

**Addendum Material**  
**Board of Pharmacy**  
**Florida Department of Health**  
**August 12-13, 2014**

Addendum Items

1. TAB 1 – C.3.i. Request for Variance of Waivers – St. Mary’s Inc.
2. TAB 1 – C.3.ii. Request for Variance of Waivers – Good Samaritan Medical Center
3. TAB 5 – B.4. Jocelyn Ariana Zuessman, File: 57034 – Pompano Beach, FL

FILED  
DEPARTMENT OF HEALTH  
DEPUTY CLERK  
CLERK *Angel Sanders*  
DATE JUL 10 2014

STATE OF FLORIDA  
BOARD OF PHARMACY

2205/20817  
RECEIVED  
DEPARTMENT OF HEALTH  
14 JUL 10 PM 2:26  
OFFICE OF THE CLERK

IN RE: PETITION FOR TEMPORARY WAIVER  
FLORIDA ADMINISTRATIVE CODE RULE 64B16-27.797

BY: TENET ST. MARY'S INC. d/b/a/ ST. MARY'S  
MEDICAL CENTER

Tenet St. Mary's, Inc. d/b/a St. Mary's Medical Center ("St. Mary's"), by and through its undersigned attorneys and pursuant to section 120.542, Florida Statutes and Florida Administrative Code Chapter 28-104, hereby requests a temporary waiver of a portion of Florida Administrative Code Rule 64B16-27.797, and as grounds there for would show:

1. The Petitioner is Tenet St. Mary's, Inc. d/b/a St. Mary's Medical Center ("St. Mary's"), located at 901 45th Street, West Palm Beach, Florida 33407. The contact information for St. Mary's for purposes of this Petition is that of its undersigned counsel.

**INTRODUCTION**

2. On March 11, 2014, the Florida Board of Pharmacy ("Board") published amendments to Florida Administrative Code Rule 6416-27.797 in a Notice of Proposed Rule in the Florida Administrative Register (hereafter referred to as "the Amended Rule"). This followed many months of analysis and public hearings. The Board of Pharmacy adopted some additional changes to the Amended Rule at its June 10, 2014 meeting.<sup>1</sup> While the Amended Rule has not been finalized in the Florida Administrative Code as of the filing of this Petition, no challenges to the Amended Rule have been filed and it is anticipated that the rule will be adopted on or before the effective date of October 1, 2014. A copy of the Amended Rule is attached as Exhibit A.

<sup>1</sup> Those changes are not material for purposes of this Petition.

3. The Amended Rule incorporates standards for compounding sterile products as contained in certain chapters of the United States Pharmacopoeia (“USP”) and most significantly for purposes of this Petition, Chapter 797 of the USP entitled: “Pharmaceutical Compounding-Sterile Preparations” (hereafter referred to as “USP 797”). The Amended Rule implements sections 465.0155 and 465.022, Florida Statutes.

4. Prior to the effective date of the Amended Rule, it has been acceptable for a pharmacy to compound oncology, chemotherapeutic and hazardous sterile preparations in a barrier isolator that is properly vented and placed and operated in accordance with the manufacturer’s guidelines but is not located in a negative pressure room.<sup>2</sup>

5. However, under USP 797 as incorporated in the Amended Rule, the compounding of sterile preparations will have to occur in a negative pressure room unless the pharmacy only prepares a “low volume of hazardous drugs.”<sup>3</sup> St. Mary’s monthly volume far exceeds the “low volume” definition. USP 797 includes other physical plant requirements as well.

6. As explained further below, the purpose of this Petition is to seek a temporary waiver of the requirement that St. Mary’s compound in a negative pressure environment that meets all of the USP 797 requirements while it completes the necessary renovations to create a new compliant negative pressure area. As described below, the renovation process is underway but additional time beyond October 1, 2014 is needed. The anticipated date for project completion is June 5, 2015 and a temporary waiver is requested until July 1, 2015 or sooner if the project is completed earlier. Until completed, St. Mary’s will continue to compound in the manner that complies with the Florida compounding rule that has been in place for many years. The St. Mary’s pharmacy has safely compounded for decades.

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<sup>2</sup> This interpretation of the then-existing rule was confirmed at the meeting of the Board on October 8, 2013.

<sup>3</sup> The Amended Rule defines “low volume” as less than 40 doses per month.

## ST. MARY'S AND ITS PHARMACY

7. St. Mary's Medical Center was first built in 1938 and includes the Palm Beach Children's Hospital as part of its 464 licensed beds divided into 329 acute care, 40 adult psychiatric, 50 comprehensive medical rehabilitation, 25 Level II NICU and 20 Level III NICU beds. With numerous expansions and additions over the years, the hospital now occupies over 650,000 gsf and includes detached patient care areas spread over the approximately one hundred acre campus. One hundred forty six beds are devoted to the Palm Beach Children's Hospital. St. Mary's has 25 operating rooms, two GE showcase interventional radiology suits, and more than 60 automated dispensing cabinet locations.

8. St. Mary's provides medical, surgical, obstetrical, oncology, pediatric, trauma (both adult and pediatric) and emergency services to the greater West Palm Beach area. St. Mary's special services include a Comprehensive Stroke Center, high-risk obstetrical unit, Level II and III neonatal intensive care unit, The Rehabilitation Institute, and the Memory Disorders Center. St. Mary's also has a wound care center, comprehensive laboratory, diagnostic and imaging services for both inpatients and outpatients. A leader in critical care medicine, St. Mary's is one of only 27 state-designated trauma centers and has a state-designated Brain and Spinal Cord Injury Program. St. Mary's Medical Center is affiliated with more than 500 primary care, specialist, and sub-specialist physicians, and has more than 1600 employees. St. Mary's is accredited by the Joint Commission.

9. St. Mary's is the local area White House designated hospital for dignitaries. The hospital is also part of the county wide disaster response team and serves as a CDC Emergency Preparedness and Response site.

10. Because the compounding pharmacy services provided at St. Mary's are mission critical to the hospital's services to children, some additional description of the Palm Beach Children's Hospital is warranted.

11. The 146-bed Palm Beach Children's Hospital works with over 175 pediatric physicians representing over 30 specialties and includes:

- Two dedicated general Pediatric Floors
- The only National Cancer Institute Children's Oncology Group approved Pediatric Hematology/Oncology Care Center in Palm Beach County
- 14-bed Pediatric Intensive Care Unit (PICU)
- 45-bed Neonatal Intensive Care Unit (NICU)
- In-house Pediatric Hospitalists, Intensivists and Neonatologists - 24/7/365
- 12-bay dedicated Pediatric Emergency Department - 24/7/365
- Pediatric MRI services
- Access to the latest treatments through Memberships in the National Cancer Institute's Children's Oncology Group and the Children's Hospital Association
- Pediatric cardiac catheterization and open heart surgery services

12. Specialized pediatric services include:

Advanced Diagnostic Imaging • Anesthesia • Asthma • Bariatrics • Brachial Plexus Injuries • Cardiology and Cardiovascular Surgery • Children's Emergency Department - 24/7 • Concussion Treatment Center • Cystic Fibrosis Center • Diabetes Program • Epilepsy Program • Gastrointestinal Endoscopy • Hematology/Oncology Program - Children's Oncology Group (COG) member • Hospitalists - 24/7 in-house • Hyperbaric Services (24/7) • Intensivists - 24/7 in-house • Limb Reconstruction and Lengthening • Maternity Services • Moderate Sedation Program • Neonatal and Pediatric Transport Team • Neonatal Intensive Care (NICU) • Neurosurgery • Nephrology • Orthopedics • Orthopedic Oncology • Pediatric Dialysis • Pediatric ENT • Pediatric Intensive Care (PICU) • Pet Therapy • Radiology • Rehabilitative Services (Acute Inpatient and Outpatient Physical, Occupational and Speech Therapy, Audiology) • Sickle Cell Center • Spine Center

13. St. Mary's is one of only ten hospitals in Florida authorized to perform pediatric cardiac catheterization and pediatric open heart surgery.

14. The hospital campus is also the site of the Quantum House, a home away from home for families of pediatric patients.

15. In 2013 St. Mary's Medical Center and the Palm Beach Children's Hospital cared for 62,331 adult and pediatric emergency department patients, almost 18,000 admissions, 8,600 surgical patients, 1,261 adult intensive care patients, 1,008 stroke alert patients, 786 pediatric intensive care patients, 629 neonatal intensive care patients, 574 step-down patients and 1,705 acute and chronic dialysis patients. As discussed further below, a significant majority of these patients receive some version of a sterile compounded product during their course of treatment.

16. The St. Mary's pharmacy department is never closed. The pharmacy has been in two locations over the 75 year history of the hospital. Both locations have been within the original 75 year old structure. The pharmacy was constructed in its current location in 1998. It occupies a total of approximately 4200 gsf.<sup>4</sup> However only approximately 725 gsf (including the buffer room and ante room) is available and dedicated to sterile compounding.

17. Noted for its bearing wall construction, the original 1938 hospital building is comprised of heavy, thick exterior walls, low floor-to-floor height and smaller spaces overall. Using old exterior doors and windows for department flow, the current pharmacy winds in and out of the old construction as load bearing construction is complex to alter. In addition to the challenging planning, the 1938 building structure is 'shallow' meaning there is limited space above the ceiling for contemporary mechanical systems -- what is needed for a contemporary pharmacy. The existing compounding operations are bounded on one side by a mechanical room on the first floor with occupied spaces above.

18. The pharmacy dispenses 10,000 pharmaceutical products and reviews nearly 2,000 new orders daily. Of the ten Florida hospitals owned by St. Mary's parent, Tenet Healthcare Corporation, St. Mary's pharmacy is the busiest. With 55 staff members and 38

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<sup>4</sup> The space is not completely contiguous. There are several offices located down a corridor from the main pharmacy space.

FTEs, the pharmacy is responsible for nearly 7,000 hours of staff support for patient care every month. The pharmacy also serves as an advanced practice site for four schools of pharmacy with over 50 students per year. The pharmacy department services a very diverse and expansive hospital that has more than 60 automated dispensing cabinet locations. The department of pharmacy practices in tandem with a number of high acuity services including adult and pediatric emergency departments, NICU, trauma, comprehensive stroke center, PICU, pediatric open heart and 30 adult critical care beds among others.

19. The St. Mary's pharmacy routinely creates the following types of sterile compounded products:

- Antibiotics • Antivirals • Antifungals • Cardiac Drips • Parenteral Nutrition • Epidurals • Pain Management • Chemotherapy • Electrolytes • Neonatal fluids • Hematology/Factor Replacement • Wound Irrigation • Peritoneal Dialysis • Continuous Renal Replacement Fluids • Anticoagulants • Antithrombotics • Investigational Agents

20. Medication commonly needed on a STAT basis include weight based antibiotics, electrolytic replacements, anticoagulation, neonatal weight-based sedation and pain management compounds, neonatal nutrition, hematology replacement factors, oncology treatments, oncology rescue agents and code response medications.

21. The following equipment and resources are used as part of St. Mary's sterile compounding activities:

- Four horizontal laminar flow hoods
- One Baxa Automated Compounder and Abacus software
- Three hospital grade refrigerators
- One hospital grade freezer
- One isolator/glove box and venting to outside
- Pressure monitors buffer and ante room
- Integrated hospital wide pressure monitoring system
- Temperature and humidity monitors buffer and ante room
- Simplifi 797 Compliance Program

- Sterile compounding references including Micromedex, USP, Neofax, Harriet Lane, Teddy Bare, and Trissels

22. In 2013, St. Mary's implemented significant changes to improve its sterile compounding facilities and practices. These included:

- Installation of a Germfree Compounding Aseptic Containment Isolator
- Installation of negative pressure hazardous air vent and motor
- Installation of pressure monitoring devices
- Installation of washable surfaces
- Installation of washing station to ante room
- Installation of buffer room washable doors to separate from ante room and maintain pressure controls
- Installation of 3 clean room hospital grade refrigerators
- Installation of Simplifi 797® documentation program
- Installation of upgraded equipment for existing air handler to meet air flow, particle counts, and positive pressure requirements
- Installation of stainless steel ante room work surface
- Installation of stainless steel buffer room work surface
- Removal of a Biological Safety Cabinet
- Removal of porous ceiling surface
- Removal of washing station from buffer room
- Removal of buffer room storage cabinets
- Removal of non-urgent medications and supplies
- Removal of non-critical papers, books, binders
- Removal of additional refrigeration units
- After all of the following actions were completed the equipment and hoods were retested to ensure compliance

23. The cost of this work was approximately \$95,000 plus an additional cost of approximately \$17,000 per year for Simplifi 797®.

24. It is noteworthy that the St. Mary's pharmacy has implemented a USP 797 quality system and uses the Simplifi 797® process to help insure that its compounding practices are done in accordance with the highest industry standards. To be more specific:

- Simplifi 797®, is a web-based USP 797 quality system, that establish the training, risk management, and quality assurance practices necessary for a safe and efficient sterile compounding environment.
- Simplifi 797® has become a standard for Tenet Pharmacy Departments for compounding documentation

- It assists in compliance management and provides staff with expert-based sterile compounding instruction linked directly to USP 797 standards.
- It allows pharmacies to achieve a state of control with standardized training, proper technique, quality assurance controls, standard operating procedures, and management oversight.
- The program was co-developed with industry expert Eric Kastango, MBA, RPh, FASHP, with policies, procedures and education program directly supporting USP 797
- This web-based application is continually updated as standards change with a reference library covering techniques, policies and procedures and competency templates.
- The program will track and review specifics for our compounding activities, with the program we created custom tasks for to serve as a reminder for pharmacy checklists and must do activities.
- Timely data and reporting access is available including trending and analysis reporting by person, site, or facility.
- Single screen dashboard is used to manage all training, schedules and tasks including auto-notification of overdue items, exceptions and out-of-range measurements.

25. In addition, Simplifi 797® includes:

- A complete set of 797 based policies, procedures and related forms
- The ability to ask and clarify questions related to USP <797> standards, rules or regulations
- Customized to provide tracking and review of quality systems specific to your pharmacy compounding sites
- Dashboard design and single screen to easily manage all tasks and schedules
- Custom tasks for non-sterile compounding or other pharmacy checklists
- Batch processing templates for storing recipes, compounding records and labeling
- Auto-notification of overdue tasks, exceptions and out of range measurements
- Auto-resolution procedures for exceptions and unacceptable measured values
- Trending and analysis reporting by person, compounding facility or sample site
- Reference library covering techniques, policies and other pertinent information

26. Routine daily, weekly and monthly cleaning occurs in the sterile compounding area in compliance with USP 797. The pressure status of the buffer room and ante room are

monitored 24 hours a day through a Siemens monitoring device that is integrated into the hospital wide pressure monitoring system. The results of the pressure status are reported through the hospital's QI process. On a monthly basis, the buffer room, ante room and compounding hoods are surface sampled. Quarterly, the ante room and buffer room are viable air sampled and particle sampled (for ISO class status). Semi-annually, the compounding hoods are air sampled. All sampling test results are maintained on site and if any deficiencies are noted immediate corrective actions are taken and resampling occurs. St. Mary's has also contracted with an independent firm to conduct quarterly air sampling to be sure standards are maintained.

27. There are three important additional points to be made regarding the sterile compounding done in the St. Mary's pharmacy:

- The Department of Health conducted a "Compounding Sterile Preparations" survey of the St. Mary's pharmacy on August 21, 2013 and the pharmacy passed with NO deficiencies
- As discussed further below, the renovations that are being constructed are being done in a way that ALL of the sterile compounding facilities and safeguards currently in place are maintained until the new space is approved and ready for occupancy
- To date there have been NO incidents of contaminated sterile compounds produced by St. Mary's department of pharmacy. There are many safety, quality, and practice standards to ensure accurate compounding activities to treat the hospital's patients with the highest level of care and to protect the staff.

#### **THE NECESSARY PHARMACY RENOVATIONS**

28. St. Mary's has been in a process to either redesign or move the sterile compounding area for the past year. During this process St. Mary's has attentively followed the state of compounding regulations in Florida and nationally. A pharmacy representative has been to the majority of the Board of Pharmacy Compounding Committee meetings for the past year.

As it became clearer that new rules and regulations would be forthcoming in the state of Florida, the pharmacy department has been working with consultants, compounding experts, and design firms to find a path forward for a compliant sterile compounding area based on the forthcoming rules. Until the final proposed Board of Pharmacy rule was released in April 2014, a final draft for construction review was not achievable.

29. Furthermore a proposed new general USP Chapter 800, Hazardous Drugs-Handling in Healthcare Settings, was published in the Pharmacopeial Forum 40(3) [May-June] edition. Since St. Mary's is a pediatric oncology hospital that is a participating member of the Children's Oncology Group, this USP chapter has significant impact on the hospital's future sterile compounding operations.

30. It is not only St Mary's goal to comply with existing USP 797 requirements but also to comply with future proposals found in USP 800 as well as possible updates to USP 797 and other guiding compounding practice principles. St. Mary's intends to be a leader in implementing the principles and techniques that are outlined in USP 800.

31. The implementation time challenges this hospital faces are unique as a result of both the building's age and design and the need to create a compounding suite that will be compliant with current and future regulations.

32. To become fully compliant with USP 797 and the Amended Rule, St. Mary's has begun a major renovation of its pharmacy.

33. Particular planning diagrams are required to meet the USP 797 functional flows. USP 797 includes a description of a series of spaces and adjacencies which must be met to have a fully compliant department. Among other spaces are:

- Negative pressure work room
- Negative pressure ante room

- Negative pressure buffer room
- Positive pressure ante room
- Positive pressure buffer room

34. Somewhat adjacent to the existing pharmacy is a portion of the current hospital building that was constructed prior to 1979 and significantly renovated in 1980. The structure of this space is primarily a single story, steel and concrete frame construction. More importantly, a large part of this area is unencumbered with existing load bearing masonry walls and therefore more flexible. As this space was also an addition, there are existing columns which pose challenges.

35. The current compounding operations encompass +/- 725 gsf. The newly planned compounding operation is approximately 1,143 gsf or a 57% increase in size. The need for this increase is primarily due to the planning requirements of USP 797 and the functional operations/volume of the department.

36. These spaces work together to help form a compliant compounding area – both negative and positive pressure – for the department. Attached hereto as Exhibit B is a diagram of the new space.<sup>5</sup> Attached as Exhibit C is a diagram that shows the entire pharmacy after completion, including the new space. Even though it will be located in a structure built in 1938, this will be a state-of-the-art compounding pharmacy.

37. The new pharmacy will meet the ventilation requirements posed by USP 797 and other codes in two fundamental ways. First, the project is being designed with a new, pharmacy-specific air handler. This air handler will allow the pharmacy compounding areas to have the correct amount of air changes, correct temperature control and correct humidity control. Secondly, this project is being designed with HEPA filtration and low wall return air ducts. The

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<sup>5</sup> This is a six-page exhibit that shows the ‘before’ and ‘after’ for each of the three phases of construction described further below.

HEPA filtration will be located at the ceiling diffusers and provide HEPA filtered air. The air will travel downward and be returned at the low wall return ducts.

38. These changes are needed because the existing air handling equipment in both the existing pharmacy and the targeted new area does not have sufficient resources to provide both the quantity of air, temperature of air and filtration of air required to meet the full requirements of USP 797.

39. It is important to understand that this plan does not cause any disruption to existing services.

40. The existing department is best suited if it is NOT renovated in place but, rather, is located in a portion of the building better able to be altered to suit the needs of the referenced space planning elements. This strategy allows for a more constructible solution as well as helps minimize disruption to current pharmacy operations.

41. The intent of this design plan is to allow the existing pharmacy to remain in operation while the new pharmacy is being constructed. Upon completion of the new pharmacy and acceptance by the local and state jurisdictions, the old pharmacy compounding operations will cease and the new pharmacy will begin operation.

42. In addition to constructing the new pharmacy in a separate location, and in order to minimize disruption, this project is being delivered in a 'phased' manner. This project will consist of three primary phases.

43. Phase 1: This phase will allow the pharmacy to be constructed outside of its current department boundary by reallocating storage space to the central sterile department. In turn, the central sterile department will vacate a portion of its existing storage area to allow the pharmacy to locate there.

44. Phase 2: Once the reallocation of storage spaces in Phase 1 has been completed, Phase 2 can begin. Phase 2 is the primary phase for the project and is depicted on Exhibit B. In this phase the new compounding areas will be constructed as well as the new support spaces and equipment including: the new air handling equipment, new ductwork distribution, new electrical service distribution, new plumbing, etc. Phase 2 is currently scheduled to be completed at the end of March 2015. When Phase 2 is completed, all sterile compounding will be moved to the new, USP 797 compliant negative pressure area.

45. Phase 3: Once the new compounding areas have been accepted by the State and local building department, the existing pharmacy compounding operations will be converted to storage. This will include box break-down and general and refrigerated storage. This is scheduled to be completed June 5, 2015.

