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Attorneys for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of ANAZAOHEALTH CORPORATION, Respondent.	PHA 2014-13-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

[redacted]

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent ANAZAOHEALTH CORPORATION (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was the holder of miscellaneous permit number PMP 179, issued by the Board of Pharmacy (hereinafter the "Board"). The miscellaneous

permit was issued on or about August 22, 2000. The miscellaneous permit will expire or forfeit on or about December 31, 2015.

2. Respondent's mailing address for purposes of this action is 5710 Hoover Boulevards, Tampa, Florida 33634.

3. On or about November 6, 2013, Respondent submitted an application to renew miscellaneous permit number PMP 179. On the application, Respondent indicated it had, within the last three years, been disciplined by the States of Florida.

4. Respondent attached a copy of a January 18, 2012 Final Order Approving Settlement Agreement with the Florida Board of Pharmacy in Department of Health vs. Anazao Health Corp., Case No.: 2009-20721 & 209-21858 (hereinafter "Florida action") (Exhibit "1"). The Florida action alleged various allegations stemming from use of a formula Respondent had obtained that contained a mathematical error. The Florida action alleged, among other things, that Respondent had compounded and failed to recognize problems with potency. As a result of the Florida action, Respondent implemented changes to its policies and procedures, agreed to an expert review, and paid costs of $70,000.

5. RICO alleges that disciplinary action was taken against Respondent by the State of Florida, and that Respondent failed to report the Florida action within thirty days as required by law.

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to report disciplinary decision within thirty days).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein the holder of a miscellaneous permit acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the January 18, 2012 Final Order Approving Settlement Agreement with the Florida Board of Pharmacy in Department of Health vs. Anazao Health Corp., Case No.: 2009-20721 & 209-21858 ("Florida action")

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 464.

7. Respondent further understands that RICO enters into this settlement agreement, and agrees to the specific terms contained in this settlement agreement, based upon Respondent's representations made herein.

8. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's miscellaneous permit number PMP 179.

9. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

10. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation of miscellaneous permit number PMP 179 in RICO No. PHA 2014-13-L.

11. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

12. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous pharmacy permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.4, C.5, C.6 and C.7 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees

that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

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IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Tampa, Florida, July 14, 2014.

ANAZAOHEALTH CORPORATION
Respondent

By: _____
Its CEO

DATED: Honolulu, Hawaii, July 16, 2014.

_____
DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF ANAZAOHEALTH CORPORATION; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; RICO CASE NO. PHA 2014-13-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

GARRETT A. LAU
Vice Chairperson

8/21/14
DATE

MARCELLA CHOCK

MARY JO KEEFE

LYDIA KUMASAKA

CAROLYN S.J. MA

KERRI OKAMURA

PVL 07/01/14

STATE OF Florida)
) SS.
COUNTY OF Hillsborough)

On this 14 day of July, 2014, before me personally appeared Jacob Beckel, to me known to be the person described, and who executed the foregoing instrument on behalf of Anazaohealth Corporation as its CEO | Chairman, and acknowledged that he/she executed the same as his/her free act and deed.

This 8 -page Settlement Agreement document dated July 14, 2014 was acknowledged before me by Jacob Beckel this 14 day of July, 2014, in the City of Tampa, in the County of Hillsborough, in the State of Florida.

MARJORIE BENSON
MY COMMISSION # FF 075536
EXPIRES: December 10, 2017
Bonded Thru Notary Public Underwriters

Marjorie Benson
Name:
Notary Public, State of

My Commission expires: 12/10/17

STATE OF FLORIDA
BOARD OF PHARMACY

Final Order No. DOH-12-0070-S-MQA
FILED DATE - 1-23-12
Department of Health
By: Angel Sanders
Deputy Agency Clerk

DEPARTMENT OF HEALTH,
Petitioner,

vs.

CASE NO.: 2009-20721 & 2009-21858
LICENSE NO.: PH 15735

ANAZAO HEALTH CORP.,
Respondent.

_____/

FINAL ORDER APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), Florida Statutes, on December 20, 2011in Gainesville, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby ordered and adjudged:

(1) The Settlement Agreement as submitted is hereby approved, adopted and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

(2) As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are $70,000.00.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

EXHIBIT "1"

DONE AND ORDERED this 18th day of January, 2012.

