona, Respondent.	Board Case No. 16-0013-PHR **CONSENT AGREEMENT FOR CIVIL PENALTY AND RECISSION OF DEVIATION**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et seq.*, Integrity Rx Specialty Pharmacy, holder of Permit No.Y005956 (hereinafter, "Respondent" or "Integrity Rx") and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Respondent understands this Consent Agreement deals with Board Complaint No. 4485 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting

any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

8. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke its acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. § 32-1901.01(A)(19).

13. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY RESPONDENT

Jeffery K. Karp

Dated: 4/21/2016

Jeffery Karp, on behalf of
Integrity Rx Specialty Pharmacy

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent Integrity Rx holds pharmacy permit no. Y005956.

3. In August of 2014, Jeffrey Karp appeared on behalf of Respondent before the Board with Paul Vasiliauskas, a representative of Vasco Rx Pharmacy, seeking a deviation related to a remote dispensing device. According to Respondent:

a. Vasco Rx would place a remote dispensing device within Integrity Rx.

b. The remote dispensing devise will contain medication compounded by Vasco Rx Pharmacy.

c. The remote dispensing device will be stocked by a pharmacist from Vasco Rx who will deliver the medication, inventory it, and log it in to the remote dispensing device.

d. The remote dispensing device will track the lot number, expiration date and the inventory in and out.

e. The remote dispensing device inventory will only be accessed and scanned by a Vasco Rx employee pharmacist.

f. A Vasco Rx Pharmacist will be on-site at Integrity Rx every day at a designated time.

g. Integrity Rx receives a prescription for a compounded medication, and after patient authorization, transfers the prescription to Vasco Rx.

h. The Vasco Rx operating system will talk to the remote dispensing device system and a label will print. Inventory will be checked by a Vasco Rx pharmacist.

i. All product dispensing will be labeled and checked by a Vasco Rx pharmacist and placed in a tote dedicated for that patient.

4. Based upon the Respondent's representations, the Board granted Respondent a deviation.

5. A routine inspection conducted at Integrity Rx on February 5, 2016, revealed the following:

a. No remote dispensing device provided by Vasco Rx was within the Integrity Rx. Rather, two file cabinets with locks labeled "property of Vasco Rx Specialty

Pharmacy" were present. Respondent indicated that no remote dispensing device was ever placed by Vasco Rx.

b. Compounded medication labeled property of Vasco Rx was found in each file cabinet drawer.

c. On request of Integrity Rx, Vasco Rx delivers compounded medication to Integrity Rx. The delivery is completed by an employee of Vasco Rx, not a pharmacist, and left with Integrity Rx staff. Respondent noted that there is not usually a delivery invoice.

d. Lot number, expiration date, inventory in and out is maintained on a perpetual paper log.

e. Respondent indicated that Jeffrey Karp has the keys to the file cabinets and either an Integrity Rx pharmacist or a technician will place the compounded medication in the file cabinet.

f. Neither Paul Vasiliauskas nor another Vasco Rx Pharmacist come to Integrity Rx.

g. Integrity Rx transfers the prescription to Vasco Rx after patient authorization using the shared computer system.

h. The prescription verification PV1 and PV2 is then completed by an Integrity Rx pharmacist, not a Vasco Rx pharmacist. A prescription label with Vasco Rx information then prints at Integrity Rx.

i. The final product dispensing is completed by an Integrity Rx pharmacist, not a Vasco Rx pharmacist.

6. On March 1, 2016, Respondent filed a written response to the Complaint wherein it acknowledged the findings set forth in paragraph 3 above and further noted that the pharmacy "clearly failed to focus on the key elements of our proposal [for the deviation] which was to provide for an *automated* system." (emphasis in the original).

7. Respondent further stated that "Based on the cost of obtaining a remote device, and due to our misbelief that we met the qualifications for shared services and therefore didn't think that the remote device was necessary for what we wanted to do, we chose to implement a program which provided security and record-keeping processes for the Vasco stock, but did not put the stock into an automated dispensing machine....[W]e realize now that the automated dispensing machine was an integral part of the program."

8. Respondent also acknowledged that Jeffrey Karp's role as pharmacist for both Integrity Rx and Vasco Rx "may not be seen as meeting what we described during the presentation in front of the Board and for that we are both deeply regretful and genuinely embarrassed."

9. According to information gathered during the inspection, approximately 2,200 prescriptions were compounded/filled contrary to the deviation granted by the Board and therefore in violation of the Board's statutes and rules.

10. Finally, Respondent noted that the program was ceased immediately after the inspection was completed. All compounded stock was returned to Vasco Rx and in its place is a more traditional process whereby prescriptions are verbally transferred to Vasco pharmacists in the Vasco pharmacy where prescriptions are filled.

CONCLUSIONS OF LAW

1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may discipline a permittee who has engaged in unprofessional conduct. A.R.S. § 32-1927.02.

3. The failure to follow the processes described in the deviation request approved by the Board constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(18) (violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, the board's statutes or rules) as it relates to A.R.S. §32-1901(8) (Compounding means the preparation, mixing, assembling, packaging or labeling of a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes the preparation of drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and the preparation of drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include the preparation of commercially available products from bulk compounds or the preparation of drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution), and Arizona Administrative Code R4-23-410(A)(3) (neither the pharmacy permittee nor a pharmacist employed by the pharmacy permittee provides a compounded pharmaceutical product to a pharmacy, medical practitioner, or other person for dispensing or distributing except that a compounded pharmaceutical product may be provided to a medical practitioner to administer to a patient of the medical practitioner if each container is accompanied by the written list required in subsection (l)(5) and has a label that includes

(1) the pharmacy name, address and telephone number, (2) the pharmaceutical product's name and the information required in subsection (I)(5) and (3) a lot or control number); and A.R.S. §32-1968(D) (any drug dispensed in accordance with subsection A of this section is exempt from the requirements of A.R.S. §32-1967(1), (10) and (11) and the packaging requirements of subsection A(7) and (8), if the drug container bears a label containing the name and address of the dispenser, serial number, date of dispensing, name of the prescriber, name of the patient, or if an animal, the name of the owner of the animal and the species of the animal, directions for use and cautionary statements, if any, contained in the order. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the internet or to a drug dispensed in violation of subsection A of this section.)

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT Respondent shall:

1. Pay a civil penalty of $10.00 per prescription filled/compounded in violation of the deviation granted by the Board and contrary to the Board's statutes and rules (2220 said prescriptions) for a total of **$22,200** within **180 days** of the effective date of this Order. The effective date of this Order is the date it is signed by the Board's Executive Director.

2. Pay the investigative costs in this matter in the sum of **$175** within **180 days** of the effective date of this Order.

3. The deviation granted to Respondent in August of 2014, is hereby **RESCINDED**.

4. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the

opportunity to be heard, may revoke, suspend or take other disciplinary actions against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 11th day of May, 2016.

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By: _____
KAMLESH GANDHI, PharmD.
Executive Director

ORIGINAL OF THE FORGOING FILED
this 11th day of May, 2016, with:

Arizona State Board of Pharmacy
1616 W. Adams, Ste. 120
Phoenix, Arizona 85007

EXECUTED COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 6th day of July, 2016, to:

Integrity Rx Specialty Pharmacy
8425 N. 90th Street, Ste. 8
Scottsdale, AZ 85258
Respondent

EXECUTED COPY OF THE FOREGOING MAILED
this 6th day of July, 2016, to:

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