46. A project schedule is attached as Exhibit D.

47. Because this project is located in a licensed hospital, it must not only go through various levels of review by the local jurisdictions in Palm Beach County; it is also subject to extensive regulatory oversight by the Florida Agency for Health Care Administration (“AHCA”). AHCA’s oversight is more extensive than that which a retail pharmacy not located in a hospital must undergo. AHCA’s initial review of the construction documents occurred on June 5, 2014. Some additional revisions were requested and those are in process but will hopefully not affect the project schedule.

48. In addition, AHCA must review the construction of each phase of the project during construction. AHCA must approve the final construction of each phase before the next phase can begin. This is separate from the local Certificate of Occupancy process.

49. AHCA inspections are done according to schedules set by the agency and generally occur on a three-week rotation. Consequently, work schedules are significantly affected by the schedules of the inspectors.

50. Of the total time for this project—260 days—65 days have been allocated just for the reviews by the various regulatory agencies that have jurisdiction. This contributes to the length of time for which this temporary waiver is requested.

51. The total cost of this project is in excess of two million dollars.

**THE PURPOSE OF THE REGULATIONS WILL BE ACHIEVED  
WHILE THE TEMPORARY WAIVER IS IN PLACE**

52. Considerable space in this Petition has been devoted to a description of the facilities and quality assurance processes in place at St. Mary's to assure that high quality sterile products are produced in a safe manner at all times.

53. As noted above, upgrades have been made to the existing sterile compounding area. The pharmacy recently passed a Department of Health Sterile Compounding Survey with zero deficiencies. A copy of that survey is attached as Exhibit E. As noted above, the hospital has implemented Simplifi 797®.

54. Various options regarding the renovation project have been considered. One of the reasons the option described in this Petition was chosen was because it allows the existing sterile compounding services to safely continue uninterrupted until the date the new space can be occupied.

55. St. Mary's has been preparing sterile compounded products for decades. There has never been an incident in which a contaminated product came out of the pharmacy. There has never been an incident in which patients or staff were endangered as a result of the sterile compounding practices of the hospital.

56. Because of the phasing and the construction plan that has been implemented, all of the existing safeguards will stay in place throughout construction and beyond.

**APPLICATION OF THE AMENDED RULE WITHOUT THE TEMPORARY  
WAIVER WOULD CREATE A SUBSTANTIAL  
HARDSHIP AND VIOLATE PRINCIPLES OF FAIRNESS**

57. Section 120.542, Florida Statutes authorizes and provides the standards for granting waivers. Subsection (2) states:

(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.

58. This waiver request meets both the hardship and fairness tests.

59. Significant patient displacement and harm would occur if sterile compounding is no longer allowed to take place at St Mary's. Sterile compounding is a mission critical process for the patients cared for at this large and very busy institution. Without the capabilities to continue compounding services in the interim period during the construction of a new sterile compounding area St. Mary's will be unable to continue the same level of services, many of which are not otherwise available in the area.

60. Outsourced compounded products have a role in modern pharmacy practice. Moving from an outsource product mix of less than 1% to 100% is not a practice model that can meet the diverse patient care needs that St. Mary's serves, especially in a pediatric hospital serving the pediatric oncology needs of a large geographical area. Many pediatric oncology

patients also require medical attention and as a result of the chemotherapy regimen are they are often dependent on injectable medications as the preferred route of administration.

61. For various acute conditions and intensified care post chemotherapy regimens the lack of immediate on demand sterile compounding capabilities would be a significant hardship for patients and families. Since most outsourced products are geared for standard adult patient types, the turnaround time for outsourcing facilities would not meet the standard of care that these patients require. Furthermore, many compounding facilities are not located in Florida and even when they are licensed through the Florida Board of Pharmacy to distribute compound pharmaceuticals, they are rarely if ever inspected by Florida pharmacy inspectors. Now that the FDA has begun inspecting these compounding facilities, the quantity of FDA warning letters and citations has grown.

62. Additionally, St. Mary's is often the recipient of patients transferred in need of specialty medications and physician management as a result of specialty practices such as hematology, trauma, stroke and surgical services. The majority of St. Mary's sterile compounding products are geared towards specific patient needs including neonatal, pediatric, pediatric open heart, trauma and other critical patient types not commonly standardized with market available products.

63. In addition, even if all the needed products could be obtained in a timely manner (which they cannot), to do so would needlessly increase the cost of health care when a temporary waiver will solve the problem.

64. While every compounding pharmacy will have to be compliant with the Amended Rule, the size of the pharmacy operation at St. Mary's, the wide array of uniquely compounded products needed in a timely manner, the time it takes to renovate a pharmacy located in a

hospital as opposed to a pharmacy not regulated by AHCA and the unique challenges presented because of the age, configuration and construction of this facility, truly means that an October 1, 2014 effective date for the Amended Rule affects St. Mary's and, more importantly, its patients, in a manner significantly different from the way it affects others.

### CONCLUSION

65. The third and final phase of the pharmacy construction project at St. Mary's is scheduled to be completed (including final inspections) on June 5, 2015. In order to provide a little room for the variables associated with a project of this size, St. Mary's is requesting a waiver of the effective date of the Amended Rule until July 1, 2015. St. Mary's commits to advising the Board of Pharmacy if the project is completed sooner and would stipulate that this temporary waiver will end when that third phase is completed. St. Mary's further stipulates as a condition of this waiver that it will continue to comply with the version of Florida Administrative Code Rule 64B16-27.797 in effect prior to October 1, 2014 and will be accountable for any violations of that rule.

66. This temporary waiver is truly critical to St. Mary's and its patients. To emphasize the importance of this request, in addition to the signature of undersigned legal counsel, this Petition is also signed by Davide Carbone, Chief Executive Officer of St. Mary's and Sheldon I. Lefkowitz, R.Ph., M.S. the pharmacy consultant of record and the Director of Pharmacy at St. Mary's to further attest to the veracity of the statements made herein and to underscore the critical need for this temporary waiver. It is also signed by Tom Chapuis, the project architect with HDR, Inc. in Tampa, Florida as the project architect to attest to the design and construction aspects of this Petition.

and Sheldon I. Lefkowitz, R.Ph., M.S. the pharmacy consultant of record and the Director of Pharmacy at St. Mary's to further attest to the veracity of the statements made herein and to underscore the critical need for this temporary waiver. It is also signed by Tom Chapuis, the project architect with HDR, Inc. in Tampa, Florida as the project architect to attest to the design and construction aspects of this Petition.

RESPECTFULLY SUBMITTED this 10<sup>th</sup> day of July 2014.



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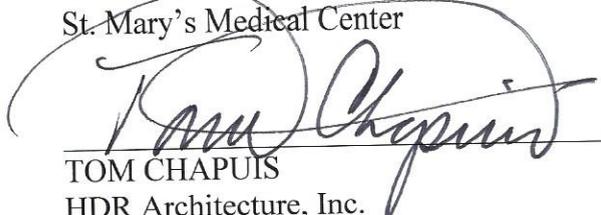
ATTESTED TO BY:

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DAVIDE CARBONE, CEO  
St. Mary's Medical Center

\_\_\_\_\_  
Date

\_\_\_\_\_  
SHELDON I. LEFKOWITZ, R.Ph., M.S.  
Consultant of Record/Director of Pharmacy  
St. Mary's Medical Center

\_\_\_\_\_  
Date

  
\_\_\_\_\_  
TOM CHAPUIS  
HDR Architecture, Inc.

\_\_\_\_\_  
Date

Project Architect (as to those portions of this Petition dealing with design and construction matters)

7.2.2014

RESPECTFULLY SUBMITTED this \_\_\_\_\_ day of July 2014.

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ATTESTED TO BY:

  
\_\_\_\_\_  
DAVIDE CARBONE, CEO  
St. Mary's Medical Center

7-9-2014  
\_\_\_\_\_  
Date

  
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SHELDON I. LEFKOWITZ, R.Ph., M.S.  
Consultant of Record/Director of Pharmacy  
St. Mary's Medical Center

7-9-2014  
\_\_\_\_\_  
Date

\_\_\_\_\_  
TOM CHAPUIS  
HDR, Inc.  
Project Architect (as to those portions of this Petition dealing with design and construction matters)

\_\_\_\_\_  
Date

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that the original of the foregoing has been furnished by hand delivery this 10<sup>th</sup> day of July, 2014 to Jaime Briggs, Agency Clerk, Office of the General Counsel, Florida Department of Health, 2585 Merchants Row Blvd., Suite 110, Tallahassee, Florida 32399 and a copies have been provided by hand delivery to:

Patrick Kennedy, M.A.  
Executive Director  
Florida Board of Pharmacy  
Florida Department of Health  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, Florida 32399

David Flynn  
Assistant Attorney General  
Office of the Attorney General  
The Capitol, PL-01  
Tallahassee, Florida 32399-1050

Joint Administrative Procedures Committee  
Room 120, The Holland Building  
Tallahassee, Florida 32399-1300

  
\_\_\_\_\_  
Michael J. Glazer

## Notice of Proposed Rule

### DEPARTMENT OF HEALTH

#### Board of Pharmacy

RULE NO.:       RULE TITLE:

64B16-27.797   Standards of Practice for Compounding Sterile Preparations (CSPs)

PURPOSE AND EFFECT: The Board proposes the rule amendment for the specific purpose of determining the necessity of incorporating and setting as the minimum standards to follow when compounding sterile products, the following chapters of the United States Pharmacopeia: 797; 1160; 71; 85; 731; and 1231.

SUMMARY: The following chapters of the United States Pharmacopeia will be incorporated into the rule as the minimum standards to follow when compounding sterile products: 797; 1160; 71; 85; 731; and 1231.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. Specifically, the Board considered that 21 U.S.C. §353a, as amended by Public Law Number 113-54 (November 27, 2013), requires compounding to comply with the applicable chapters of the United States Pharmacopeia (USP) on compounding. Therefore, any economic impact is a direct result of federal mandates. Further, the Board considered that all institutional pharmacies are already mandated to comply with the compounding provisions that are being incorporated. Finally, the Board considered that since approximately 2008, Board rule requirements essentially required compliance with the provisions of the USP which are being incorporated. The Board considered that having to come into compliance with laws and rules that are already effective is not an economic impact that is applicable for consideration for this proposed rule amendment. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.0155, 465.022 FS.

LAW IMPLEMENTED: 465.0155, 465.022 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Tammy Collins, Acting Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of Rule 64B16-27.797 follows. See Florida Administrative Code for present text.)

64B16-27.797 The Standards of Practice for Compounding Sterile Products Preparations (CSPs).

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) Adoption of the United States Pharmacopoeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopoeia (USP):

- (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
- (b) Chapter 1160, Pharmaceutical Calculations in Prescription Compounding;
- (c) Chapter 71, Sterility Tests;
- (d) Chapter 85, Bacterial Endotoxins Test;
- (e) Chapter 731, Loss on Drying; and
- (f) Chapter 1231, Water for Pharmaceutical Purposes.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopoeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A copy of the USP chapters referenced in this rule may be examined and inspected, but not copied, at the office of the Board of Pharmacy in Tallahassee, Florida. A subscription to all relevant chapters is available for purchase at [www.uspnf.com](http://www.uspnf.com).

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Federal Current Good Manufacturing Practices per 21 C.F.R. §§ 210.1 - 211.3.

(4) Specific Exceptions to the United States Pharmacopoeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see *Table 1*) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month.

(5) Additional Exceptions: The Board encourages the use of a Petition for Rulemaking to inform the Board of a request to add an additional exception to subsection (5) of this rule. A Petition for Rulemaking is controlled by Section 120.54(7) of the Florida Statutes.

(6) Rule Conflicts: On October 1, 2014 this rule shall control notwithstanding any rule to the contrary located throughout the provision of Chapter 64B16, F.A.C. Upon the effective date of this rule, the board will begin the process of repealing all rules that conflict with this rule.

THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10, 10-1-14.

The Board has determined that posting the material on the Internet would constitute a violation of the federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination at the Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254 and at the Department of State, Administrative Code and Register Unit, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-0250.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 11, 2014

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: December 20, 2013

## Notice of Change/Withdrawal

### DEPARTMENT OF HEALTH

#### Board of Pharmacy

RULE NO.:      RULE TITLE:

64B16-27.797   Standards of Practice for Compounding Sterile Preparations (CSPs)

#### NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 40, No. 48, March 11, 2014 issue of the Florida Administrative Register.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee and input at the hearing. The changes are as follows:

1. The following language will be added to the end of the paragraph located above subsection (2):

The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3254 and at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250.

2. Subsection (3) shall now read as follows:

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. § 351 (2012), adopted and incorporated herein by reference, available at [http://www.flrules.org/Gateway/reference.asp?No=Ref-\\_\\_\\_\\_\\_](http://www.flrules.org/Gateway/reference.asp?No=Ref-_____) and 21 C.F.R. Parts 210 and 211 (2011), adopted and incorporated herein by reference, available at [http://www.flrules.org/Gateway/reference.asp?No=Ref-\\_\\_\\_\\_\\_](http://www.flrules.org/Gateway/reference.asp?No=Ref-_____).

3. For subsection (4), subparagraph (c) will be added and shall read as follows:

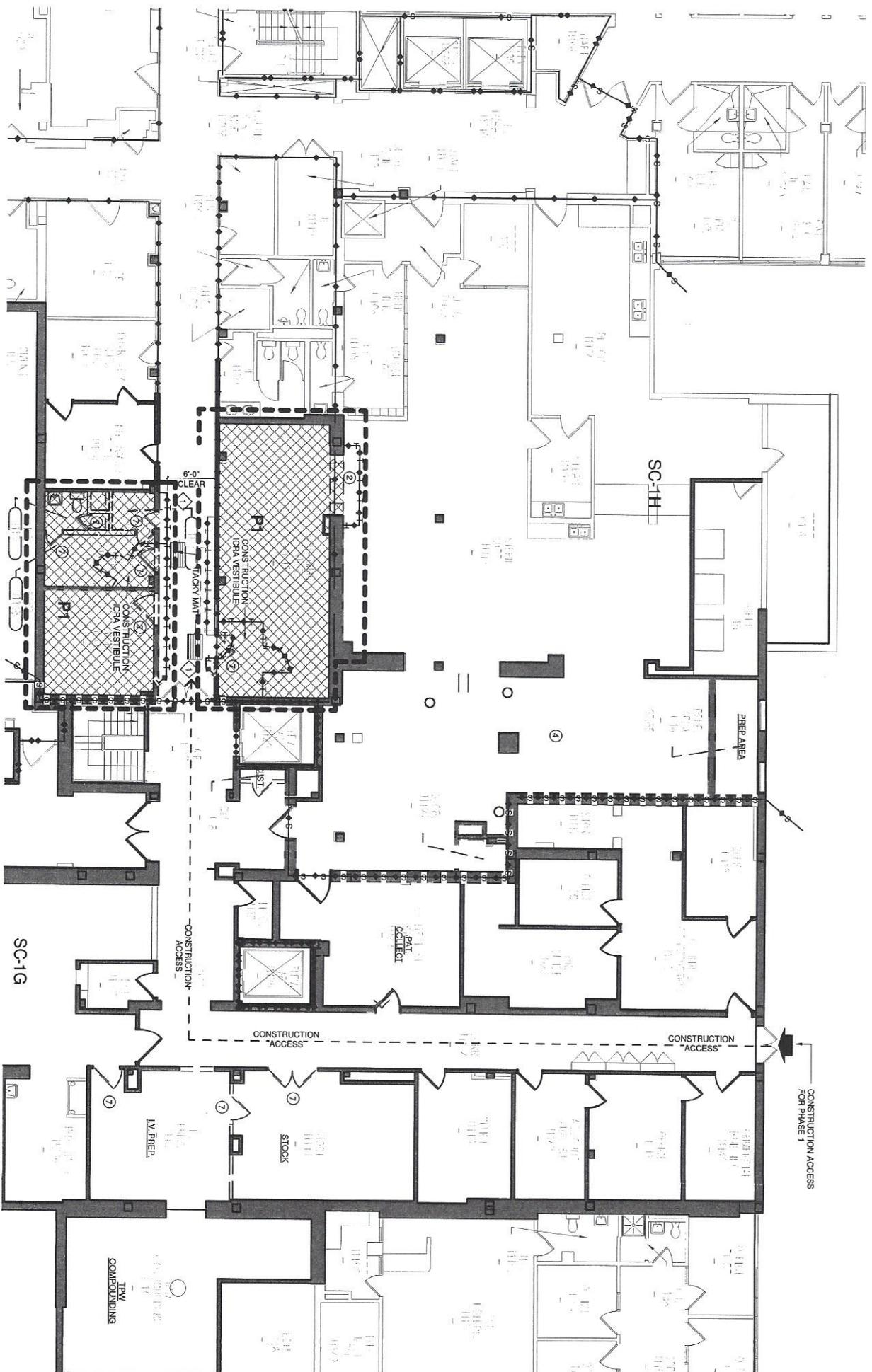
(c) USP Chapter 797 provides as follows in the “Facility Design and Environmental Controls” section: “An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended.” Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quotes as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

4. Subsections (5) and (6) shall be removed in their entirety.

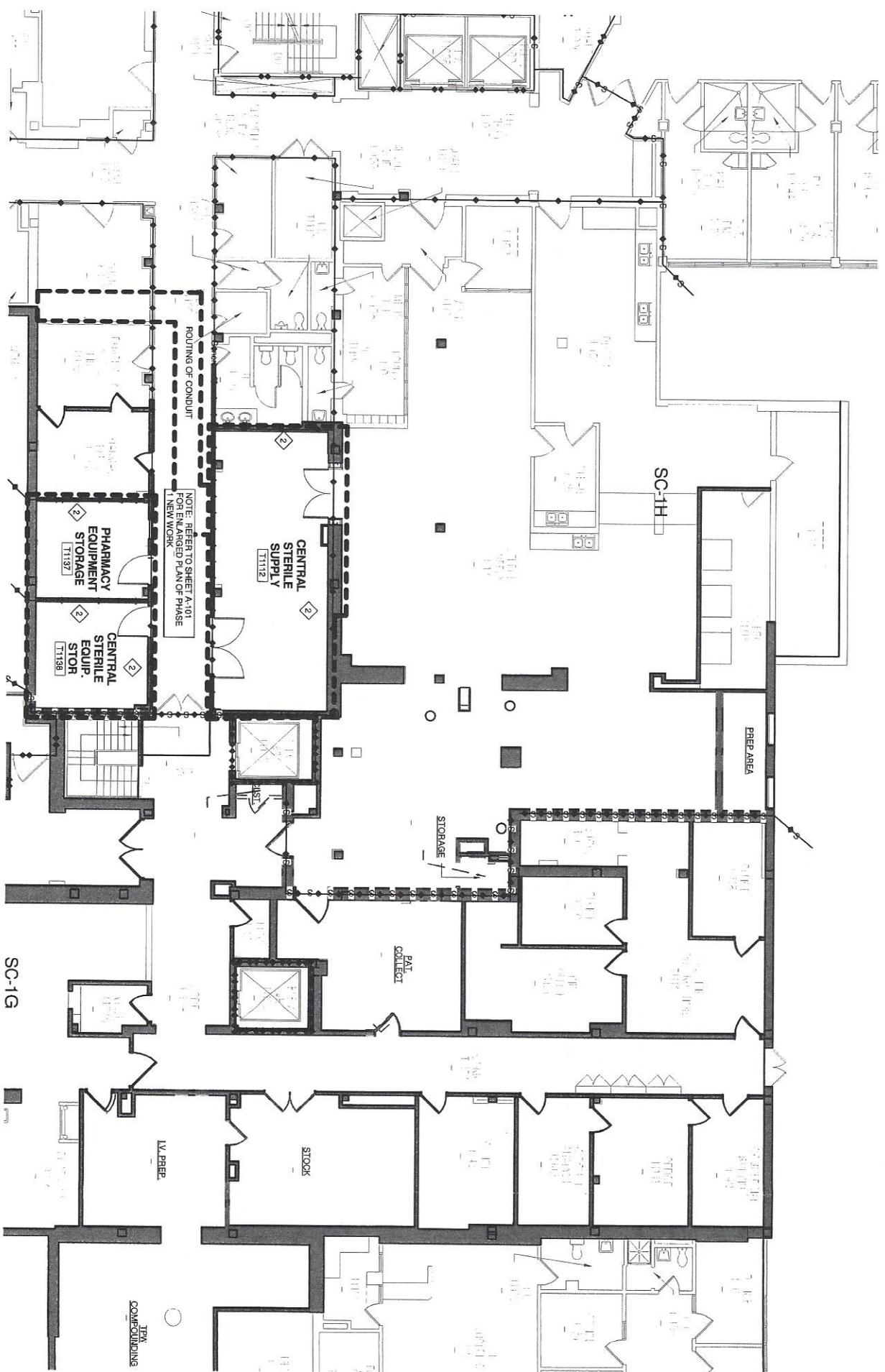
5. The language that reads “THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014” shall now read as follows: “PROPOSED EFFECTIVE DATE: OCTOBER 1, 2014.”