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Carl "Fritz" Hayes, BPharm, Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW UNLESS WAIVED

A PARTY WHO IS ADVERSELY AFFECTED BY THIS ORDER IS ENTITLED TO JUDICIAL REVIEW, UNLESS WAIVED, PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to Anazao Health Corp., 5710 Hoover Boulevard, Tampa, Florida 33634; Edwin A. Bayo, Esquire, 2022-2 Raymond Diehl Road, Tallahassee, Florida 32308, by interoffice delivery to David Bibb, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399-3265, and by interoffice delivery to Allison Dudley, Assistant Attorney General, Department of Legal Affairs, The Capitol, PL-01, Tallahassee, Fl 32399-1050 this 23rd day of January, 2012.

Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASES NOS. 2009-20721
2009-21858

ANAZAOHEALTH CORPORATION,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the pending Administrative Complaint, as filed with the Agency Clerk, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Respondent, ANAZAOHEALTH CORPORATION (hereinafter "Respondent") operated a pharmacy under Community pharmacy permit number PS 20156 and Special-Parenteral and Enteral Extended Scope pharmacy permit number PS 15735. Respondent's mailing address of record is 5710 Hoover Boulevard, Tampa, Florida 33634.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456, 465, and 499, Florida Statutes.

3. Respondent denied the allegations contained in the Administrative Complaint and requested a hearing involving disputed issues of material fact.

4. After considerable review by experts retained by both parties, and in anticipation of settlement, the allegations in the Administrative Complaint have been revised by the drafting of an Amended Administrative Complaint. The Respondent neither admits nor denies the allegations contained in the Amended Administrative Complaint, but agrees that the terms of this Settlement Agreement constitute a fair and acceptable resolution to this matter.

STIPULATED LAW

1. Respondent, by and through its duly-authorized corporate representative, admits that it is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department, and further admits that the allegations in the Amended Administrative

Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, by and through its duly-authorized corporate representative, shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Amended Administrative Complaint-** In consideration of Respondent's entry into this agreement, upon approval of this Settlement Agreement by the Board, the Department shall amend the presently-pending, original Administrative Complaint, as filed with the Agency Clerk in this matter, to the form of the proposed Amended Administrative Complaint (attached hereto as Exhibit A). Such amended complaint shall be deemed filed by the Board's acceptance of this agreement.

3. **Fine**- Respondent agrees to pay and the Board shall impose an administrative fine of **THREE THOUSAND DOLLARS** ($3,000). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order

approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

4. **Costs**- Respondent agrees to pay and the Board of Pharmacy shall impose administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **SEVENTY THOUSAND DOLLARS** ($70,000). Total costs at the time of entry into this settlement are approximately ninety-five thousand dollars, however, in light of this settlement agreement, costs shall be capped at the heretofore stated amount of seventy thousand dollars. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

5. **Remediation**- As a condition of settlement, Respondent, by and through its duly-authorized corporate representative, agrees to implement the changes to their Standard Operating Procedures and to its pharmacy's general policies and procedures in keeping with the Department's required changes as found collectively in Exhibit B.

It is recognized by the parties herein that subsequent to the adverse incidents which gave rise to the initiation of an investigation of Respondent, certain subsequent remedial measures (SMRs) were taken by the Respondent in order to improve its processes. These SMRs have resulted in improvements in the consistency, accuracy and purity of the drug lots and the individual prescriptions compounded by Respondent. Therefore, as a condition of settlement, Respondent shall retain all SMRs and shall further improve their standards as described in Exhibit B.

During this remediation period, Department shall have the right to have its pharmacy and Drug Devices and Cosmetics (DDC) inspectors and investigators conduct as many as four (4) inspections of the Respondent's pharmacy per year. Such inspectors shall inspect for compliance with all laws and rules governing the Respondent, and may further inspect to ascertain compliance with the requirements and restrictions attached hereto as Exhibit B.

6. **Expert Review**- It is further agreed that approximately six months after the acceptance of this settlement agreement by the Board, the Department's and Respondent's retained experts in this case shall jointly select a third expert in the field of sterile compounding pursuant to

USP 797 guidelines. This expert shall be granted full access by the Respondent to inspect its premises. Such expert shall inspect for compliance with all laws and rules governing the Respondent, and may further inspect to ascertain compliance with the requirements and restrictions attached hereto as Exhibit B. Such expert shall issue a report of his/her findings to the Board of Pharmacy, with a copy to both the Respondent and to the Department. The Department and the Respondent shall each pay one-half of the costs of the Expert's review.

7. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy including, but not limited to, the guidelines set out by the United States Pharmacopeia (USP).

8. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order**- It is expressly

understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order. Similarly, the proposed Amended Administrative shall be deemed amended only upon acceptance of this Agreement by the Board or upon acceptance by all parties of a Counter-Offer by the Board incorporating the Amended Administrative Complaint.

9. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent, by and through its duly-authorized corporate representative, for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and

matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses**- Respondent shall keep current its mailing and practice addresses with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 24th day of August, 2011.

JACOB BECKEL, Chairman & CEO
ANAZAOHEALTH CORPORATION
CASE NOS. 2009-20721, 2009-21858

STATE OF FLORIDA }
}
COUNTY OF Hillsborough }

Before me personally appeared JACOB BECKEL, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 24th day of August, 2011.

Vickie J. Carver
Notary Public
My Commission Expires: 10/15/2013

VICKIE J. CARVER
MY COMMISSION # DD 919643
EXPIRES: October 15, 2013
Bonded Thru Notary Public Underwriters

APPROVED this 20th day of September, 2011.

H. Frank Farmer, Jr., MD, PhD, FACP
State Surgeon General

David C. Bibb
Assistant General Counsel

Counsel for Petitioner
David C. Bibb
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Florida Bar No. 190330
Tel: 850.245.4640
Fax: 850.245.4682

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v.

Case Nos.: 2009-20721
2009-21858

ANAZAOHEALTH CORP.,

Respondent.

_____/

AMENDED ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health (the "department"), files this as its amended administrative complaint (the "complaint") before the Board of Pharmacy (the "board") against Respondent, AnazaoHealth Corporation ("Anazao"), and states as follows:

General Allegations

1. Pursuant to Section 20.43, Florida Statutes and Chapters 456, 465 and 499, Florida Statutes, the department is the executive agency charged with regulating the practice of pharmacy and the distribution of prescription drugs in and into this state.

2. At all times material to this complaint, Anazao operated a pharmacy under Community Pharmacy Permit number PS 20156 and

Special-Parenteral and Enteral Extended Scope pharmacy permit number PS 15735 (collectively, the "permits").[1]

3. These permits authorize operation of a pharmacy by Anazao within the state of Florida, specifically at Anazao's address of record: 5710 Hoover Boulevard, Tampa, Florida.

4. A Community Pharmacy permit authorizes the holder to (i) purchase, receive and possess prescription drugs while under the professional supervision of a pharmacy department manager pharmacist, and (ii) employ pharmacists engaging in the professional pharmacy practices of compounding and dispensing prescription drugs.

5. A Special-Parenteral and Enteral Extended Scope pharmacy permit limits the holder, again through employee pharmacists, to (i) rendering certain sterile preparations, and (ii) performing certain parenteral and enteral compounding functions.[2]

Pharmacy Compounding

6. "Compounding" is defined in Rule 64B16-27.700, Florida Administrative Code ("F.A.C."), to mean: "the professional act by a

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[1] For purposes of this complaint, "parenteral" refers to a sterile preparation of drugs for injection through one or more layers of the skin, and "enteral" refers to a sterile preparation of drugs for delivery directly into the digestive system.

[2] For purposes of this complaint, "sterile" means devoid of viable microorganisms.

pharmacist . . . incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner . . . ."[3]

7. Included in "compounding" by Rule 64B16-27.700(1), Florida Administrative Code, are the following patient specific uses:

> (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
> (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
> (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

8. In addition to compounding drugs for a specific patient, Rule 64B16-27.700, F.A.C. (the "compounding rule") authorizes compounded drugs to be furnished to a practitioner for "office use," defined as follows:

> the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with [this subsection (3)] provided:
> (a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the

[3] For purposes of this complaint, "product" is the equivalent of "preparation."

practitioner's office before the expiration date of the drug;
(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;
(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

9. A pharmacy which compounds drugs is required to maintain records in accordance with Rule 64B16-28.140(4), F.A.C.:

Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:
(a) Date of compounding.
(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.
(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.
(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.
(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.
(g) The quantity in units of finished products or grams of raw materials.
(h) The package size and number of units prepared.
(i) The name of the patient who received the particular compounded product.

10. Rule 64B16-28.860(5)(d), F.A.C. provides that records for the compounding of drugs under a Special-Parenteral and Enteral Extended Scope permit shall include:

> lot number traceability of components used during compounding, documentation of any equipment used during compounding, documentation of staff performing compounding, and records recording ultimate dispensing of the compounded product.