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Patrick Kennedy, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

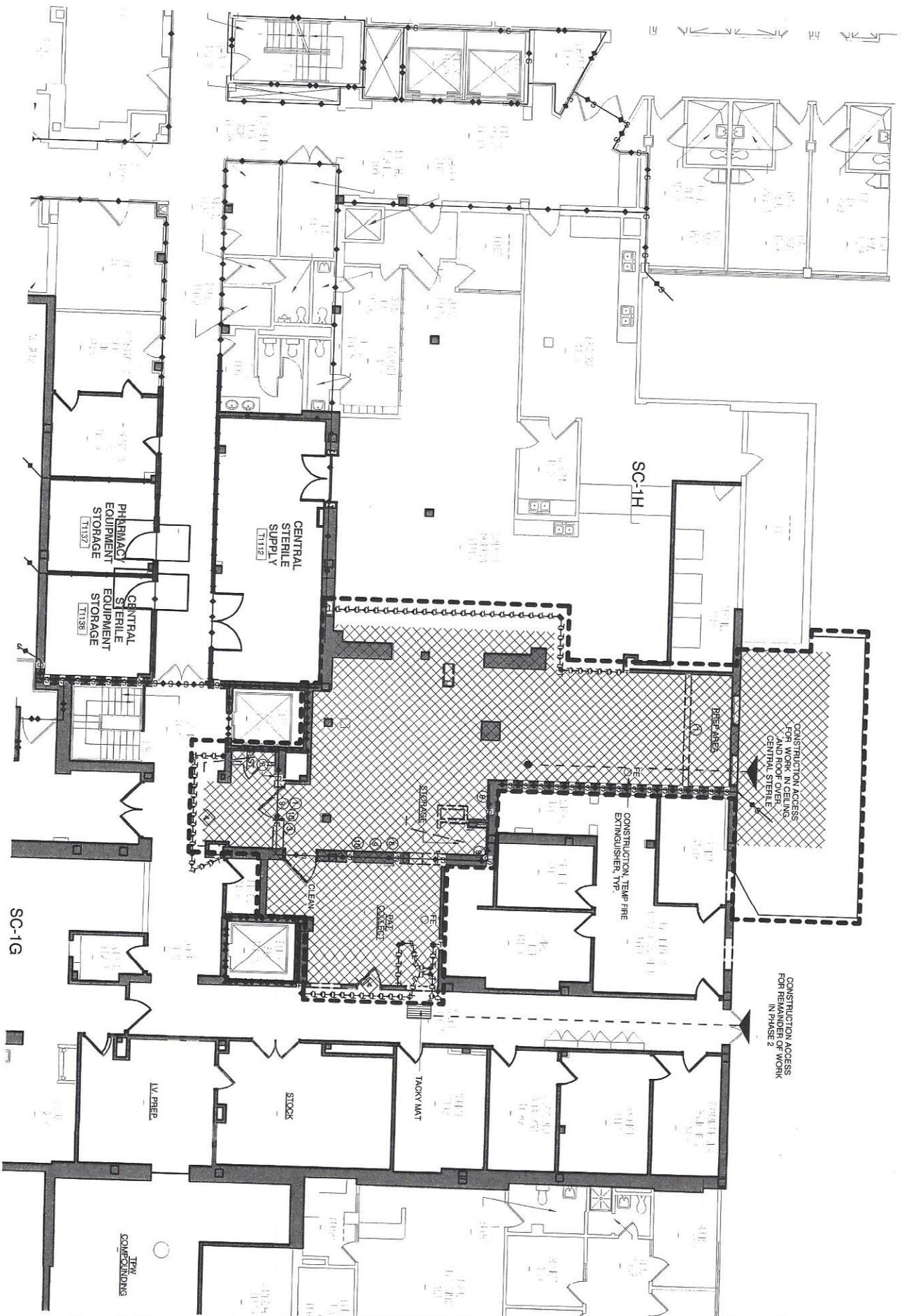
# PHASE 1 BEFORE



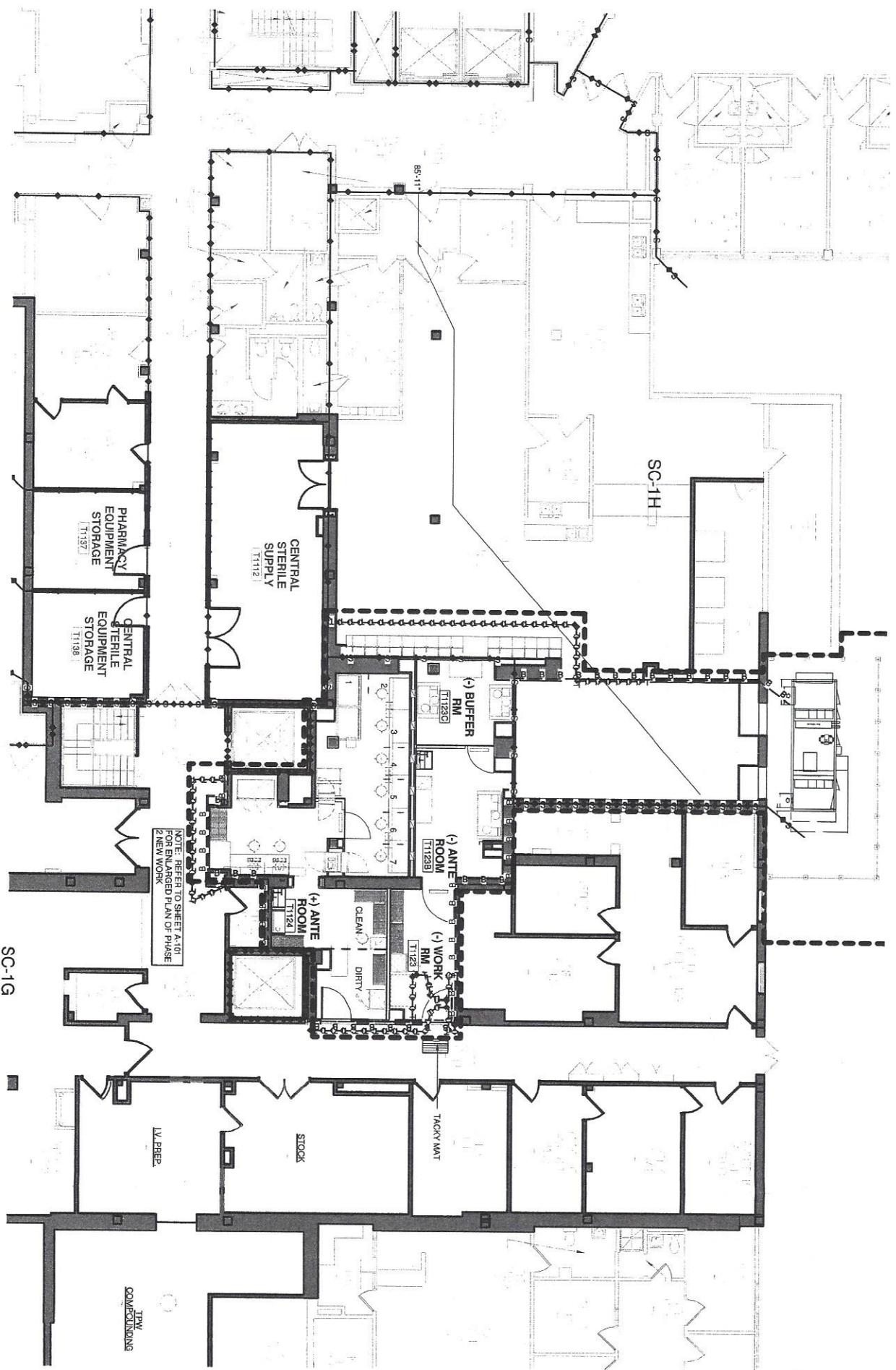
# PHASE 1 AFTER



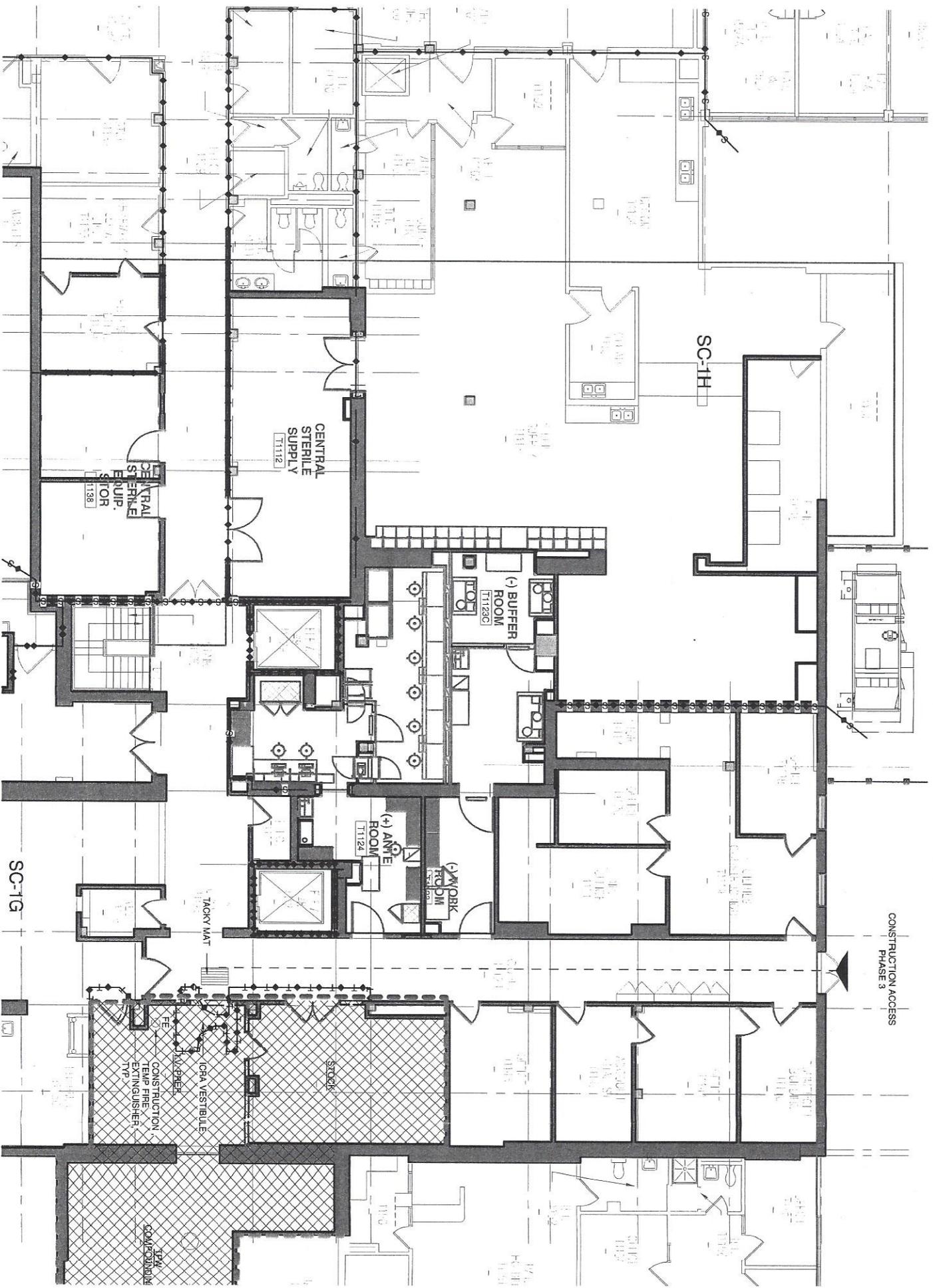
# PHASE 2 BEFORE



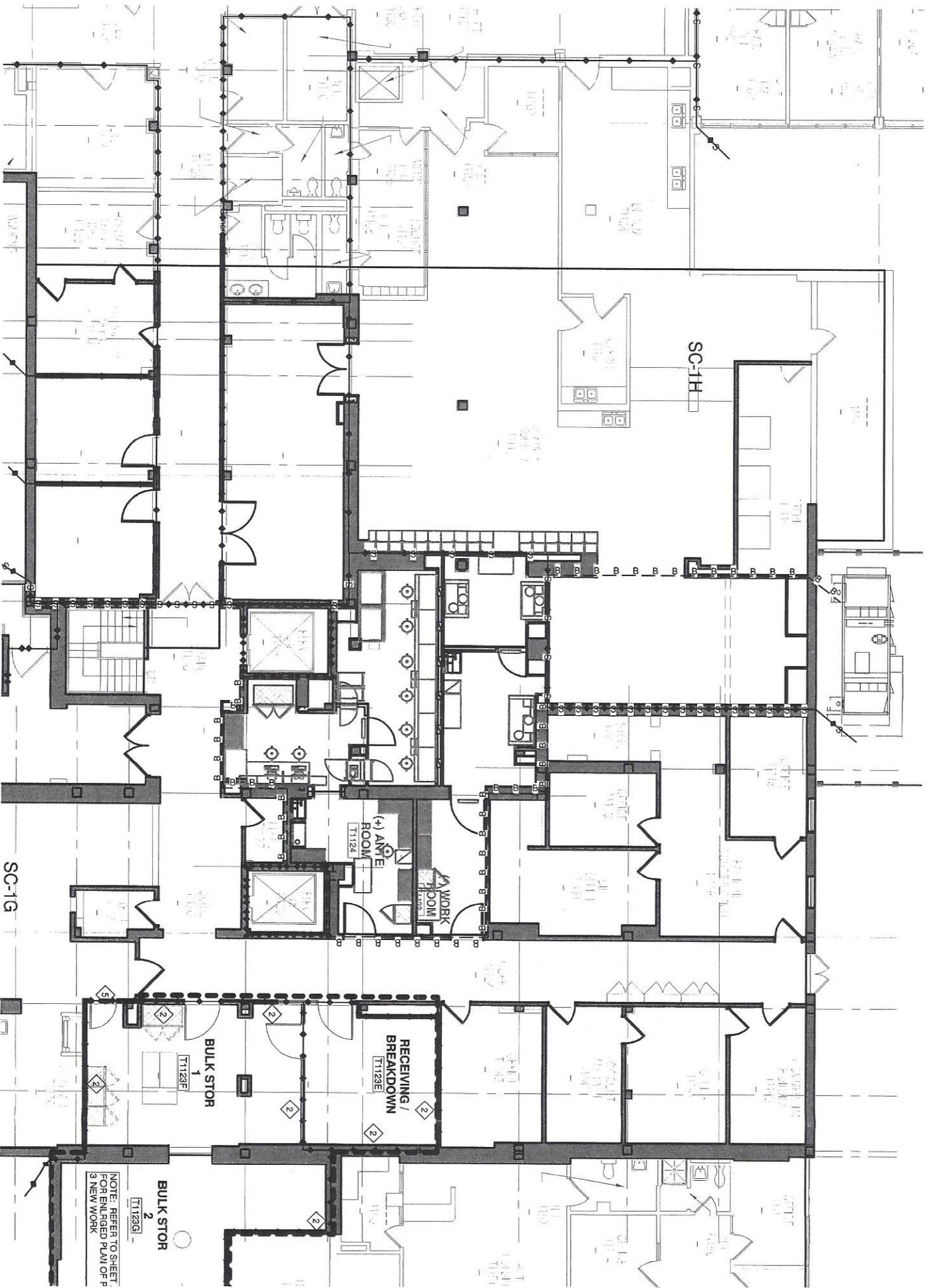
# PHASE 2 AFTER



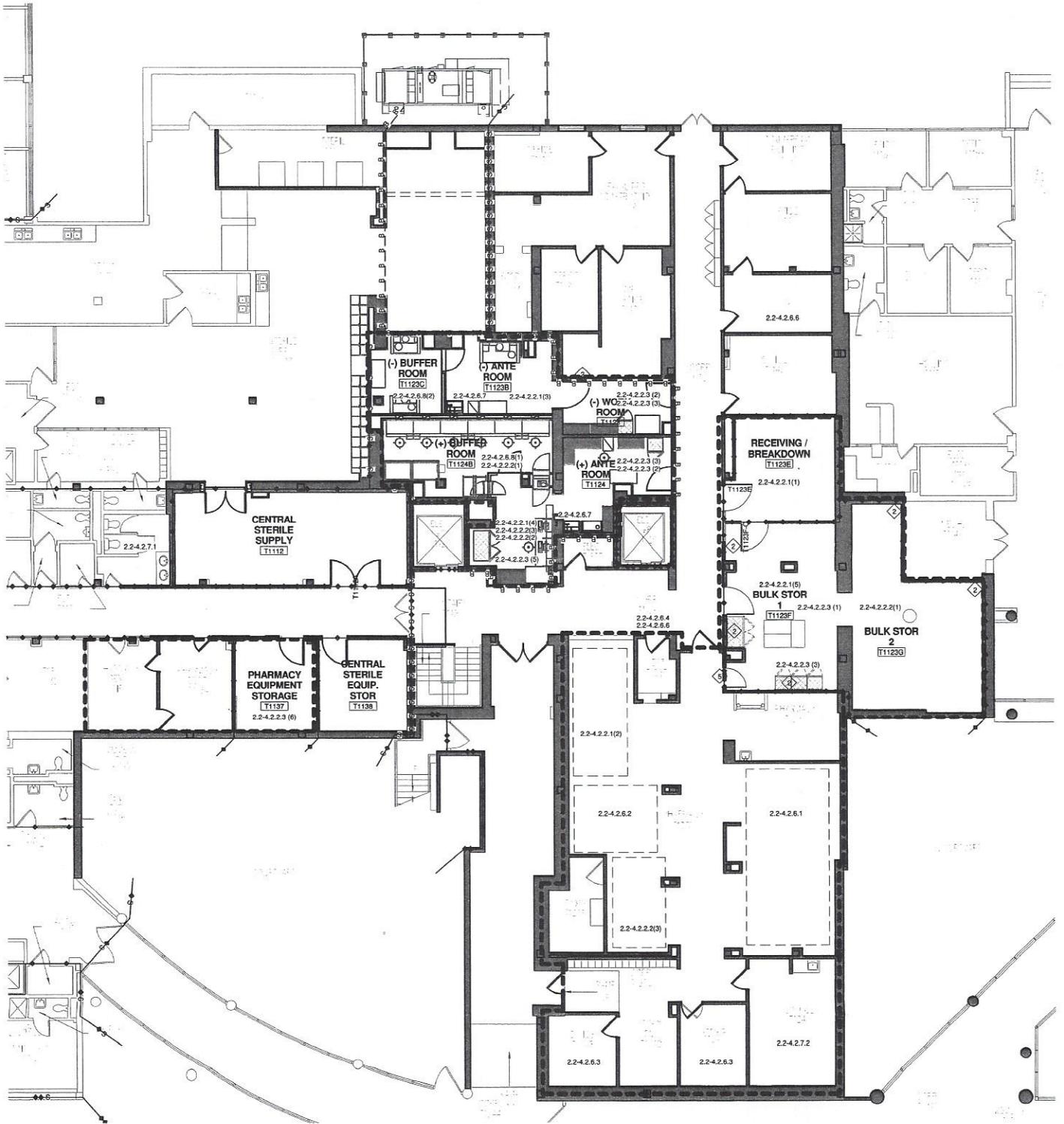
# PHASE 3 BEFORE



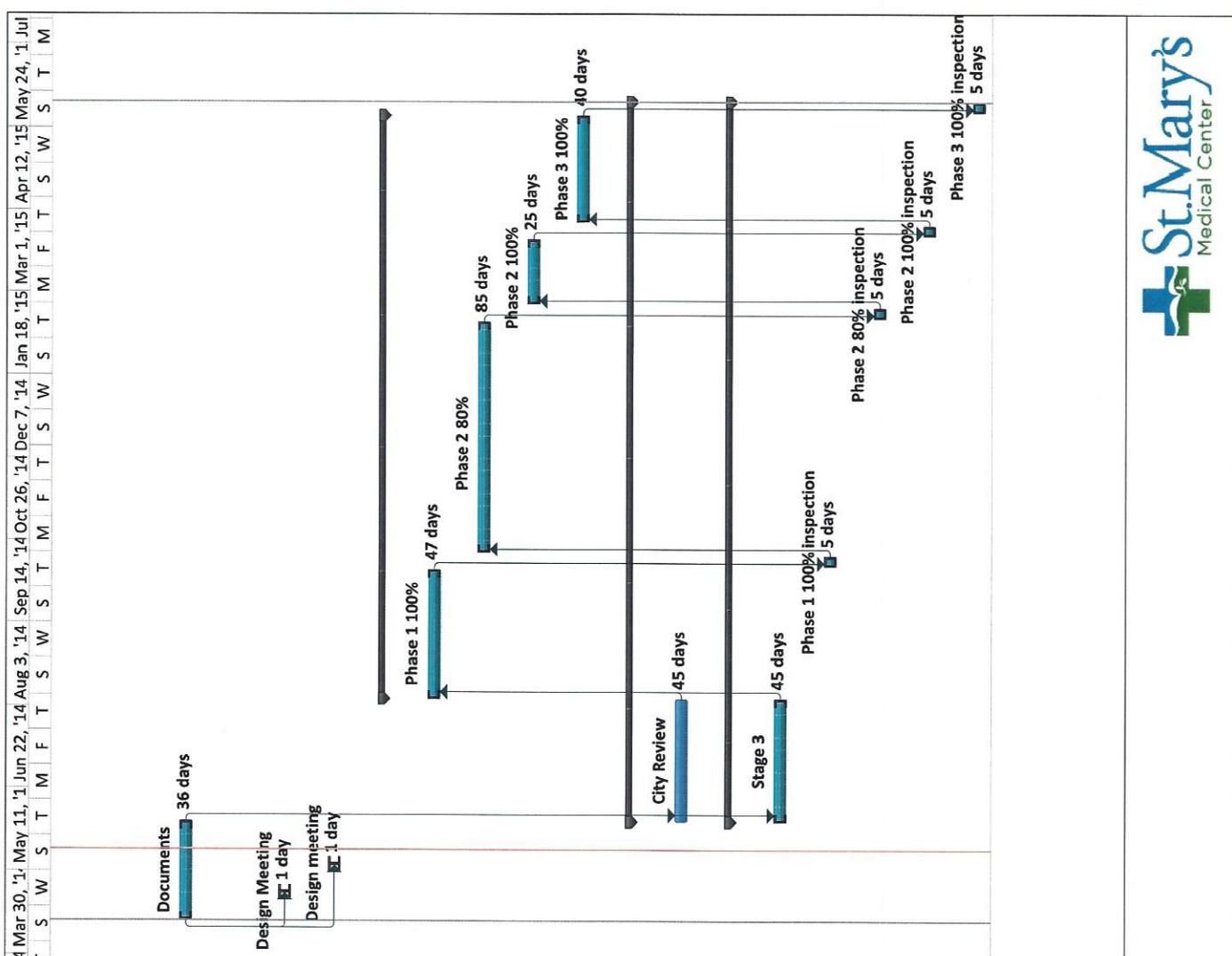
# PHASE 3 AFTER



# RENOVATED PHARMACY



ID	Task Name	Duration	Start	Finish
1				
2	<b>SMMC Pharmacy</b>			
3	Documents	36 days	Wed 4/16/14	Wed 6/4/14
4	Meetings	11 days	Wed 4/30/14	Wed 5/14/14
5	Design Meeting	1 day	Wed 4/30/14	Wed 4/30/14
6	Design meeting	1 day	Wed 5/14/14	Wed 5/14/14
7	Construction	212 days	Thu 8/7/14	Fri 5/29/15
8	Phase 1 100%	47 days	Thu 8/7/14	Fri 10/10/14
9	Phase 2 80%	85 days	Mon 10/20/14	Fri 2/13/15
10	Phase 2 100%	25 days	Mon 2/23/15	Fri 3/27/15
11	Phase 3 100%	40 days	Mon 4/6/15	Fri 5/29/15
12	AHJ	262 days	Thu 6/5/14	Fri 6/5/15
13	City Review	45 days	Thu 6/5/14	Wed 8/6/14
14	AHCA	262 days	Thu 6/5/14	Fri 6/5/15
15	Stage 3	45 days	Thu 6/5/14	Wed 8/6/14
16	Phase 1 100% inspection	5 days	Mon 10/13/14	Fri 10/17/14
17	Phase 2 80% inspection	5 days	Mon 2/16/15	Fri 2/20/15
18	Phase 2 100% inspection	5 days	Mon 3/30/15	Fri 4/3/15
19	Phase 3 100% inspection	5 days	Mon 6/1/15	Fri 6/5/15





STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES

Florida  
HEALTH

WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

File # 10045

Insp # 120578

ROUTINE  CHANGE LOC  NEW  CURRENTLY NOT OPERATING  CHANGE OWNER

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT TENET ST MARY'S, INC		PERMIT NUMBER 17998	DATE OF INSPECTION 8/21/2013
DOING BUSINESS AS ST. MARY'S HOSPITAL		DEA NUMBER BT7347328	PRESCRIPTION DEPARTMENT MANAGER SHELDON I LEFKOWITZ
STREET ADDRESS 901 45TH STREET		TELEPHONE # (561) 650-6014	EXT.
CITY WEST PALM BCH	COUNTY 60	STATE/ZIP 33407	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 2193
COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE
see attached list			
SATISFACTORY    N/A    YES    NO			

High-Risk Level CSPs

1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i)4.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(i), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Medium and Low-Risk Level CSPs

4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Barrier Isolator or Compounding Environment

6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Antineoplastic Drugs (Cytotoxins)

9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

General Requirements

12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Remarks: THIS FACILITY CURRENTLY ENGAGES IN LOW, MEDIUM AND HAZARDOUS (CHEMO) STERILE COMPOUNDING. HEPATEST INC. COMPLETED A CERTIFICATION OF THE PRIMART ENGINEERING EQUIPMENT ON 5/17/13 AND FOUND THE BARRIER ISOLATOR AND 4 LAMINAR FLOW HOODS COMPLIANT AT ISO 5 LEVELS. COMPREHENSIVE INC OF CARY, NC CERTIFIED THE BUFFER ROOM AND ANTE ROOM AT ISO 7 & ISO 8 LEVELS ON 1/28/13. CURRENT CERTIFICATION WAS COMPLETED ON 8/4 & 8/5 2013. ALL PERSONNEL AUTHORIZED TO COMPOUND HAVE COMPLETED MEDIA FILL TESTS AND COMPETANCY EXAMS. CLEANING LOGS FOR FLOORS, WALLS, CEILINGS, HOODS AND SURFACES ARE WELL DOCUMENTED AS WELL AS TEMPERATURE, HUMIDITY AND PRESSURE DIFFERENTIALS.

ALL DEFICIENCIES FROM THE PREVIOUS INSPECTION ON 1/7/13 HAVE BEEN CORRECTED AS FOLLOWS:  
-CHEMO COMPOUNDS ARE NOW PREPARED IN A BARRIER ISOLATOR UNDER NEGATIVE PRESSURE AND VENTED TO THE OUTSIDE  
-ALL PERSONNEL WERE PROPERLY GOWNED AND GARBED WHILE IN THE BUFFER ROOM.  
-ALL REQUIRED POLICY AND PROCEDURES WERE OBSERVED.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT SHELDON LEFKOWITZ RPH

Institutional Representative  
INV 797 Revised 12/12, 12/11 Created 8/11

08-21-2013  
Date

Investigator/Sr. Pharmacist Signature

ID wi95

FILED  
DEPARTMENT OF HEALTH  
DEPUTY CLERK  
CLERK *Angel Sanders*  
DATE *July 23, 2014*

STATE OF FLORIDA  
BOARD OF PHARMACY

RECEIVED  
DEPARTMENT OF HEALTH  
14 JUL 23 PM 3:08  
OFFICE OF THE CLERK

IN RE: PETITION FOR TEMPORARY WAIVER  
FLORIDA ADMINISTRATIVE CODE RULE 64B16-27.797

BY: TENET GOOD SAMARITAN, INC. d/b/a/ GOOD SAMARITAN  
MEDICAL CENTER

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Tenet Good Samaritan, Inc. d/b/a Good Samaritan Medical Center ("Good Samaritan"), by and through its undersigned attorneys and pursuant to section 120.542, Florida Statutes and Florida Administrative Code Chapter 28-104, hereby requests a temporary waiver of a portion of Florida Administrative Code Rule 64B16-27.797, and as grounds therefore would show:

1. The Petitioner is Tenet Good Samaritan, Inc. d/b/a Good Samaritan Medical Center ("Good Samaritan"), located at 1309 N. Flagler Dr, West Palm Beach, Florida 33401. The contact information for Good Samaritan for purposes of this Petition is that of its undersigned counsel.

**INTRODUCTION**

2. On March 11, 2014, the Florida Board of Pharmacy published amendments to Florida Administrative Code Rule 6416-27.797 in a Notice of Proposed Rule in the Florida Administrative Register (hereafter referred to as "the Amended Rule"). The Board of Pharmacy adopted some additional changes to the Amended Rule at its June 10, 2014 meeting.<sup>1</sup> While the amendments have not been formally adopted as of the filing of this Petition, no challenges to the Amended Rule have been filed and it is anticipated that the rule will be filed for adoption on or before the effective date of the amendments. That effective date is October 1, 2014. A copy of the most recent version of the Amended Rule is attached as Exhibit A.

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<sup>1</sup> Those changes are not material for purposes of this Petition.

2205/17794

3. The Amended Rule incorporates standards for compounding sterile hazardous products as contained in certain chapters of the United States Pharmacopiea ("USP") and most significantly for purposes of this Petition, Chapter 797 of the USP entitled: "Pharmaceutical Compounding-Sterile Preparations" (hereafter referred to as "USP 797"). This Amended Rule implements sections 465.0155 and 465.022, Florida Statutes.

4. Prior to the effective date of the Amended Rule, it has been acceptable for a pharmacy to compound sterile hazardous preparations in a barrier isolator that is properly vented and placed and operated in accordance with the manufacturer's guidelines but is not located in a negative pressure room.<sup>2</sup>

5. However, under USP 797 as incorporated in the Amended Rule, the compounding of sterile hazardous preparations will have to occur in a negative pressure room unless the pharmacy only prepares a "low volume of hazardous drugs."<sup>3</sup> Good Samaritan's monthly volume far exceeds the "low volume" definition. USP 797 includes other physical plant requirements as well.

6. The purpose of this Petition is to seek a temporary waiver of the requirement that Good Samaritan compound in a negative pressure environment that meets all of the USP 797 requirements while it completes the necessary renovations to create a new compliant space. As described below, the renovation process is underway but additional time beyond October 1, 2014 is needed. The anticipated date for project completion is July 31, 2015 and a temporary waiver is requested until September 1, 2015 or sooner of the project is completed earlier. Until completed, Good Samaritan will continue to compound in the manner that complies with the Florida compounding rule that has been in place for many years.

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<sup>2</sup> This interpretation of the then-existing rule was confirmed at the meeting of the Board on October 8, 2013.

<sup>3</sup> The Amended Rule defines "low volume" as less than 40 doses per month.

## GOOD SAMARITAN AND ITS PHARMACY

7. Good Samaritan Medical Center was first built in 1920 and includes The Cancer Institute at Good Samaritan Medical Center as part of its 333 licensed beds. Within its acute care bed complement, Good Samaritan dedicates 34 beds to adult oncology. The hospital also has 22 intensive care and 7 Level II NICU beds. With numerous expansions and additions over the years, the hospital now occupies over 460,000 gsf. Good Samaritan has 17 operating rooms, two Philips Allure FD 20 and one Phillips Allure FD 10 interventional radiology suits, and more than 50 automated dispensing cabinet locations.

8. Good Samaritan provides medical, oncologic, surgical, obstetrical, cardiovascular, medical detox and emergency services to the greater West Palm Beach area. Good Samaritan's special services include a Primary Stroke Center, membership in the Advanced Neuroscience Network, Comprehensive Community Cancer Center, Gamma Knife PERFEXION, Medical Detox Unit, Level II neonatal intensive care unit, The Cardiac and Vascular Institute, Digestive Disease Institute and Bariatric Surgery. Good Samaritan also has a Sleep Disorders Center and diagnostic and imaging services for both inpatients and outpatients. Good Samaritan Medical Center is affiliated with more than 300 primary care, specialist, and sub-specialist physicians, and has more than 900 employees.

9. Good Samaritan is accredited by the Joint Commission and is the recipient of numerous awards including: 2013 Get with the Guidelines Stroke Gold Award, 2013 Get with the Guidelines Heart Failure Gold Plus Award, Comprehensive Community Cancer Center Award by the American College of Surgeons and the 2013 CIGNA Center of Excellence Award for COPD.

10. Good Samaritan is also part of the county wide disaster response team.

11. Because the sterile compounding pharmacy services provided at Good Samaritan are such an important part of the hospital's services to adult oncologic patients, some additional description of the Cancer Institute is warranted.

12. The Cancer Institute works with over 15 oncologic specialists and includes:

- 34 bed inpatient oncology unit
- Comprehensive Breast Center
  - 3-D Mammography
  - High-Definition MRI
  - Radioactive Seed Localization
  - Patient Navigator
- Mary Crowley Cancer Research Center
- Sari Asher Center for Integrative Cancer Care
- American Cancer Society Signature Programs
  - American Cancer Society's I Can Cope
  - American Cancer Society's Looking Good...Feel better
  - American Cancer Society's Man to Man
  - American Cancer Society's Reach to Recovery
- Robotic surgery
- Interventional Radiology
  - Transcatheter Arterial Chemoembolization ("TACE") procedures are performed at Good Samaritan in which beads "loaded" with chemotherapy are inserted. To our knowledge, Good Samaritan is the only place in Palm Beach County where this procedure is performed.
- Partnership with Florida Cancer Specialists and Research Institute

13. Specialized oncologic services include:

- Advanced Screening and Diagnostic Imaging
- Radiation Oncology
- Gamma Knife
- PERFEXION
- Oncologic Surgery
- TACE Procedures
- Intrathecal Chemotherapy Administration
- Parenteral Chemotherapy Administration

14. In 2013 Good Samaritan Medical Center cared for 33,800 adult and pediatric emergency department patients, approximately 8800 inpatient admissions, 6,600 surgical patients, 798 adult intensive care patients, 369 stroke alert patients, 1,700 acute dialysis patients and 1,200 adult oncology patients. A significant number of these patients receive some version

of a sterile compounded product during their course of treatment. The pharmacy compounded 3,700 chemotherapeutic doses in 2013.

15. The Good Samaritan pharmacy department is never closed. The pharmacy has been in several locations over the 94 year history of the hospital. Presently the pharmacy is within a 46 year old structure. The pharmacy was constructed in its current location in 1991. It occupies a total of approximately 3,345 gsf. However, only approximately 376 gsf (including the ante area and buffer room) is available and dedicated to sterile compounding. Following construction, the compounding areas will almost double in size when the ante room, buffer room, chemotherapy hood room and bulk IV supply area are counted.

16. The overall pharmacy is an open plan with private/semi-private rooms for the offices, consult, toilet, narcotic vault and compounding area. The existing compounding area is one large room that is sub-divided internally with shelving and a demarcation line so that one enters the ante area and then crosses a line embedded in the floor into the hood area. The chemotherapy hood, although self-contained, sits adjacent to one of the non-chemotherapy laminar flow hoods in the corner of the room. There are two 6' laminar flow hoods for non-chemotherapy compounding and one 4' Germ-Free glove box isolator used for chemotherapy compounding. Exhibit B is a series of diagrams showing the planned renovations. The first page includes a diagram of the current pharmacy.<sup>4</sup>

17. The pharmacy dispenses 2100 pharmaceutical products and reviews 1500 medication orders daily. Of the ten Florida hospitals owned by Good Samaritan's parent, Tenet Healthcare Corporation, Good Samaritan's pharmacy is the busiest with respect to sterile compounding of hazardous substances for adult patients. With 28 staff members and 22 FTEs, the pharmacy is responsible for nearly 3,200 hours of staff support for patient care every month.

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<sup>4</sup> The current floor plan is labeled "Phase I Demo."

18. The pharmacy also serves as an advanced practice site for pharmacy students with 10 students per year. The pharmacy department services a diverse hospital that has more than 50 automated dispensing cabinet locations. The department of pharmacy practices in tandem with high acuity services including adult emergency medicine, interventional cardiology, and 22 adult critical care beds.

19. The Good Samaritan pharmacy routinely creates the following types of sterile compounded products:

- Antibiotics • Antivirals • Antifungals • Cardiac Drips • Parenteral Nutrition • Epidurals • Pain Management • Chemotherapy • Electrolytes • Hematology/Factor Replacement • Anticoagulants • Antithrombotics •

20. Medication commonly needed on a STAT basis include weight based antibiotics, electrolytic replacements, anticoagulation, oncology treatments, oncology rescue agents, code response medications, intrathecal chemotherapy, methotrexate for ectopic pregnancies. Additionally, the following hazardous sterile preparations cannot be outsourced due to their need intraprocedurally: chemotherapy beads for hepatic chemoembolization and intraoperative chemotherapy bladder irrigation.

21. The following equipment and resources are used as part of Good Samaritan's sterile compounding activities:

- Two horizontal laminar flow hoods
- One Pinnacle Automated Compounder and software
- One refrigerator
- One glovebox isolator with venting to the outside
- Pressure monitors ante and buffer room
- Temperature and humidity monitors ante and buffer room
- Simplifi 797 Compliance Program
- Sterile compounding references including Micromedex, USP, Neofax, Harriet Lane, Teddy Bear Book on Pediatric Injectable Drugs, and Trissels

22. It is noteworthy that the Good Samaritan pharmacy has implemented and uses the Simplifi 797<sup>®</sup> process to help insure that its compounding practices are done in accordance with the highest industry standards. To be more specific:

- Simplifi 797<sup>®</sup> is a web-based USP Chapter 797 quality system, that establishes the training, risk management, and quality assurance practices necessary for a safe and efficient sterile compounding environment.
- Simplifi 797<sup>®</sup> has become a standard for Tenet pharmacy departments for compounding documentation
- It assists in compliance management and provides staff with expert-based sterile compounding instruction linked directly to USP 797 standards.
- It allows pharmacies to achieve a state of control with standardized training, proper technique, quality assurance controls, standard operating procedures, and management oversight.
- The program was co-developed with industry expert Eric Kastango, MBA, RPh, FASHP, with policies, procedures and education program directly supporting USP 797
- This web-based application is continually updated as standards change with a reference library covering techniques, policies and procedures and competency templates.
- The program will track and review specifics for our compounding activities, with the program we created custom tasks for to serve as a reminder for pharmacy checklists and must do activities.
- Timely data and reporting access is available including trending and analysis reporting by person, site, or facility.
- Single screen dashboard is used to manage all training, schedules and tasks including auto-notification of overdue items, exceptions and out-of-range measurements.

23. In addition, Simplifi 797<sup>®</sup> includes:

- A complete set of 797 based policies and procedures and related forms
- The ability to ask and clarify questions related to USP <797> standards, rules or regulations
- Customized to provide tracking and review of quality systems specific to the pharmacy's compounding sites
- Dashboard design and single screen to easily manage all tasks and schedules
- Custom tasks for non-sterile compounding or other pharmacy checklists
- Batch processing templates for storing recipes, compounding records and labeling
- Auto-notification of overdue tasks, exceptions and out of range measurements

- Resolution procedures for exceptions and unacceptable measured values
- Trending and analysis reporting by person, compounding facility or sample site
- Reference library covering techniques, policies and other pertinent information

24. Routine daily, weekly and monthly cleaning occurs in the ante room area and sterile compounding area in compliance with USP 797. The pressure status of the buffer and ante areas are monitored 24 hours a day through a Dickson monitoring device that is integrated into an audible alarm within the main pharmacy. On a regular basis, among other safeguards, the buffer room and compounding hoods are surface sampled; the ante and buffer areas are air sampled; and the compounding hoods are air sampled. All sampling test results are maintained on site and if any deficiencies are noted, immediate corrective actions are taken and resampling occurs.

25. There are three important additional points to be made regarding the sterile compounding done in the Good Samaritan's pharmacy:

- The Department of Health conducted a "Compounding Sterile Preparations" survey of the Good Samaritan's pharmacy on December 12, 2013 and the pharmacy passed with minor deficiencies which included policy revisions to match current practices which are in alignment with USP 797. Those matters have been addressed.
- As discussed further below, the renovations that are being constructed are being done in a way that all of the sterile compounding facilities and safeguards currently in place are maintained until the new space is approved and ready for occupancy.
- To date there have been NO incidents of contaminated sterile compounds produced by Good Samaritan's department of pharmacy. There are many safety, quality, and practice standards to ensure accurate compounding activities to treat the hospital's patients with the highest level of care and to protect the staff.

## THE NECESSARY PHARMACY RENOVATIONS

26. Good Samaritan has been in a process to redesign the sterile compounding area for the past 6 months. During this process Good Samaritan has attentively followed the state of compounding regulations in Florida and nationally. As it became clearer that new rules would be forthcoming in the state of Florida, the pharmacy department has been working with consultants and design firms to find a path forward for a compliant sterile compounding area based on the forthcoming rules. Until the final proposed Board of Pharmacy rule was released in April 2014, a final draft for construction review was not achievable.

27. The implementation time challenges this hospital faces are unique as a result of both the building's age and design, the challenge of creating a compounding suite that will be compliant with current and future regulations, and the need to do construction in a way that allows sterile compounding to continue in a safe and compliant manner.