11. The United States Pharmacopeia ("USP") is a non-government, official public standards authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. Chapter <797> of the USP, "Pharmaceutical Compounding-Sterile Preparations", details the procedures and requirements for compounding sterile preparations and sets standards that apply to all practice settings in which sterile preparations are compounded. These standards are intended to prevent patient harm from inaccurate or contaminated compounded sterile products, for example, from microbial

contamination, excessive bacteria endotoxins, variability in the intended strength of a product, use of ingredients of inappropriate quality, or other unintended physical or chemical contaminants.

12. Florida has incorporated portions of Chapter <797> into its regulation on compounding sterile products. See Rule 64B16-27.797, Fla. Admin. Code.

13. Rule 64B16-27.797(4), F.A.C., provides that a pharmacy which compounds drugs is required to prepare and maintain a Policy and Procedures Manual:

> A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, and delivery of sterile preparation prescriptions. The policy and procedure manual shall be available for inspection by the Department and include at a minimum:
> (a) Use of single dose and multiple dose containers not to exceed United States Pharmacopeia 797 guidelines.
> (b) Verification of compounding accuracy and sterility.
> (c) Personnel training and evaluation in aseptic manipulation skills.
> (d) Environmental quality and control:
> 1. Air particle monitoring for hoods (or Barrier Isolator), clean room and buffer area (or anteroom) when applicable;
> 2. Unidirectional airflow (pressure differential monitoring);
> 3. Cleaning and disinfecting the sterile compounding areas;
> 4. Personnel cleansing and garbing;
> 5. Environmental monitoring (air and surfaces).
> (e) Personnel monitoring and validation.

(f) Finished product checks and tests.
(g) Method to identify and verify ingredients used in compounding.
(h) Labeling requirements for bulk compounded products:
1. Contents;
2. Beyond-Use-Date; and
3. Storage requirements.
(i) Packing, storage, and transportation conditions.

14. Rule 64B16-27.797(7), F.A.C., provides that a pharmacy which compounds drugs is required to have a documented, ongoing quality assurance control program that monitors personnel performance, equipment and preparations. Appropriate samples of finished preparations shall be examined to assure that the pharmacy is capable of consistently preparing sterile preparations meeting specifications.

Legal Authority for Disciplinary Action

15. Section 465.023(1)(c), Florida Statutes (2006-2009) provides that violation of any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy; of Chapter 499, Florida Statutes, known as the Florida Drug and Cosmetic Act; of 21 U.S.C. Sections 301-392, known as the Federal Food, Drug, and Cosmetic Act; of 21 U.S.C. Sections 821 et seq., known as the Comprehensive Drug Abuse and Prevention and Control Act; or of Chapter 893, constitutes grounds for disciplinary proceedings by the Board of Pharmacy.

16. Section 465.016(1)(g), Florida Statutes (2006-2009) provides that using in the compounding of a prescription or furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed constitutes grounds for disciplinary proceedings by the Board of Pharmacy.

17. Section 465.016(1)(l), Florida Statutes (2006-2009) provides that the compounding, dispensing, or distributing of a legend drug other than in the course of the professional practice of pharmacy constitutes grounds for disciplinary proceedings by the Board of Pharmacy.

Anazaohealth Compounding Process

18. At the times relevant to the complaint, the process of producing many prescription compounded drugs by Respondent began with production of stock lots (called "premixes" by Anazao") of bulk drug solutions for a variety of drugs at varying concentrations in anticipation of receiving prescriptions or orders for those drugs. Typically, a stock lot of active pharmaceutical ingredient ("API") solution is prepared according to a formula or recipe; the lot, typically made in 500 ml or 1000 ml quantities, is composed of an API and, usually, normal saline or sterile water. The process being used by Anazao involved injecting the API into a 500 ml or

1000 ml stock bag of normal saline or sterile water so that the solution would be mixed inside the bag itself. Each lot is assigned a lot number used to track the batch solution as it is used in the preparation of prescriptions and orders.

19. A sample from each lot, provided by Respondent, is tested by a laboratory for bacterial endotoxins, sterility, concentration, and potency prior to the lot being used for preparation of prescriptions or orders. Respondent submits the sample with the results it intended to achieve, referred to by Respondent as the Expected Concentration. (The laboratory report restates the Expected Concentration as the reported concentration.)

20. If the lot was found to be out of the acceptable USP potency concentrations (90% - 110% of the stated API potency), then Anazaohealth would "rework" the lot by adding additional API or additional diluent (diluting material such as saline), then sending a sample from that lot for testing until said sample was found to be within the acceptable range. The lots would then be used in the preparation of other, lower potency lots or in the preparation of individual prescriptions.