28. Architecturally, there will need to be two buffer (clean/hood) rooms; one for the hazardous IV preparations and one for the non-chemo/non-hazardous IV preparations. In addition a designated ante room will be added to permit staff to perform personal hygiene and garbing procedures, stage components, and perform order entry and CSP labeling. Furthermore, work must be done on the exterior of the building to extend the exhaust duct up the side of the building because, currently, the vent occurs at the first floor level in a courtyard, onto the roof, and then up above the uppermost floor of the hospital.

29. Fairly extensive engineering work is required as well. The existing air handling unit, AHU-B3, which serves the general pharmacy cannot meet the requirements of USP 797.<sup>5</sup>

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<sup>5</sup> The pharmacy is currently compliant with Florida law because the existing glove box is separately vented to the outside.

30. A new dedicated air handling unit and other mechanical upgrades will meet the following USP 797 requirements:

- 30 air changes per hour supply air into Compounding (Buffer) Room, Ante Room and Chemo Hood Room.
- Filtration of 99.97% HEPA.
- Temperature and Humidity control.
- Positive pressure Compounding Room and Ante Room.
- A new dedicated exhaust fan located on an upper roof will maintain the Chemo Hood room at negative pressure.
- A new dedicated exhaust fan to serve the chemo hood located on a upper roof.

31. There is less than ten feet from the basement floor to the deck. In order to install ductwork to serve the new compounding rooms, a gypsum fur-down is needed for the ductwork. The bottom of the fur-down will be about seven feet above the floor. This will allow the remaining ceiling in the compounding rooms to be as high as possible.

32. The existing basement location, with its low ceiling heights, overcrowded space between the ceiling and the structure, and the inability to provide an exhaust to the exterior of the building other than along one wall is unique and challenging. This is one of the features that makes this project more difficult, unique and potentially different from those faced by other compounding pharmacies.

33. Architecturally, the IV Prep area will be renovated and expanded in place. The desired end result is to create a storage area for IV supplies and an anteroom where the current IV area is located with the two new buffer rooms where existing offices are located. The offices and narcotic vault will be relocated to an area currently occupied by housekeeping. The toilet will be brought into compliance with accessibility requirements. For this to occur, the narcotic vault must be relocated. The required compounding counter and sink for the pharmacy will be relocated adjacent to the expanded and renovated toilet. Two new mechanical rooms will be

added to provide address the air flow and needs of the IV area; they will be located in part of the existing shop area. A copy of the phased renovation plan is attached as Exhibit B.

34. It is important to understand that this plan allows for the compounding to continue in a safe manner that is compliant with the requirements of the version of Rule 64B16-27.797 before adoption of the Amended Rule. There may be a few days in which temporary partitions must be constructed to separate different areas of the pharmacy. If there are days in which the proper environment cannot be maintained to safely compound, Good Samaritan commits to make alternate arrangements and not compound hazardous drugs (or conduct any other activity that cannot be safely conducted). However, it is not anticipated that such activity will happen often. Further, the timing of any interruptions can be planned in a way to avoid any significant disruption.

35. For compounding to continue safely during construction, the project must be completed in phases even though that will add to the total time for project construction.

36. The phases for this project are summarized as follows:

Phase 1:

Temporary Reduction in size of the existing IV area,

- a. Keeping the existing sink in a reduced ante area,
- b. Keeping the existing and currently functioning chemo hood in place
- c. Relocating one of the existing non-chemo hoods in a reduced buffer area

Providing a temporary wall in the existing staff break area in order to use the existing sink for the pharmacy compounding sink (this used to be the IV lab area). There is no door separating the break area from the pharmacy area, so the sink will technically be in the pharmacy area. Providing a door in the temporary wall for access to what remains of the staff area.

Phase 2:

Relocation of the offices and narcotic vault to the existing housekeeping areas.

Phase 3:

Relocation area for ante area and both buffer rooms  
Renovate toilet to be accessible  
Relocate compounding sink

Phase 4:

Renovate existing IV area for IV storage area  
Remove temporary wall in break room area.

37. Here is the current project schedule:

AHCA Stage One submittal:	July 10, 2014
AHCA Stage Two face to face:	September 30, 2014
AHCA Final Submittal:	October 23, 2014
Final Bids Due:	November 13, 2014
Construction Phase One:	Nov. 18, 2014 – January 16, 2015
Construction Phase Two:	Jan. 22 - April 17, 2015
Construction Phase Three:	April 23 – July 3, 2015
Construction Phase Four:	July 8 – July 31, 2015

38. As noted above, because this project is located in a licensed hospital, it must not only go through various levels of review by the local jurisdictions in Palm Beach County; it is also subject to extensive regulatory oversight by the Florida Agency for Health Care Administration (“AHCA”). AHCA’s review includes not only the specific references in the schedule listed above; it also includes inspections that must occur during and at the end of each phase of construction.

39. AHCA inspections are done according to schedules set by the agency and generally occur on a three-week rotation. Consequently, work schedules are significantly affected by the schedules of the inspectors.

40. The total cost of this renovation is approximately \$1,500,000.

**THE PURPOSE OF THE REGULATIONS WILL BE ACHIEVED  
WHILE THE TEMPORARY WAIVER IS IN PLACE**

41. Considerable space in this Petition has been devoted to a description of the facilities and quality assurance processes in place at Good Samaritan to assure that high quality sterile products are produced in a safe manner at all times.

42. Good Samaritan has been preparing sterile compounded products for decades. There has never been an incident in which a contaminated product was produced by the pharmacy. There has never been an incident in which patients or staff were endangered as a result of the sterile compounding practices of the hospital.

43. Because of the phasing and the construction plan that has been implemented, all of the existing safeguards will stay in place throughout construction and beyond.

**APPLICATION OF THE AMENDED RULE WITHOUT THE TEMPORARY  
WAIVER WOULD CREATE A SUBSTANTIAL  
HARDSHIP AND VIOLATE PRINCIPLES OF FAIRNESS**

44. Section 120.542, Florida Statutes authorizes and provides the standards for granting waivers. Subsection (2) states:

(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.

45. This waiver request meets both the hardship and fairness tests.

46. Significant patient displacement and harm would occur if sterile compounding is no longer allowed to take place at Good Samaritan. Sterile compounding is a mission critical process for the patients cared for at this large and very busy institution. Without the capabilities to continue compounding services in the interim period during the construction of a new sterile compounding area Good Samaritan will be unable to continue the same level of services, some of which are not otherwise available in the area. Patients come to Good Samaritan for diagnostic and surgical care of their oncologic disease processes. The inability of the hospital to continue their care through the provision of chemotherapy infusions would cause patients to leave a facility where there is comfort and familiarity and go to a facility in which they know no one. This would impart undue stress and anxiety on a patient population that is already fraught with stress and anxiety due to their disease process.

47. Outsourced compounded products have a role in modern pharmacy practice. Moving from an outsource product mix of less than 1% to 100% is not a practice model that can meet the diverse patient care needs that Good Samaritan serves, especially with the hospital's heavy emphasis on serving the oncology needs of a large geographical area. Many oncology patients also require medical attention and as a result of the chemotherapy regimen and they are often dependent on injectable medications as the preferred route of administration. Outsourcing these medications would place patients at risk due to the long-turn-around-time. Also, outsourcing chemotherapy can result in patients having to spend one or two unnecessary extra days in the hospital while they wait for their chemotherapy to be prepared and delivered. This imparts additional stress, anxiety and costs on patients as well as places them at risk for hospital-acquired infections, falls, and many other negative sequelae. Outsourcing chemotherapy would

also impart a financial burden to the facility from both an increased length of stay and an increased acquisition cost of outsourced chemotherapy.

48. For various acute conditions and intensified care post chemotherapy regimens, the lack of immediate on-demand sterile compounding capabilities would be a significant hardship for patients and families. Since most outsourced products are geared for standard dosing, the turnaround time for outsourcing facilities would not meet the standard of care that these patients require as many doses are weight-based. Furthermore, many compounding facilities are not located in Florida and even when they are licensed through the Florida Board of Pharmacy to distribute compound pharmaceuticals, they are rarely if ever inspected by Florida pharmacy inspectors. Now that the FDA has begun inspecting these compounding facilities, the quantity of FDA warning letters and citations has grown.

49. In addition, even if all the needed products could be obtained in a timely manner (which they cannot), to do so would needlessly increase the cost of health care when a temporary waiver will solve the problem.

50. While every compounding pharmacy will have to be compliant with the Amended Rule, the size of the pharmacy operation at Good Samaritan, the wide array of uniquely compounded products needed in a timely manner, the time it takes to renovate a pharmacy located in a hospital as opposed to a pharmacy not regulated by AHCA and the unique challenges presented because of the age, configuration and construction of this facility, truly means that an October 1, 2014 effective date for the Amended Rule affects Good Samaritan and, more importantly, its patients, in a manner significantly different from the way it affects others.

## CONCLUSION

51. The final phase of construction is currently scheduled to be completed on July 31, 2015. However, this project is still in its early stages and schedules can change. In order to provide a little room for the variables associated with a project of this size and complexity, Good Samaritan is requesting a waiver of the effective date of the Amended Rule until September 1, 2015. Good Samaritan commits to advising the Board of Pharmacy if the project is completed sooner and would stipulate that this temporary waiver will end when that final phase is completed. Good Samaritan further stipulates as a condition of this waiver that it will continue to comply with the version of Florida Administrative Code Rule 64B16-27.797 in effect prior to October 1, 2014 and will be accountable for any violations of that rule.

52. This temporary waiver is truly critical to Good Samaritan and its patients. To emphasize the importance of this request, in addition to the signature of undersigned legal counsel, this Petition is also signed by Mark Nosacka, Chief Executive Officer of Good Samaritan and Debra R. Taldi, PharmD., the Director of Pharmacy at Good Samaritan to further attest to the veracity of the statements made herein and to underscore the critical need for this temporary waiver. It is also signed by Kellee Bowers, AIA, the project architect with Sterling Barnett, Little in Arlington, Texas to attest to the design and construction aspects of this Petition.

RESPECTFULLY SUBMITTED this 23<sup>rd</sup> day of July 2014.



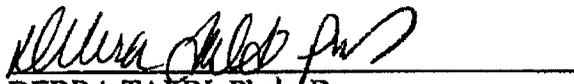
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Attorneys for Tenet Good Samaritan, Inc.  
d/b/a Good Samaritan Medical Center

ATTESTED TO BY:



MARK NOSACKA, CEO  
Good Samaritan Medical Center



DEBRA TALDI, PharmD,  
Director of Pharmacy, Good Samaritan Medical Center

KELLEE BOWERS, AIA  
Sterling, Barnett Little  
Project Architect (as to those portions of this Petition dealing with design and construction matters)

RESPECTFULLY SUBMITTED this \_\_\_\_\_ day of July 2014.

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Attorneys for Tenet Good Samaritan, Inc.  
d/b/a Good Samaritan Medical Center

ATTESTED TO BY:

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MARK NOSACKA, CEO  
Good Samaritan Medical Center

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DEBRA TALDI, PharmD.  
Director of Pharmacy, Good Samaritan Medical Center



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KELLEE BOWERS, AIA  
Sterling, Barnett Little  
Project Architect (as to those portions of this Petition dealing with design and construction matters)

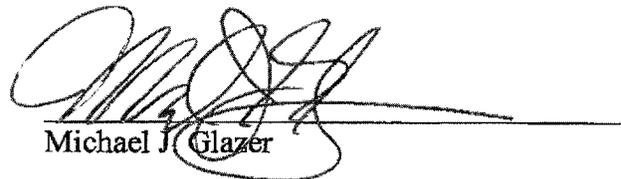
**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that the original of the foregoing has been furnished by hand delivery this 23<sup>rd</sup> day of July, 2014 to Jaime Briggs, Agency Clerk, Office of the General Counsel, Florida Department of Health, 2585 Merchants Row Blvd., Suite 110, Tallahassee, Florida 32399 and a copies have been provided by hand delivery to:

Patrick Kennedy, M.A.  
Executive Director  
Florida Board of Pharmacy  
Florida Department of Health  
4052 Bald Cypress Way, Bin C-04  
Tallahassee, Florida 32399

David Flynn  
Assistant Attorney General  
Office of the Attorney General  
The Capitol, PL-01  
Tallahassee, Florida 32399-1050

Joint Administrative Procedures Committee  
680 Pepper Building  
111 W. Madison Street  
Tallahassee, Florida 32399-1400

  
Michael J. Glazer

# **EXHIBIT A**

## Notice of Proposed Rule

### DEPARTMENT OF HEALTH

#### Board of Pharmacy

RULE NO.:      RULE TITLE:

64B16-27.797    Standards of Practice for Compounding Sterile Preparations (CSPs)

**PURPOSE AND EFFECT:** The Board proposes the rule amendment for the specific purpose of determining the necessity of incorporating and setting as the minimum standards to follow when compounding sterile products, the following chapters of the United States Pharmacopeia: 797; 1160; 71; 85; 731; and 1231.

**SUMMARY:** The following chapters of the United States Pharmacopeia will be incorporated into the rule as the minimum standards to follow when compounding sterile products: 797; 1160; 71; 85; 731; and 1231.

#### SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. Specifically, the Board considered that 21 U.S.C. §353a, as amended by Public Law Number 113-54 (November 27, 2013), requires compounding to comply with the applicable chapters of the United States Pharmacopeia (USP) on compounding. Therefore, any economic impact is a direct result of federal mandates. Further, the Board considered that all institutional pharmacies are already mandated to comply with the compounding provisions that are being incorporated. Finally, the Board considered that since approximately 2008, Board rule requirements essentially required compliance with the provisions of the USP which are being incorporated. The Board considered that having to come into compliance with laws and rules that are already effective is not an economic impact that is applicable for consideration for this proposed rule amendment. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

**RULEMAKING AUTHORITY:** 465.005, 465.0155, 465.022 FS.

**LAW IMPLEMENTED:** 465.0155, 465.022 FS.

**IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.**

**THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS:** Tammy Collins, Acting Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

**THE FULL TEXT OF THE PROPOSED RULE IS:**

(Substantial rewording of Rule 64B16-27.797 follows. See Florida Administrative Code for present text.)

64B16-27.797 The Standards of Practice for Compounding Sterile Products Preparations (CSPs).

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) Adoption of the United States Pharmacopeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

- (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
- (b) Chapter 1160, Pharmaceutical Calculations in Prescription Compounding;
- (c) Chapter 71, Sterility Tests;
- (d) Chapter 85, Bacterial Endotoxins Test;
- (e) Chapter 731, Loss on Drying; and
- (f) Chapter 1231, Water for Pharmaceutical Purposes.

All referenced chapters of the USP, in subsection (1) are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A copy of the USP chapters referenced in this rule may be examined and inspected, but not copied, at the office of the Board of Pharmacy in Tallahassee, Florida. A subscription to all relevant chapters is available for purchase at [www.uspnf.com](http://www.uspnf.com).

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Federal Current Good Manufacturing Practices per 21 C.F.R. §§ 210.1 - 211.3.

(4) Specific Exceptions to the United States Pharmacopeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see Table 1) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month.

(5) Additional Exceptions: The Board encourages the use of a Petition for Rulemaking to inform the Board of a request to add an additional exception to subsection (5) of this rule. A Petition for Rulemaking is controlled by Section 120.54(7) of the Florida Statutes.

(6) Rule Conflicts: On October 1, 2014 this rule shall control notwithstanding any rule to the contrary located throughout the provision of Chapter 64B16, F.A.C. Upon the effective date of this rule, the board will begin the process of repealing all rules that conflict with this rule.

THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History—New 6-18-08, Amended 1-7-10, 10-1-14.

The Board has determined that posting the material on the Internet would constitute a violation of the federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination at the Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254 and at the Department of State, Administrative Code and Register Unit, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-0250.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 11, 2014

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: December 20, 2013

## Notice of Change/Withdrawal

### DEPARTMENT OF HEALTH

#### Board of Pharmacy

RULE NO.:      RULE TITLE:

64B16-27.797    Standards of Practice for Compounding Sterile Preparations (CSPs)

#### NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 40, No. 48, March 11, 2014 issue of the Florida Administrative Register.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee and input at the hearing. The changes are as follows:

1. The following language will be added to the end of the paragraph located above subsection (2):

The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3254 and at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250.

2. Subsection (3) shall now read as follows:

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. § 351 (2012), adopted and incorporated herein by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-> and 21 C.F.R. Parts 210 and 211 (2011), adopted and incorporated herein by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref->.

3. For subsection (4), subparagraph (c) will be added and shall read as follows:

(c) USP Chapter 797 provides as follows in the "Facility Design and Environmental Controls" section: "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended." Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quotes as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

4. Subsections (5) and (6) shall be removed in their entirety.

5. The language that reads "THIS RULE SHALL TAKE EFFECT OCTOBER 1, 2014" shall now read as follows: "PROPOSED EFFECTIVE DATE: OCTOBER 1, 2014."

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Patrick Kennedy, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

# **EXHIBIT B**

PROJECT YEAR  
 ARCHITECT  
 INTERIOR DESIGN  
 MECHANICAL/ELECTRICAL  
 PLUMBING  
 CIVIL ENGINEERS  
 STRUCTURAL  
 P.E.  
 INTERIOR DESIGN  
 MECHANICAL/ELECTRICAL  
 PLUMBING

**GOOD SAMARITAN  
 MEDICAL CENTER  
 PHARMACY RENO.**

908 N. FLORIAN DRIVE, WEST PALM BEACH, FL 33401

**PHASE 1  
 DRAWINGS**

DATE: 07/28/14  
 SCALE: AS SHOWN

**A1.00**

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JAMES S. LITTLE  
 ARCHITECTURE, INC.  
 1001 N. 10TH AVE., SUITE 100  
 WEST PALM BEACH, FL 33411

**DEMOLITION LEGEND**  
 ITEMS SHOWN DASHED INDICATE ITEMS TO BE DEMOLISHED

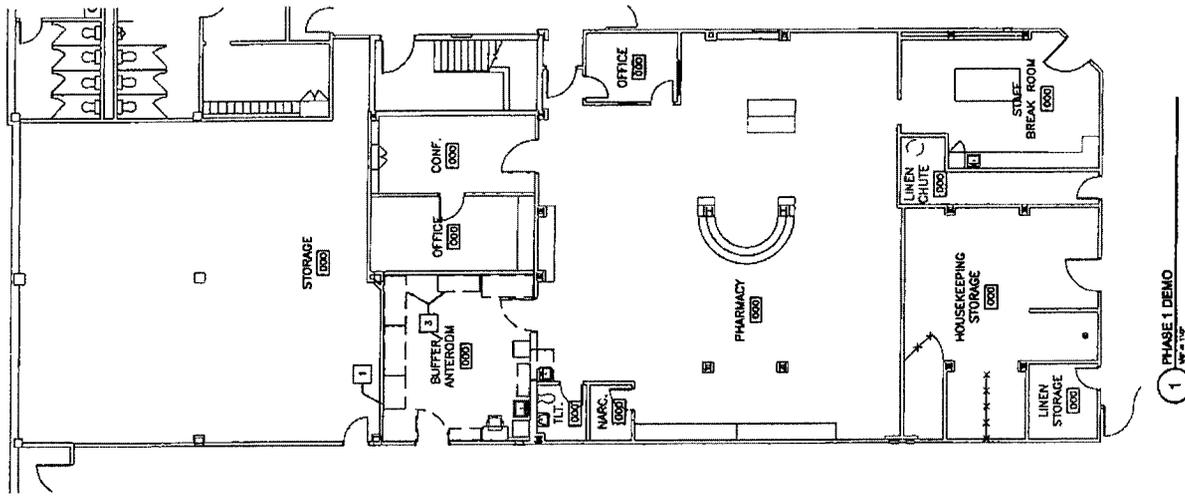
- WINDOWS
- PARTITIONS
- CURTAIN TRACK
- DOORS AND FRAMES
- TOILET FIXTURES
- URINAL FIXTURES
- SINK FIXTURES
- TOP SINK FIXTURES
- CABINET FIXTURES
- MILLWORK
- TELEPHONE BOOTH

**GENERAL NOTES**

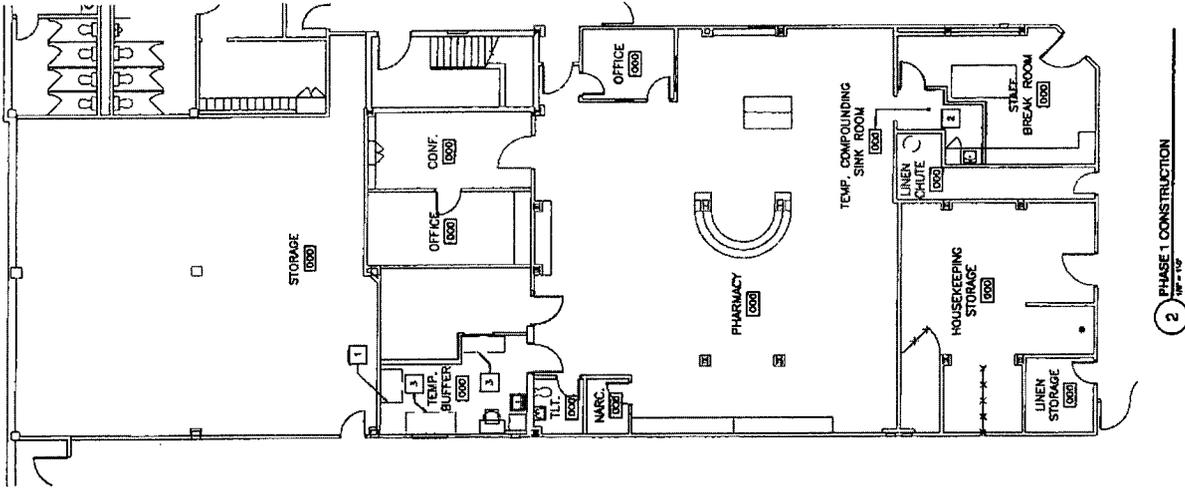
1. IDMA PLANS TO BE SUBMITTED AND APPROVED PRIOR TO EACH PHASE.
2. PARTIAL CONTROL PARTITIONS ARE TO BE ERECTED PRIOR TO ANY WORK.
3. ALL DEMOLITION WORK SHALL BE COMPLETED PRIOR TO CONSTRUCTION OF NEW WORK.
4. ALL SAFETY TO BE MAINTAINED PRIOR TO BEGINNING CONSTRUCTION OF WORK.

**KEYED NOTES**

1. CURRENT CHINA HOOD REMAINS IN-PLACE WITH EXISTING EXHAUST UNTIL PHASE 1.
2. REQUIRED COMPARTMENTS ARE DEMONSTRATED IN CONSTRUCTION OF PHASE 1. ALL WORK SHALL BE CONSTRUCTED TO SEPARATELY COMPARTMENT FUNCTION FROM BREAK ROOM.
3. TEMPORARILY RELOCATE HOOD AND REFRIGERATOR.



1 PHASE 1 DEMO



2 PHASE 1 CONSTRUCTION

PROJECT YEAR  
 ARCHITECT  
 INTERIOR DESIGN  
 MECHANICAL/ELECTRICAL  
 PLUMBING/MECHANICAL/LIFTS  
 STRUCTURAL  
 CIVIL WORKERS

**GOOD SAMARITAN  
 MEDICAL CENTER  
 PHARMACY RENO.**  
 1808 N. FLORER DRIVE, WEST PALM BEACH, FL 33401

TITLE  
**PHASE 2  
 DRAWINGS**

DATE  
 02/04/2010

SCALE  
 1/8" = 1'-0"

PROJECT NO.  
 A2.00

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 JAMES K. LITTLE  
 ARCHITECTS  
 1001 W. 10TH AVENUE  
 SUITE 100  
 DENVER, CO 80202  
 TEL: (303) 733-1100  
 FAX: (303) 733-1101  
 WWW.JKLARCHITECTS.COM

**DEMOLITION LEGEND**  
 ITEMS SHOWN DASHED INDICATE ITEMS TO BE DEMOLISHED

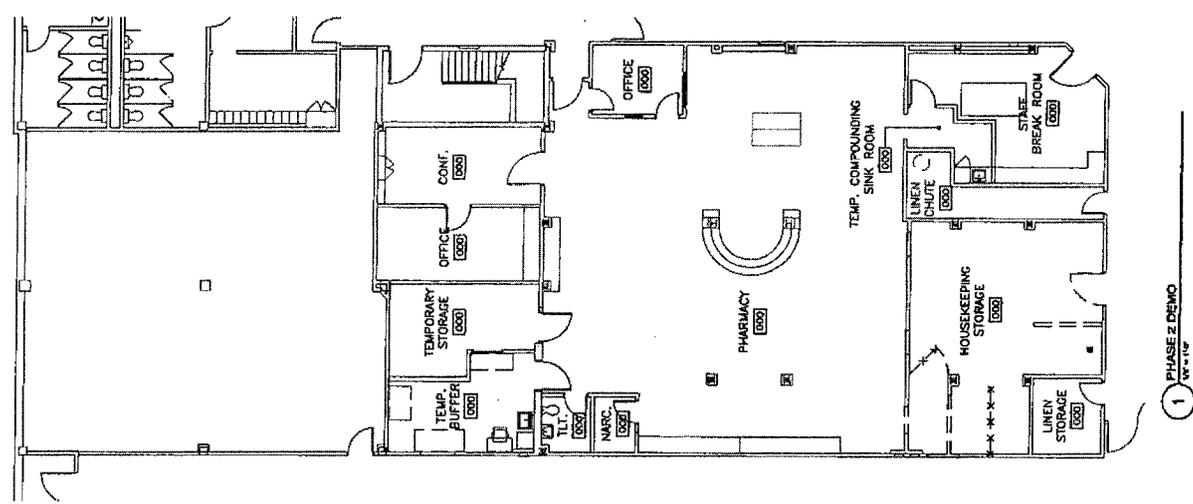
- WINDOWS
- - - PARTITIONS
- - - CURTAIN TRACK
- - - DOORS AND FRAMES
- TOILET FIXTURES
- URINAL FIXTURES
- SINK FIXTURES
- WIP SINK FIXTURES
- SINKS
- FIXTURES
- MILLWORK
- TELEPHONE BOOTH

**GENERAL NOTES**

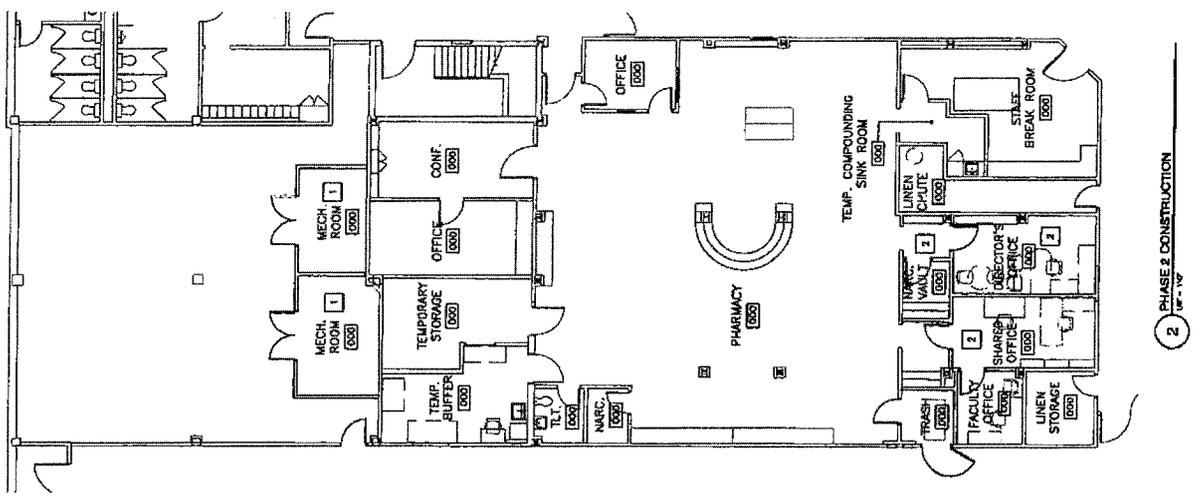
1. IDEA PLANS TO BE SUBMITTED AND APPROVED PRIOR TO EACH PHASE.
2. PRIOR TO TYPED PARTITIONS ARE TO BE ERECTED PRIOR TO ANY WORK.
3. WORKING CONDITIONS TO BE MAINTAINED THROUGHOUT CONSTRUCTION.
4. ALL SERVICES TO BE ADVANCED PRIOR TO REFINISHING COMPOUNDED IN PLACE.

**KEYED NOTES**

1. CONSTRUCT NEW MECHANICAL ROOMS AND INSTALL EQUIPMENT TO SERVE NEW ROOMS.
2. WALL.



1 PHASE 2 DEMO  
 1/8" = 1'-0"



2 PHASE 2 CONSTRUCTION  
 1/8" = 1'-0"

PROJECT YEAR: 2014  
 PROJECT NAME: GOOD SAMARITAN PHARMACY RENOVATION  
 ARCHITECT: JAMES S. LITTLE ARCHITECTS, INC.  
 1008 N. PALM BEACH DRIVE, WEST PALM BEACH, FL 33401  
 TEL: (561) 847-1000  
 FAX: (561) 847-1007  
 CIVIL ENGINEER: JAMES S. LITTLE ARCHITECTS, INC.  
 STRUCTURAL: JAMES S. LITTLE ARCHITECTS, INC.  
 MECHANICAL: JAMES S. LITTLE ARCHITECTS, INC.  
 ELECTRICAL: JAMES S. LITTLE ARCHITECTS, INC.  
 INTERIOR DESIGN: JAMES S. LITTLE ARCHITECTS, INC.

# GOOD SAMARITAN PHARMACY RENOVATION

TITLE: PHASE 3 DRAWINGS

DATE: 07/08/14  
 DRAWN BY: JSL  
 CHECKED BY: JSL

SCALE: A3.00

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### DEMOLITION LEGEND

ITEMS SHOWN DASHED INDICATE ITEMS TO BE DEMOLISHED

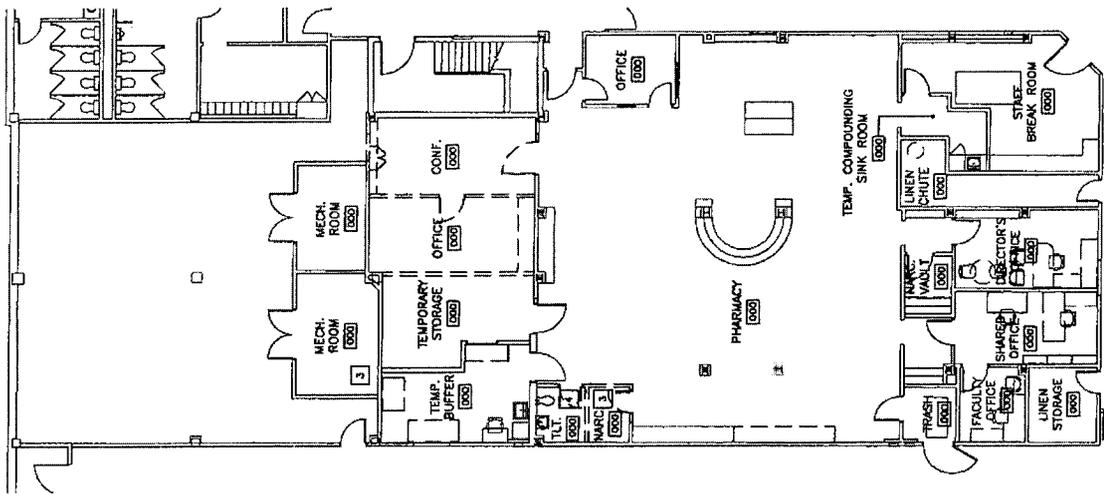
- WINDOWS
- PARTITIONS
- CURTAIN TRACK
- DOORS AND FRAMES
- TOILET FIXTURES
- URINAL FIXTURES
- SINK FIXTURES
- HOP SINK FIXTURES
- SHOWER FIXTURES
- MILLWORK
- TELEPHONE BOOTH

### GENERAL NOTES

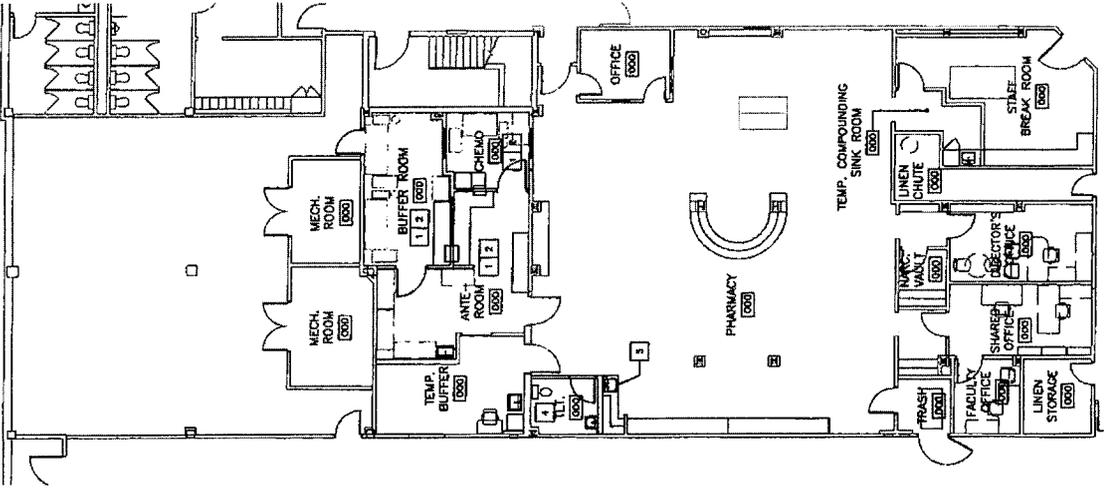
1. IDEA PLANS TO BE SUBMITTED AND APPROVED PRIOR TO EACH PHASE
2. DUST CONTROL PARTITIONS ARE TO BE ERECTED PRIOR TO ANY WORK
3. NEW COMPounding TABLES PLACE ELSEWHERE
4. ALL WORK TO BE COMPLETED PRIOR TO RESUMING COMPounding IN ORDER

### KEYED NOTES

1. ANTE BUFFER AND CHUTE ROOMS TO BE CONSTRUCTED
2. ALL EQUIPMENT ASSOCIATED WITH ANTE BUFFER AND CHUTE ROOMS TO BE INSTALLED IN FINAL LOCATION
3. EXISTING MANOMETRIC VAULT TO BE DEMOLISHED. EXISTING TOILET TO BE EXPANDED AND BROUGHT INTO COMPLIANCE WITH ACCESSIBILITY CODES.
4. NEW COMPounding SINK TO BE INSTALLED.



1 PHASE 3 DEMO



2 PHASE 3 CONSTRUCTION

PROJECT TEAM  
 ARCHITECT  
 STRONGHOLD ARCHITECTURE  
 100 N. FLORISSANT BLVD  
 PALM BEACH, FL 33480  
 TEL: (561) 855-1000  
 FAX: (561) 855-1002

CIVIL ENGINEER

STRUCTURAL

M.E.P.  
 PERM CONSULTING  
 100 N. FLORISSANT BLVD  
 PALM BEACH, FL 33480

EXTERIOR DESIGN  
 STRONGHOLD ARCHITECTURE  
 100 N. FLORISSANT BLVD  
 PALM BEACH, FL 33480  
 TEL: (561) 855-1000  
 FAX: (561) 855-1002

200 N. FLORISSANT DRIVE, WEST PALM BEACH, FL 33411  
**GOOD SAMARITAN  
 MEDICAL CENTER  
 PHARMACY RENOV.**

PHASE 4  
**DRAWINGS**

PROJECT NO.  
 2012000

REVISIONS  
 07/06/04

DATE  
**A4.00**

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 AND RETRIEVAL SYSTEM, WITHOUT  
 THE WRITTEN PERMISSION OF  
 STRONGHOLD ARCHITECTURE  
 JULY 1, 2014

**DEMOLITION LEGEND**  
 ITEMS SHOWN DASHED INDICATE ITEMS TO BE  
 DEMOLISHED

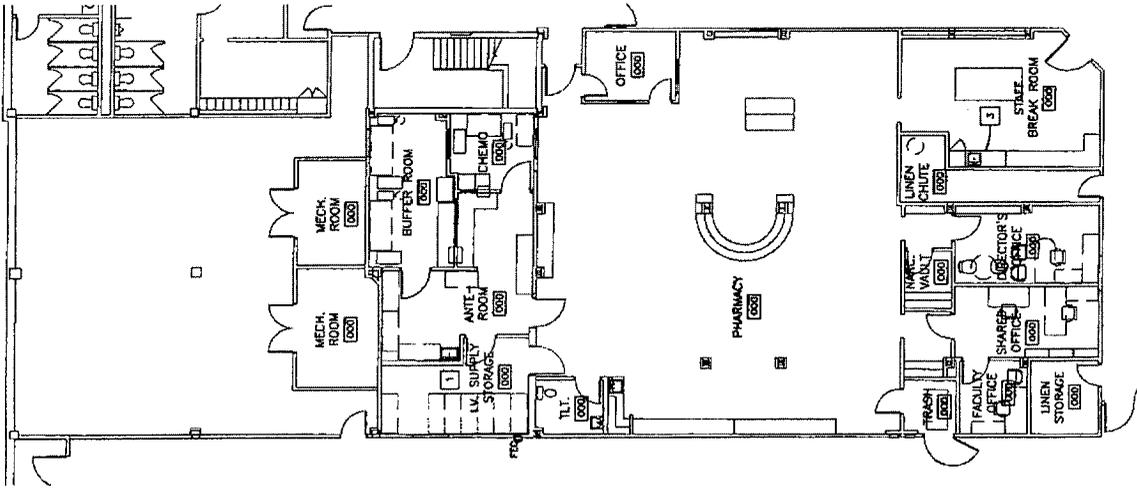
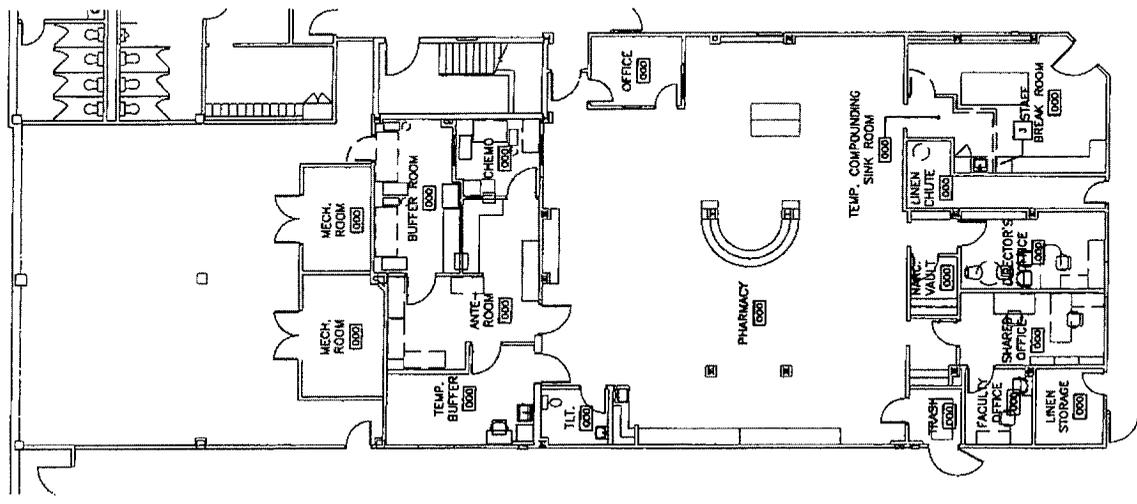
WINDOWS  
 PARTITIONS  
 CURTAIN TRACK  
 DOORS AND FRAMES  
 TOILET FIXTURES  
 URINAL FIXTURES  
 SINK FIXTURES  
 HOP SINK FIXTURES  
 SPOONER FIXTURES  
 WALLWORK  
 TELEPHONE  
 BOOTH

**GENERAL NOTES**

1. UGA PLANS TO BE SUBMITTED AND APPROVED PRIOR TO EACH PHASE.
2. DUST CONTROL PARTITIONS ARE TO BE CREATED PRIOR TO ANY WORK.
3. HOOD COMPARTING TAKES PLACE ELSEWHERE DURING CONSTRUCTION.
4. AIR SUPPLY TO BE BALANCED PRIOR TO RESUMING COMPARTING IN HOODS.

**KEYED NOTES**

1. TEMPORARY BUFFER ROOM TO BE CONVERTED TO STERILE SUPPLY ROOM.
2. TEMPORARY PARTITION AND GORE TO BE REMOVED.
3. PORTION OF COUNTERTOP AND CABINETS TO BE DEMOLISHED. INSTALL NEW TO BRING BREAK ROOMS INTO COMPLIANCE WITH ACCESSIBILITY CODES.



1 PHASE 4 DEMO

2 PHASE 4 CONSTRUCTION

October 7, 2010

Mr. Jason M. Miller  
Kenton City Prosecutor  
111 W. Franklin  
Kenton, OH 43326

Re: Tom Saywell  
D.O.B. 8/11/90

Dear Mr. Miller:

This information is being provided at the request of the above-mentioned student whom I understand is a participant in the Court's Diversion Program after having been charged with Underage Consumption on or about 8/11/10. Mr. Saywell shared that he is required to complete an alcohol education and assessment program as part of his Diversion agreement.