Count One – Unsafe Compounding

21. The department incorporates and realleges paragraphs 1 through 20 hereof as if set out at length herein

22. Anazao compounded and sold to practitioners in Florida Hyaluronidase Preservative Free Injection (hereinafter Hyaluronidase), a prescription drug.

23. Anazao had purchased a smaller pharmacy which had been engaged in the practice of compounding Hyaluronidase for intra-articular use, for use in patients have knee or other joint surgery.

24. Anazao purchased the compounding formula (i.e., the "recipe") for Hyaluronidase from a third-party pharmacy compounding company.

25 At or around the same time, another use for Hyaluronidase was proposed involving intra-occular injection, for eye surgery patients. This formula, intended for much smaller volume injections, was a "scaled down" version of the intra-articular Hyaluronidase formula.

26. Upon information and belief, the formula for intra-occular use Hyaluronidase which Anazaohealth received form the third party pharmacy compounding company contained a mathematical error involving the ratio of chemicals to be mixed with the Hyaluronidase API.

27. Anazao made no efforts to independently verify the formula received from the third party was error-free, efficacious or safe.

28. Anazao marketed Hylaronidase for intra-occular use to physicians in the State of Florida.

29. Anazao compounded and sold to practitioners in Florida Hyaluronidase Preservative Free Injection, including, without limitation, Lot Numbers 15824, 15859, 15927, 16032 and 16102. The Hyaluronidase caused injury to patients in Florida.

30. By preparing a prescription drug based upon an erroneous formula received from a third-party, without taking efforts to determine that the drug as formulated error-free, efficacious and safe, and where such prescription drugs injured patients receiving such drug, Anazao violated Section 465.023(1)(c), Florida Statutes (2008), by practicing outside the course of the professional practice of pharmacy in violation of 465.016(1)(i), Florida Statutes (2008).

Count Two – Quality Assurance

31. The department incorporates and realleges paragraphs 1 through 30 hereof as if set out at length herein

32. A compounding pharmacy must be able to produce a high quality and consistent result with every preparation. If the pharmacy .complies with minimum standard operating procedures, each batch of stock solution will be consistent with all other batches of that stock solution.

33. At various times, the reported concentration of certain compounded products, including, without limitation, Hyaluronidase, failed to meet expected concentrations, and failed to meet acceptable USP concentrations, as described in paragraphs 18-20 above, because of factors associated with adding the API directly into the stock bag of saline or sterile water. These factors included the solubility of small amounts of API and variations in the content of stock saline and sterile water bags.

34. By continuing to compound drugs whose reported concentrations did not meet expected concentrations, Anazao violated Section 465.023(1)(c), Florida Statutes (2006-2008) by violating Rule 64B16-27.797(7) for failing to implement a quality assurance program that would ensure the consistent preparation of compounded drugs meeting the expected specifications.

Count Three – Failure to Engage in Quality Improvement

35. The department incorporates and realleges paragraphs 1 through 34 hereof as if set out at length herein.

36. Rule 64B16-27.300(3)(a), Florida Administrative Code provides that each pharmacy shall establish a Continuous Quality Improvement Program.

37. Anazao ignored the empirical data and, rather than reexamine and revise its pharmacy practices and procedures, continued to compound, sell and dispense these compounded products, attempting to compensate for sub-potent and super-potent concentrations by, among other things, reworking the preparations.

38. By failing to recognize and address its problems of inconsistent API potency results within its compounding process and failing to revise its compounding policies and procedures until after the investigation of this matter to improve the consistency of the potency of its compounded lots, Anazao failed its duty to address quality improvement, and therefore violated Section 465.023(1)(c), Florida Statutes (2006-2008), by violating a rule of the Board, through a violation of Rule 64B16-27.300(3)(a), Florida

Administrative Code, for failing to engage in continuous quality improvement.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties on Respondent: permanent revocation or suspension of license, restriction of practice, administrative fine, reprimand, probation, corrective action, refund of fees billed or collected, remedial education, or any other relief that the Board deems appropriate.

RESPECTFULLY SUBMITTED this 21st day of December, 2011.

H. Frank Farmer, Jr., M.D., Ph.D., F.A.C.P.
State Surgeon General

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Original Complaint: PCP: 07.27.10
PCP Members: Melvin & Risch

DOH v. AnazaoHealth Corporation / Case Nos. 2009-20721 & 2009-21858

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses, and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on Anazao in addition to any other discipline imposed.