Please allow this correspondence to confirm that Mr. Saywell has successfully completed the AlcoholEdu for Sanctions program which is a 3 hour online science-based course designed to teach students about the effects of alcohol on the mind and body, and to assist them in making safer and healthier decisions about alcohol use. In addition to completing the Sanctions program, Mr. Saywell was also seen for clinical follow-up here at the Counseling Center to discuss what he learned as a result of completing the program and to complete further assessments. Those assessments are not suggestive of alcohol dependence although he does acknowledge a pattern of what could be considered high risk drinking. He has made changes in his drinking pattern since his arrest and was provided information on harm reduction strategies which research has shown to be useful in reducing the probability of one suffering negative alcohol related consequences when implemented.

Thank you for your attention to these matters. Please do not hesitate to contact me should the need arise.

Respectfully,

Michael D. Schafer, Ph.D., LICDC  
Director of Counseling  
Clinical Psychologist  
Licensed Independent Chemical Dependency Counselor

April 19, 2011

Mr. Lee Hood  
Attorney at Law  
231 N. Main St.  
Ada, OH 45810

Re: Tom Saywell  
D.O.B. 8/11/90

Dear Mr. Hood:

Please allow this letter to serve as confirmation that Mr. Saywell contacted the Counseling Center on 3/25/11 for evaluation and treatment pursuant to his arrest for Underage Consumption. Mr. Saywell was first involved with the Counseling Center in October 2010 when he completed an alcohol prevention course as part of his Diversion contract. A copy of the correspondence documenting his successful completion sent to Kenton City Prosecutor Jason Miller is attached.

Mr. Saywell has been seen on a regular basis since March 2011. He has chosen to abstain from alcohol and has been successful in doing so. He recognizes the seriousness of this offense and the impact it could have on his future. I have recommended that he continue in outpatient counseling and he has agreed to do so. I anticipate his further cooperation. If you should have any questions regarding Mr. Saywell's treatment progress, please do not hesitate to contact me.

Respectfully,

Michael D. Schafer, Ph.D., LICDC  
Director of Counseling  
Clinical Psychologist  
Licensed Independent Chemical Dependency Counselor

Enc.

## August 13, 2014 Board of Pharmacy Meeting

### Credentials

#### **Registered Pharmacy Technician Applicant with Disciplinary History & Health History listed on the Application**

Jocelyn Ariana Zuessman  
1500 NE 4<sup>th</sup> Street, Unit B  
Pompano Beach, FL 33060  
File 20776

### Application Completion Date:

July 10, 2014

### Summary

Ms. Zuessman submitted an application for registered pharmacy technician on May 15, 2014.

Ms. Zuessman answered "yes" to the following disciplinary history questions:

"Has disciplinary action even been taken against your pharmacist or any other professional license in this state or any other state or U.S. jurisdiction?"

"Are you presently being investigated or is any disciplinary action pending against you?"

Ms. Zuessman has a radiologic technologist license that is currently suspended by the Bureau of radiation control. The suspension was imposed on November 21, 2013; and the University of Florida is requiring Ms. Zuessman to be evaluated by PRN. She has recently been reported for non-compliance with PRN.

Ms. Zuessman also answered "yes" to the following health history question:

"During the last five years, have you been treated for or had a recurrence of a diagnosed physical impairment that has impaired your ability to practice pharmacy?"

### Supplemental Documentation:

Application  
Personal Statement  
Disciplinary Documents  
Training Program Certificate  
Letter from Physician

Prepared on July 10, 2014: by Akhiem Roberson

## Ranne, Elizabeth

---

**From:** jocelyn zuessman <jzuessman@gmail.com>  
**Sent:** Tuesday, July 08, 2014 7:30 AM  
**To:** Ranne, Elizabeth  
**Subject:** \*\*File 57034\*\*  
**Attachments:** Medical Documentation.pdf; Tech Certificate.pdf

Mrs. Elizabeth Ranne,

I was referred to PRN by my pharmacy school (UF College of Pharmacy). However,

I could not be evaluated until my medical health was cleared as PRN does not address medical issues. At the time of referral, I no longer had health insurance and missed the PRN appointments due to my declining health. At that time I was not aware that my medical health needed to be cleared before PRN could evaluate me and had been extremely overwhelmed with very little financial support. As a result of missing the PRN appointments, my X-ray license has been suspended until my evaluation by PRN can be completed. PRN is still willing to evaluate me given the circumstances. I need a pharmacy tech license in order to do so since I will be reapplying to get back into pharmacy school.

I have been instructed that I can only be evaluated by PRN under a pharmacy tech license since pharmacy school has been the source of the referral. This means that even though my X-ray license was suspended, PRN stated they could only evaluate me once I had medical clearance and a pharmacy tech license.

I have not been evaluated by PRN yet. After speaking with my PRN case manager, she did not think any additional documentation from them would be necessary. In order for PRN to complete an evaluation I need a pharmacy technician license (UF) and medical health clearance (already obtained and sent to your office).

My PRN case manager is Christina Gaudiana, LMHC  
Email: [christinag@flprn.org](mailto:christinag@flprn.org) (fastest method)  
Phone#: 1(800) 888-8776 EXT.226  
FAX: (904) 261-3996

I am currently being monitored by a hematologist and dermatologist. While I continue to have leukocytosis and thrombocytosis, I have been doing much better since the initial onset of symptoms over two years ago. It has been agreed upon that it is most likely autoimmune and may take some time before I receive a definitive diagnosis. I have been working for Walgreens for 7 weeks now as a pharmacy technician and they have been extremely supportive towards me getting back into pharmacy school.

Please advise on what  
documentation may be needed

in order to facilitate an evaluation by PRN so that I may rectify my  
X

-ray license suspension and reapply to pharmacy school. There are no court documents or criminal records involved in this situation. The only disciplinary action is the X-ray license suspension instituted by the FL DOH. This resulted from being unable to undergo PRN evaluation since medical health clearance must be obtained first and then processed under a pharmacy technician license (I was instructed that I could not be evaluated under my X-ray license).

Please contact me and/or my PRN case manager for any further clarification.

Thank You Kindly,

Jocelyn Zuessman

[jzuessman@gmail.com](mailto:jzuessman@gmail.com)  
(407) 340-4660

## Roberson, Akhiem

---

**From:** jocelyn zuessman <jzuessman@gmail.com>  
**Sent:** Friday, June 13, 2014 9:00 PM  
**To:** Roberson, Akhiem  
**Subject:** File Number 57034

Mr. Akhiem Roberson,

I'm writing to clarify my application status. I was informed that there are pending court records needed.

I was referred to PRN by my pharmacy school. However, I could not be evaluated until my medical health was cleared as PRN does not address medical issues. Due to missing the PRN appointments, my X-ray license is suspended until my evaluation by PRN can be completed. In order for PRN to evaluate me I also need a pharmacy tech license since I will be reapplying to get back into pharmacy school. I was told I can only be evaluated by PRN under a pharmacy tech license since pharmacy school had been the source of the referral. I sent my medical clearance along with my tech certificate to your office. I am currently being monitored by a hematologist.

Please advise on what needs to be done in order to facilitate an evaluation by PRN so that I may rectify my x-ray license suspension and reapply to pharmacy school. There are no court documents involved in this situation. I'm not sure why that has been recorded as something pending for my application to be complete.

Thank You,

Jocelyn Zuessman  
407-340-4660

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

November 25, 2013

Ms. Jocelyn Ariana Zuessman  
3972 N. W. 23rd Circle  
Gainesville, FL 32605

Final Order Filed: November 21, 2013  
Complaint Number: 201305310  
License Number: 66726

Dear Ms. Zuessman:

Your licensing Board has **suspended** your license to practice in the state of Florida. Please submit the following documents to my attention at the address below within 30 days:

- \* original decorative wall certificate;
- \* current wallet license card; and
- \* current wall license.

If you no longer have any of these documents, please provide a notarized statement attesting to that fact.

If you wish to return to active practice after your obligations have been met, you must continue to renew your license during this period of Suspension. If you have any questions about renewing your license, please contact the Board/Council office at (850) 488-0595.

You must comply with all requirements of the Final Order within the time frames specified. Please review the Final Order carefully and save copies of any necessary documents.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268, option #7.

Sincerely,

Melodie Moore  
Compliance Officer

/mam  
Enclosures

**Florida Department of Health**

Division of Medical Quality Assurance • Bureau of Enforcement  
4052 Bald Cypress Way, Bin C-76 • Tallahassee, FL 32399-3251  
PHONE: (850) 245-4268 • FAX: (850) 488-0796

[www.FloridasHealth.com](http://www.FloridasHealth.com)

TWITTER: HealthyFLA  
FACEBOOK: FLDepartmentofHealth  
YOUTUBE: fldoh



**MAIN TERMS OF THE FINAL ORDER**

**This summary is provided as a courtesy. It is your responsibility to read and understand the Final Order to ensure compliance with all terms described therein. Please reference the case number listed on all correspondence forwarded to this office pertaining to this case.**

CASE INFORMATION	
Case Number:	201305310
Respondent Name:	Jocelyn Ariana Zuessman
Final Order Date:	11/21/2013
Today's Date:	11/25/2013

<b>Licensee:</b>	Jocelyn Ariana Zuessman	<b>Profession:</b>	7601 : Radiologic Technology		
<b>Mailing Address:</b>	3972 Nw 23rd Circle Gainesville, FL 32605	<b>File Nbr:</b>	66726		
		<b>License Nbr:</b>	66726		
		<b>License Status:</b>	Suspended/Active		
<b>Attorney:</b>	None on Record				
<b>Monitor:</b>	None on Record				
<b>Supervisor:</b>	None on Record				
<b>Appeal:</b>	N				
<b>Discipline Imposed:</b>	<b>Start Date</b>	<b>End Date</b>	<b>Comments</b>		
Suspension	11/21/2013		Suspension of Respondent's CRT certificate number 66726 until Respondent submits to a PRN-facilitated evaluation and is determined by PRN to be safe to practice as a CRT. Probation for 3 years.		
<b>Compliance Record:</b>	<b>Due Date</b>	<b>Cmpl Date</b>	<b>Amt Imposed</b>	<b>Amt Paid</b>	
Return license	12/21/2013				
PRN Evaluation					
PRN	Professionals Resource Network, (PRN) P.O. Box 1020, Fernandina Beach, FL 32035-1020, Telephone Number: 1 (800) 888-8776; Fax Number: (904) 277-8004				
<b>Mailing Address:</b>	Division of Medical Quality Assurance Consumer Services Unit - Compliance Management 4052 Bald Cypress Way, Bin C-76 Tallahassee, Florida 32399-3258 (850) 245-4268 Option: 7 Fax: (850) 488-0796 Email: MQA_AlliedHealthComplianceOfficer @ doh.state.fl.us		<b>Please make all payments to: DEPARTMENT OF HEALTH</b> <b>Payment Address:</b> Department of Health/HMQACS Compliance Management Unit Bin C76 Post Office Box 6320 Tallahassee, Florida 32314-6320		

My Account People Business Alerts Leverages Charts Metrics Reports

**Dynamic Desktop** **Advanced Person** **Phone** **Business** **Real-Time MVR** **Add/Remove Tabs**

<b>Full Name:</b> <b>ZUESSMAN</b>	<b>Business:</b> <b>JOCELYN</b>	<b>Phone:</b> 590-60-3924	<b>Real-Time MVR:</b> 590-60-3924
<b>Address:</b>	<b>City:</b>	<b>State:</b>	<b>Zip:</b>
<b>Phone:</b>	<b>Cell:</b>	<b>Work:</b>	<b>Home:</b>
<b>Business:</b>	<b>Industry:</b>	<b>Company:</b>	<b>Address:</b>
<b>DOB:</b>	<b>Sex:</b>	<b>Height:</b>	<b>Weight:</b>
<b>DL:</b>	<b>DL State:</b>	<b>DL Exp:</b>	<b>DL Class:</b>
<b>Exp L:</b>	<b>Exp R:</b>	<b>Exp C:</b>	<b>Exp O:</b>

**Announcements:**

Use of Recent Searches is subject to your privacy policy selection.

Use of Recent Alerts is subject to your privacy policy selection.

**Recent Searches:**

Use of Recent Searches is subject to your privacy policy selection.

Use of Recent Alerts is subject to your privacy policy selection.

**Statistics:**

Today is: Thursday, January 23, 2014

You last signed in on: Thursday, January 23, 2014 at 10:00 AM

Account ID: 123456789

**Advanced Person Search Results**

**Search Terms Used - Last Name: ZUESSMAN; First Name: JOCELYN; SSN: 890-60-3924;**

Full Name	SSN	Phone	Business	Real-Time MVR	Address	City	State	Zip
JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN	890-60-3924 Le.D: 11/23/14 DL State: FL Exp L: 11/23/14 Exp R: 11/23/14 Exp C: 11/23/14 Exp O: 11/23/14	590-60-3924 590-60-3924 590-60-3924 590-60-3924 590-60-3924	JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN JOCELYN ZUESSMAN	590-60-3924 590-60-3924 590-60-3924 590-60-3924 590-60-3924	123456789 123456789 123456789 123456789 123456789	123456789 123456789 123456789 123456789 123456789	FL FL FL FL FL	32801 32801 32801 32801 32801

MML

**Rick Scott**  
Governor

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**HEALTH**

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

Enclosed is a copy of your Board Order. Within the next ten business days, you will receive at your Board Address of Record an information packet from your Compliance Officer. Please remember that your Final Order is a public document and will remain on your license indefinitely. **Your compliance officer may change during your monitoring period because of staff changes.**

You must comply with all requirements of the Board Order within the time frames specified. Please review the Board Order carefully and save copies of any necessary documents. For more information regarding compliance with final orders, please visit our website at [http://www.doh.state.fl.us/mqa/enforcement/enforce\\_csu.html](http://www.doh.state.fl.us/mqa/enforcement/enforce_csu.html).

**IMPORTANT**

Payment in full of all fines and costs imposed by your Order is due upon the due date specified by the Order. Failure to pay all fines and costs on or before the due date specified will result in the following:

•A referral will be filed with Consumer Services for investigation regarding non-compliance with your Final Order and possible further disciplinary action.

•Failure to pay in full fines and costs by the due date specified in the Final Order will result in the account being deemed "past due". Payment of "past due" accounts will avoid assignment to a collection agency for collection; however, it will not result in closing of the referral for non-compliance with your Final Order."

Upon compliance with conditions of the order, a letter of completion will be sent to you.

If your order was dismissed by the Board, you will not receive any further correspondence from the Department. This letter does not apply to your case.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. You can contact your compliance officer at the below email address:

MQA\_AlliedHealthComplianceOfficer@doh.state.fl.us  
MQA\_MedicalComplianceOfficer@doh.state.fl.us  
MQA\_NursingComplianceOfficer@doh.state.fl.us

If you have any questions, please contact the Compliance Management Unit at (850) 245-4268 or fax (850) 488-0796.

10/17/2014  
BY: \_\_\_\_\_

**Florida Department of Health**

Division of Medical Quality Assurance • Bureau of Enforcement  
4052 Bald Cypress Way, Bin C-76 • Tallahassee, FL 32399-1701  
PHONE: 850-245-4268 • FAX 850/488-0796

**www.FloridasHealth.com**

TWITTER:HealthyFLA  
FACEBOOK:FLDepartmentofHealth  
YOUTUBE: fldoh

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL**

**DEPARTMENT OF HEALTH,**

**PETITIONER,**

**v.**

**CASE NO. 2013-05310**

**JOCELYN ZUESSMAN, C.R.T.,**

**RESPONDENT.**

---

**ADMINISTRATIVE COMPLAINT**

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this administrative Complaint before the Department against Respondent, Jocelyn Zuessman, C.R.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of Radiologic Technology pursuant to Section 20.43, Florida Statutes; and Chapter 468, Part IV, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a Certified Radiologic Technologist (C.R.T.), within the State of Florida, having been first issued certificate number 66726.

3. Respondent's address of record is 3972 NW 23<sup>rd</sup> Circle, Gainesville, Florida, 32605.

4. In or during the spring of 2012, Respondent was a senior student at the University of Florida, College of Pharmacy, in the Doctor of Pharmacy Program.

5. In the University of Florida spring semester, 2012, Respondent began to encounter difficulties with her course work in the Doctor of Pharmacy Program by the following: a) Missing scheduled examinations; 2) Being removed from, and receiving a grade of "N" in, the Advanced Pharmacy Practice Experience (hereafter, "APPE"); 3) Failing a pharmacy elective course; and/or Receiving an "Incomplete" in another pharmacy elective course.

6. In the University of Florida summer semester, 2012, Respondent attempted to complete the AAPE, but did not meet expectations and was suspended from the course until such time as the University of Florida, College of Pharmacy, received documentation that Respondent was healthy mentally and physically and ready to meet course expectations.

7. On or about September 6, 2012, the University of Florida, College of Pharmacy, Senior Associate Dean of Professional Affairs, wrote to Respondent at 14312-303 Avalon Reserve Blvd., Orlando, Florida, 32825, advising her that the decision had been made to refer Respondent to the Professional Resource Network (hereafter, "PRN") for an evaluation.

8. On or about September 6, 2012, the University of Florida, College of Pharmacy, Senior Associate Dean of Professional Affairs, wrote to Respondent at 14312-303 Avalon Reserve Blvd., Orlando, Florida, 32825, advising her that she would remain suspended from continuing pharmacy studies until a report was received from a representative of PRN.

8. On or about September 6, 2012, the University of Florida, College of Pharmacy, Senior Associate Dean of Professional Affairs, referred Respondent to PRN for an evaluation alleging that Respondent was unable to function as a health care profession, or to perform the duties of a health care professional, with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or other materials or as a result of any mental or physical condition.

9. PRN is the impaired practitioners program for the Board of Radiologic Technology, designated pursuant to Section 456.076, Florida

Statutes. PRN is a program that monitors the evaluation, care, and treatment of impaired professionals. PRN also provides for the exchange of information between treatment providers and the Department for the protection of the public.

10. On or about September 19, 2012, PRN wrote to Respondent, via certified mail return receipt requested, at 14312-303 Avalon Reserve Blvd., Orlando, Florida, 32825, requesting that she contact PRN within three (3) days of receipt of the letter from PRN.

11. On or about October 1, 2012, PRN's certified letter to Respondent was returned indicating that the forwarding time had expired and listing a different address in Orlando, Florida.

12. On or about October 16, 2012, the University of Florida, College of Pharmacy, Senior Associate Dean of Professional Affairs, contacted Respondent via e-mail at [jzuessman@ufl.edu](mailto:jzuessman@ufl.edu) and advised her of the September 6, 2012, letter and requested she contact PRN.

13. As of on or about November 7, 2012, Respondent had failed to contact PRN to schedule an evaluation.

14. As of on or about November 7, 2012, Respondent was no longer enrolled in the University of Florida, College of Pharmacy.

15. As of on or about November 7, 2012, Respondent's pharmacy intern license number 24554 was null and void.

16. On or about November 16, 2012, Respondent contacted PRN.

17. On or about November 16, 2012, PRN provided Respondent with five (5) names of evaluators, and their phone numbers.

18. On or about November 16, 2012, PRN requested Respondent schedule an evaluation by November 30, 2012, with one of the five (5) evaluators whose names were sent to Respondent.

19. Between November 27, 2012, and January 16, 2013, three (3) PRN evaluations were scheduled for Respondent.

20. Between November 27, 2012, and January 16, 2013, Respondent failed to attend any of the three (3) PRN evaluations scheduled for her.

21. On or about March 29, 2013, PRN filed a report with the Department of Health indicating that Respondent was not in compliance with the requests and requirements of PRN.

22. On or about March 29, 2013, PRN filed a report with the Department of Health indicating that Respondent's inability to complete assignments, classes, and rotations at the University of Florida, College of

Pharmacy has lead to concerns by PRN about Respondent's mental health and possibility substance abuse.

23. On or about March 29, 2013, PRN filed a report with the Department of Health indicating that indicated that, absent a PRN evaluation eliminating the aforementioned PRN concerns, any attempt by Respondent to practice as a Pharmacy Intern or Certified Radiologic Technologist would create a danger to the public's health, safety and welfare.

Count One – Impairment

24. Petitioner re-alleges paragraphs one (1) through twenty-three (23) as if fully set forth a length herein.

25. Section 468.3101(1)(g), Florida Statutes (2012), provides that a CRT is subject to discipline for being unable to practice radiologic technology or to perform the duties of a radiologist assistant with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or other materials or as a result of any mental or physical condition.

26. As evidenced by Respondent's history of an inability to complete assignments, classes, and rotations at the University of Florida,

College of Pharmacy, PRN's concerns about Respondent's mental health and possibility substance abuse, and Respondent's refusal to attend a PRN evaluation, Respondent is unable to practice Radiologic Technology with reasonable skill and safety to patients.

27. Based on the foregoing, Respondent violated Section 468.3101(1)(g), Florida Statutes (2012).

Count Two – Refusal to Comply PRN Directives

28. Petitioner re-alleges paragraphs one (1) through twenty-three (23) as if fully set forth a length herein.

29. Section 468.3101(1)(n), Florida Statutes (2012), subjects a CRT to discipline for failing to comply with the recommendations of the Department's impaired practitioner program for treatment, evaluation, or monitoring.

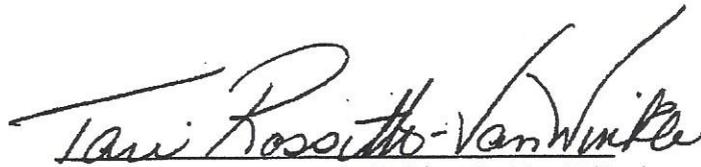
30. Respondent has refused to attend three (3) scheduled PRN evaluations as requested by PRN.

31. -Based on the foregoing, Respondent violated Section 468.3101(1)(n), Florida Statutes.

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

SIGNED this 15<sup>th</sup> day of May, 2013.

John H. Armstrong, MD, FACS  
Surgeon General & Secretary



Tari Rossitto-Van Winkle, R.N., J.D.  
Assistant General Counsel  
DOH Prosecution Services Unit  
4052 Bald Cypress Way, Bin C-65  
Tallahassee, Florida 32399-3265  
Florida Bar Number: 0613908  
(850) 245 - 4444 ex. 8139 Telephone  
(850) 245 - 4681 Facsimile  
tari\_rossitto-vanwinkle@doh.state.fl.us

**FILED**

DEPARTMENT OF HEALTH  
DEPUTY CLERK

CLERK: *Bridget Coates*

DATE: AUG 23 2013

PCP Date: April 30, 2013

PCP Members: James Futch, Ben Register & Daisy King

### Certificate of Service

I hereby certify that a true and correct copy of the foregoing has been furnished by U.S. Certified Mail to JOCELYN ZUESSMAN, C.R.T., 3972 NW 23<sup>rd</sup> Circle, Gainesville, Florida, 32605, on this 10<sup>th</sup> day of May, 2013.

*Tari Rossitto-Van Winkle*

Tari Rossitto-Van Winkle, R.N., J.D.  
Assistant General Counsel

### NOTICE OF RIGHTS

Respondent has the right to request or petition for an administrative hearing to be conducted in accordance with Sections 120.569 and 120.57, Florida Statutes. Respondent has the right to be represented by counsel or other qualified representative. Administrative hearings are governed by Rule 28-106, Florida Administrative Code. A request or petition for an administrative hearing must be in writing and must be received by the Agency Clerk within twenty-one (21) days from the day you received this Administrative Complaint. A request or petition for a hearing must be in conformance with Chapter 28-106.2015(5), Florida Administrative Code and must be sent to the Agency Clerk at the following address:

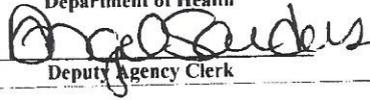
Department of Health  
Prosecution Services Unit  
Attention: Tari Rossitto-Van Winkle, R.N., J.D.  
4052 Bald Cypress Way, Bin #C65  
Tallahassee, Florida 32399-1701

Mediation is not available as an alternative remedy.

Your failure to submit an a petition or request for a formal hearing (Election of Rights) within twenty-one (21) days from receipt of this Administrative Complaint will constitute a waiver of your right to a hearing, and this complaint will thereby become a final order of the Department.

FILED DATE: NOV 21 2013

Department of Health

By:   
Deputy Agency Clerk

STATE OF FLORIDA  
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,  
BUREAU OF RADIATION CONTROL

Petitioner,

vs.

DOH CASE NO.: 2013-0212  
RAD CASE NO.: 2013-05310

JOCELYN ZUESSMAN, C.R.T.,

Respondent.

FINAL ORDER

THIS MATTER comes before the Department of Health for entry of a Final Order pursuant to Petitioner's Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact.

ISSUE

Whether the Respondent has waived the right to an administrative hearing, and whether the undisputed facts support the conclusions of law outlined in the filed Administrative Complaint charging Jocelyn Zuessman, ("Respondent") with violating sections 468.3101(1)(g) and 468.3101(1)(n), Florida Statutes. Whether the relief requested by the Department of Health ("Department" or "Petitioner"), requesting the suspension of Respondent's certification as a C.R.T. until found safe to practice by the Professionals Resource Network ("PRN"), followed by probation, should be granted.

PROCEDURAL BACKGROUND

1. On or about May 10, 2013, the Petitioner issued an Administrative Complaint charging Respondent with violating sections 468.3101(1)(g) and 468.3101(1)(n), Florida Statutes.

2. The Administrative Complaint included a Notice of Rights which advised Respondent of the right to request an administrative hearing in accordance with sections 120.569 and 120.57, Florida Statutes. The Notice of Rights advised that the request must be in writing and must be received by the Agency Clerk within twenty-one (21) days. The Notice of Rights also stated:

Your failure to submit a petition or request for a formal hearing (Election of Rights) within twenty-one (21) days from receipt of this Administrative Complaint will constitute a waiver of your right to a hearing, and this complaint will thereby become a final order of the Department.

3. On May 10, 2013, the Department sent a copy of the Administrative Complaint to Respondent's address of record by certified mail. The Department did not receive a signed certified mail receipt indicating delivery of the documents.

4. On July 23, 2013, a Department investigator attempted to personally serve the Administrative Complaint on the Respondent, but was unable to make service after conducting a diligent search. An Affidavit of Service or Diligent Search indicated that the Department investigator searched for Respondent at all addresses shown in the Department investigation, all official addresses shown in Respondent's licensing records, and at all addresses listed by the local telephone company, the Division of Motor Vehicles, and utility companies.

5. Respondent's address of record is in Gainesville, Florida, located in Alachua County, Florida.

6. On August 29, 2013, September 5, 2013, September 12, 2013, and September 19, 2013, the Department published a Notice of Action in The Record, a weekly newspaper published in Alachua County, Florida. The Notice of Action advised that an Administrative Complaint had been filed against Respondent and directed the

Respondent to contact the Department by October 17, 2013.

7. Respondent did not submit a petition requesting a hearing within 21 days from the last publication date for the Notice of Action. The Agency Clerk for the Department of Health, in an affidavit signed on October 22, 2013, verified that no responsive pleading from the Respondent had been received by the Department. The Executive Director of the Program of Radiologic Technology, in an affidavit signed on October 22, 2013, verified that no responsive pleading from the Respondent had been received by the Program.

#### FINDINGS OF FACT

8. The facts alleged in the Administrative Complaint, attached as Exhibit A, are adopted and incorporated by reference in this Final Order. The following facts are included in the Administrative Complaint.

9. Respondent is a certified radiologic technologist ("CRT"), holding certificate number 66726.

10. Respondent was referred to the Professionals Resource Network ("PRN") by the University of Florida, College of Pharmacy.

11. PRN requested Respondent to schedule an evaluation. Respondent scheduled three evaluations, but failed to attend any of them.

#### CONCLUSIONS OF LAW

12. The Department of Health has jurisdiction pursuant to section 20.43 and chapter 468, Part IV, Florida Statutes.

13. Sections 120.569 and 120.57, Florida Statutes, and Florida Administrative Code Chapter 28-106, govern this procedure.

14. After unsuccessful attempts to serve the Administrative Complaint by

certified mail and by personal service, and after conducting a diligent search, the Department published the Notice of Action for four consecutive weeks in a newspaper published in Alachua County, the location of Respondent's address of record. Respondent properly followed the requirements of section 120.60(5), Florida Statutes, for substitute service of process.

15. By failing to respond to the Administrative Complaint, the Respondent has waived the right to an administrative hearing in this matter, pursuant to Florida Administrative Code Rule 28-106.111(4), which states, "Any person who receives written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters."

16. Because the Respondent has waived the right to a hearing, the facts alleged in the Administrative Complaint are not in dispute.

17. Section 468.3101(1)(g), Florida Statutes, subjects a certificateholder to discipline for being unable to practice radiologic technology with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or other materials or as a result of any mental or physical condition.

18. Taking all facts in the Administrative Complaint as true, Respondent exhibited behaviors that indicated possible impairment; however, an evaluation to determine if Respondent was unable to practice with reasonable skill and safety was not conducted. The facts in the Administrative Complaint do not prove that Respondent is unable to practice radiologic technology with reasonable skill and safety.

19. Section 468.3101(1)(n), Florida Statutes, subjects a licensee to discipline for failing to comply with the recommendations of the department's impaired practitioner program for treatment, evaluation, or monitoring. A letter from the

director of the impaired practitioner program that the certificateholder is not in compliance shall be considered conclusive proof under this part.

20. The Department's impaired practitioner program is PRN, pursuant to section 468.315, Florida Statutes and Florida Administrative Code Rule 64E-3.011.

21. Respondent was referred to PRN when her performance in the pharmacy educational program raised concerns that she may have a substance abuse problem. Based on this referral, PRN recommended that Respondent engage in an evaluation. Respondent did not comply with the evaluation. Failure to comply with an evaluation recommended by PRN is a violation of section 468.3101(1)(n), Florida Statutes.

22. Florida Administrative Code Rule 64E-3.011(n), sets out disciplinary guidelines for violations of section 468.3101(1)(n), Florida Statutes. Those guidelines recommend imposing, at a minimum, an evaluation by PRN, compliance with PRN recommendations and indefinite suspension until able to resume competent practice followed by probation for three years.

23. Petitioner has requested that Respondent's certificate to practice as a CRT be suspended indefinitely until Respondent is able to demonstrate she is able to safely practice as a CRT by submitting to a PRN evaluation and complying with any treatment or monitoring recommended as a result of that evaluation, followed by a five year probation period. This is consistent with the disciplinary guidelines, with the exception of the length of the probation, which is three years in the guidelines.

#### ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is determined that Respondent was properly served the Administrative Complaint pursuant to section 120.60(5), Florida Statutes. Respondent failed to request a hearing within twenty-one

(21) days and waived her right to an administrative hearing in this matter. The facts outlined in the Administrative Complaint establish that Respondent violated section 468.3101(1)(n) Florida Statutes. It is ordered that the following penalties be imposed against the Respondent:

1. Suspension of Respondent's CRT certificate number 66726 until Respondent submits to a PRN-facilitated evaluation and is determined by PRN to be safe to practice as a CRT.

2. Completion of any treatment recommended by PRN and, if recommended by PRN, entrance into and compliance with a PRN monitoring contract. Failure to comply with PRN recommendations for treatment or monitoring will be a violation of this final order.

3. Following the term of suspension, probation for a period of three years during which Respondent will comply with all PRN treatment, evaluation and monitoring recommendations.

DONE and ORDERED in Department of Health offices in Tallahassee, Leon County, Florida, this 19<sup>th</sup> day of November, 2013.

John H. Armstrong, MD, FACS  
Surgeon General & Secretary



---

Celeste Phipp, MD, MPH  
Deputy Secretary for Health  
Florida Department of Health

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been sent by regular U.S. mail to Jocelyn Zuessman, C.R.T. 3972 NW 23<sup>rd</sup> Circle, Gainesville, Florida 32605 and by hand delivery and/or by inter-office mail to Tari Rossitto-Van Winkle, Assistant General Counsel, Florida Department of Health, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399, this 21<sup>st</sup> day of November, 2013.



Deputy Agency Clerk  
Florida Department of Health

7012 3050 0001 9149 6255

**NOTICE OF RIGHT TO JUDICIAL REVIEW**

A PARTY ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS MUST BE INITIATED BY FILING A NOTICE OF APPEAL WITH THE CLERK OF THE DEPARTMENT OF HEALTH AND A COPY OF THE NOTICE OF APPEAL, ACCOMPANIED BY THE FILING FEE, WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES OR THE FIRST DISTRICT COURT OF APPEAL. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF THE FILING OF THIS FINAL ORDER.

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
BUREAU OF RADIATION CONTROL

DEPARTMENT OF HEALTH,  
PETITIONER,

v.

CASE NO. 2013-05310

JOCELYN ZUESSMAN, C.R.T.,  
RESPONDENT.

---

**ADMINISTRATIVE COMPLAINT**

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this administrative Complaint before the Department against Respondent, Jocelyn Zuessman, C.R.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of Radiologic Technology pursuant to Section 20.43, Florida Statutes; and Chapter 468, Part IV, Florida Statutes.
2. At all times material to this Administrative Complaint, Respondent was a Certified Radiologic Technologist (C.R.T.), within the State of Florida, having been first issued certificate number 66726.

Department of Health v. JOCELYN ZUESSMAN, CRT, TEMP GR  
Case Nos. 2012-00944, 2013-05310



3. Respondent's address of record is 3972 NW 23<sup>rd</sup> Circle, Gainesville, Florida, 32605.

4. In or during the spring of 2012, Respondent was a senior student at the University of Florida, College of Pharmacy, in the Doctor of Pharmacy Program.

5. In the University of Florida spring semester, 2012, Respondent began to encounter difficulties with her course work in the Doctor of Pharmacy Program by the following: a) Missing scheduled examinations; 2) Being removed from, and receiving a grade of "N" in, the Advanced Pharmacy Practice Experience (hereafter, "APPE"); 3) Failing a pharmacy elective course; and/or Receiving an "Incomplete" in another pharmacy elective course.

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13. As of on or about November 7, 2012, Respondent had failed to contact PRN to schedule an evaluation.

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20. Between November 27, 2012, and January 16, 2013, Respondent failed to attend any of the three (3) PRN evaluations scheduled for her.
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22. On or about March 29, 2013, PRN filed a report with the Department of Health indicating that Respondent's inability to complete assignments, classes, and rotations at the University of Florida, College of

Pharmacy has lead to concerns by PRN about Respondent's mental health and possibility substance abuse.

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Count One -- Impairment

24. Petitioner re-alleges paragraphs one (1) through twenty-three (23) as if fully set forth a length herein.

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26. As evidenced by Respondent's history of an inability to complete assignments, classes, and rotations at the University of Florida,

College of Pharmacy, PRN's concerns about Respondent's mental health and possibility substance abuse, and Respondent's refusal to attend a PRN evaluation, Respondent is unable to practice Radiologic Technology with reasonable skill and safety to patients.

27. Based on the foregoing, Respondent violated Section 468.3101(1)(g), Florida Statutes (2012).

Count Two – Refusal to Comply PRN Directives

28. Petitioner re-alleges paragraphs one (1) through twenty-three (23) as if fully set forth a length herein.

29. Section 468.3101(1)(n), Florida Statutes (2012), subjects a CRT to discipline for failing to comply with the recommendations of the Department's impaired practitioner program for treatment, evaluation, or monitoring.

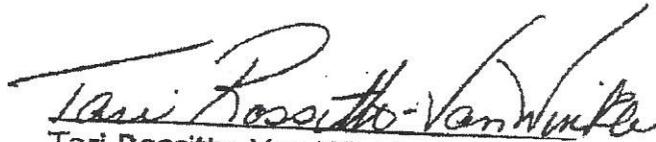
30. Respondent has refused to attend three (3) scheduled PRN evaluations as requested by PRN.

31. -Based on the foregoing, Respondent violated Section 468.3101(1)(n), Florida Statutes.

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

SIGNED this 15<sup>th</sup> day of May, 2013.

John H. Armstrong, MD, FACS  
Surgeon General & Secretary



Tari Rossitto-Van Winkle, R.N., J.D.  
Assistant General Counsel  
DOH Prosecution Services Unit  
4052 Bald Cypress Way, Bin C-65  
Tallahassee, Florida 32399-3265  
Florida Bar Number: 0613908  
(850) 245 - 4444 ex. 8139 Telephone  
(850) 245 - 4681 Facsimile  
tari\_rossitto-vanwinkle@doh.state.fl.us

**FILED**

DEPARTMENT OF HEALTH  
DEPUTY CLERK

CLERK: *Bridget Coates*

DATE: AUG 23 2013

PCP Date: April 30, 2013

PCP Members: James Futch, Ben Register & Dalsy King

**Certificate of Service**

I hereby certify that a true and correct copy of the foregoing has been furnished by U.S. Certified Mail to JOCELYN ZUESSMAN, C.R.T., 3972 NW 23<sup>rd</sup> Circle, Gainesville, Florida, 32605, on this 10<sup>th</sup> day of May, 2013.

*Tari Rossitto-Van Winkle*  
Tari Rossitto-Van Winkle, R.N., J.D.  
Assistant General Counsel

**NOTICE OF RIGHTS**

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Department of Health  
Prosecution Services Unit  
Attention: Tari Rossitto-Van Winkle, R.N., J.D.  
4052 Bald Cypress Way, Bin #C65  
Tallahassee, Florida 32399-1701

Mediation is not available as an alternative remedy.

Your failure to submit an a petition or request for a formal hearing (Election of Rights) within twenty-one (21) days from receipt of this Administrative Complaint will constitute a waiver of your right to a hearing, and this complaint will thereby become a final order of the Department.

**Mission:**  
To protect, promote, & improve the health of all people in Florida through integrated state, county & community efforts.



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

**Initial Application for Licensure**  
**Florida Board of Pharmacy**  
**Florida Department of Health**

**Basic Data**

Profession: REGISTERED PHARMACY TECHNICIAN  
Application Type: REGISTERED PHARMACY TECHNICIAN INITIAL APPLICATION  
Name: MS. JOCELYN ARIANA ZUESSMAN  
Date of Birth: 11/30/1984  
Place of Birth: SALT LAKE CITY UTAH  
Email Address: JZUESSMAN@GMAIL.COM

**Mailing Address**

1500 NE 4TH ST  
UNIT B  
POMPANO BEACH, FL 33060

**Physical Location or Address of Employment**

1500 NE 4TH ST  
UNIT B  
POMPANO BEACH, FL 33060

**Phone Numbers**

Home: 407-340-4660  
Business: 407-340-4660

**Equal Opportunity Data**

Gender: FEMALE  
Race: WHITE

**Education History**

Course Provider:	UNIVERSITY OF FLORIDA
Course Approved By:	FLORIDA BOARD OF PHARMACY APPROVED
Course Completion Date:	05/12/2014

**Other Name History**

No Other Name History data entered.

**Secondary Work Location**

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**Other State Licenses**

License Number:	CRT66726	License Number:	PSI24554
License Type:	RADIOLOGIC TECHNOLOGI	License Type:	PHARMACY INTERN
Licensure Date:	09/30/2005	Licensure Date:	11/18/2008
Date of Expiration:	11/30/2010	Date of Expiration:	01/30/2013
Country:	UNITED STATES	Country:	UNITED STATES
State:	FLORIDA	State:	FLORIDA

**Criminal History**

Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to a crime in any jurisdiction other than a minor traffic offense?

Your answer: **NO**

**Discipline History**

Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state or U.S. jurisdiction?

Your answer: **YES**

Name of Agency: PRN  
Final Action: NON-COMPLIANCE WITH PRN  
Action Date: 11/30/2012  
Appeal Status: NO

REFERRED TO THE PHYSICIAN RESOURCE NETWORK FROM THE UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY, DOCTORATE PROGRAM. MY HEALTH HAD DECLINED AND I DID NOT HAVE HEALTH INSURANCE AT THE TIME OF REFERRAL. THE PHYSICIAN RESOURCE NETWORK WAS NOT ABLE TO EVALUATE ME UNTIL MY MEDICAL HEALTH/STATUS HAD BEEN DOCUMENTED. I'M CURRENTLY IN THE PROCESS OF SUBMITTING MEDICAL CLEARANCE TO THE PHYSICIAN RESOURCE NETWORK SO THAT I CAN COMPLETE THE EVALUATION. THE PHARMACY TECHNICIAN PROGRAM WAS ALSO A REQUIREMENT TO COMPLETE THE PHYSICIAN RESOURCE NETWORK EVALUATION AS MY INTERN LICENSE IS NULL AND VOID. MY CASE MANAGER IS CHRISTINA GAUDIANA. THE BEST WAY TO REACH HER IS VIA THE FOLLOWING EMAIL ADDRESS, CHRISTINAG@FLPRN.ORG.

Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?

Your answer: **NO**

Are you presently being investigated or is any disciplinary action pending against you?

Your answer: **YES**

Name of facility: PRN  
Date: 11/30/2012  
Action Taken: NON-COMPLIANCE WITH PRN  
Appeal Status: NO

PLEASE SEE ABOVE

**Questions related to Section 456.0635(2), Florida Statutes**

- Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? Your answer: **NO**
- For the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation? Your answer: **N/A**
- For the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes). Your answer: **N/A**
- For the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation? Your answer: **N/A**
- Have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? Your answer: **N/A**
- Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? Your answer: **NO**
- Has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended? Your answer: **N/A**
- Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? Your answer: **NO**
- If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years? Your answer: **N/A**
- Have you ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program? Your answer: **NO**
- Have you been in good standing with a state Medicaid program for the most recent five years? Your answer: **N/A**
- Did the termination occur at least 20 years before the date of this application? Your answer: **N/A**
- Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? Your answer: **NO**
- On or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? Your answer: **N/A**

**Additional Information**

Availability for Disaster: Will you be available to provide health care services in special needs shelters or help staff disaster medical assistance teams during times of emergency or major disaster? Your answer: **YES**

**Military Veteran Fee Waiver**

Date of Discharge: Your answer: **N/A**