AGENDA
Department of Business and Professional Regulations
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL
February 12, 2013
9:30 a.m.

Conference Call Number 1-888-670-3525
Conference Code 925-988-7749

Council Members:
Gary Cacciatore, Pharm.D., J.D., Chair, Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Albert Garcia, Board of Pharmacy
Joseph Brecko, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Jenn Ungru, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Physician- Vacant

DRPR Staff:
Reggie Dixon, Executive Director,
Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Mike Walker, Deputy Secretary
Robert Jeromagan, Compliance Manager
Dinah Skrnic, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order and Introductions: Gary Cacciatore, Chair

TAB 1: Approval Meeting Minutes August 16, 2012

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD
1. Federal Pedigree

TAB 3: Controlled Substance Reporting – Dinah Skrnic and Mindy Heindl

TAB 4: Executive Director's Report – Reginald Dixon
1. Language Borrow and Loan – Florida Society Health System Pharmacist
2. Cancer Drug Donation Program
3. Rules
4. Meningitis
5. 2013 Legislative Session
6. CSR Auditing
7. DDC 2013 Legislative Report

TAB 5: Compounding Update-Mark Whitten, Executive Director – Board of Pharmacy

TAB 6: HB 517 Communication – Patrick Barnes

TAB 7: 2013 Meeting Dates- Approval

TAB 8: Other Business

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Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
The Drug Wholesale Distributor Advisory Council announces a telephone conference call to which all persons are invited.

DATE AND TIME: February 12, 2013, 9:30 a.m.
PLACE: Conference Call Number (888) 670-3525; Conference Code 9259887749

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business
A copy of the agenda may be obtained by contacting: The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047; 7 days prior to meeting.
http://www.myfloridalicense.com/dbpr/ddc/council_meeting.html

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Division of Drugs, Devices and Cosmetics at (850) 717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, (800) 955-8771 (TDD) or (800) 955-8770 (Voice).

For more information, you may contact: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047; or (850) 717-1800.
Drug Wholesale Distributor Advisory Council Meeting
August 16, 2012
Draft Meeting Minutes

9:30 a.m. Call to Order by Gary Cacciatore, Chair
The meeting was called to order by the Chair, Mr. Cacciatore.

Roll Call taken by Dinah Skrnich.

The following council members were present:
Mr. Cacciatore, Mr. Ayotte, Mr. Brecko, Mr. Ellis, Mr. Brock, Mr. Mahoney, Mr. Barnes.

The following council members were absent: Mr. Garcia, Ms. Zeiler.

A quorum was present:

Tab 1: Approval of May 17, 2012 Meeting Minutes
Motion by: Mr. Mahoney and seconded by Mr. Barnes to approve the minutes. Motion Carried.

Tab 2: Chair's Report - Mr. Gary Cacciatore

1. Federal Pedigree –
Mr. Ayotte gave a brief report on this item regarding Prescription Drug User Fee Act. No action was needed.

Mr. Barnes asked when will the California serialization go into effect.

Mr. Cacciatore stated the dates are 2015 for Manufacturer, 2016 for Wholesaler and 2017 for Pharmacies.

TAB 3: Controlled Substance Reporting – Kristen Grosch

Ms. Grosch informed the council that the reporting has increased for the controlled substance reporting from 18% to 24%.

The department will soon begin testing the FTP process. We will be working with one of the distributors to test the process.

Mr. Dixon informed the council that the department will begin the enforcement of this in the near future.
1. 61N-1.011 Wholesale Distribution of Prescription Drugs. Exceptions
Mr. Dixon stated there was a question about this rule and the emergency medical reasons. After speaking with the Department of Health there was previous history on this rule promulgation that had been started at the Department of Health. There was an error when the rule went through the process and the word “or” was omitted from the published language. The Department can have this corrected by stating a technical error had occurred.

This rule does not apply if a distribution center is out of commission from and emergency such as a fire of the facility. The company needs to have a business continuity plan in place.

2. Borrow and Loan
Mr. Dixon stated there was a question at the last meeting about borrow and loan of prescription drugs from a hospital setting. After further research and discussion with different individuals the Department has come to the conclusion that the terminology of borrow and loan is outdated.

Mr. Dixon stated the Department will be working with the associations and industry on creating new terminology. Mr. Barnes and Mr. McQuone will work with the Department on providing language for this process.

Mr. McQuone will provide the Department with a copy of the language once it is drafted.

Mr. Dixon stated that the department will be educating our inspectors on this issue. The Department will be reviewing any cases that come in from the inspectors on a case by case basis for compliance.

3. 2013 Legislative Proposals
Mr. Dixon gave a brief over-view of the 2013 Legislative suggestions from the industry.

Mr. Dixon explained how the process works for the department.

Mr. Barnes stated there was previous discussion on repackager and the Department stated it would require a legislative change. I would like to add this to the legislative list.

Mr. Ciacirote stated to clarify the legislative change that is required. Is it basically creating and out of state repackager permit.
Mr. Barnes stated that is one of them and the other is ownership when product is transferred from the wholesaler to the repacker who actually owns it at that point of time.

Mr. Jermigan stated there is and existing exemption from the definition of wholesale distribution for and out and back transaction from a hospital or health care provider to a repacker for that purpose. The problem is the existing statutory language contains the word "return" and that implies it has to come to the hospital first. The question has been can the hospital purchase drugs have them drop shipped to the repacker and then shipped to the hospital.

That one word is creating a certain amount of in efficiency in handling and shipping cost. You have to pay to ship the drugs to repacker from the hospital now. There are existing exemptions that allow for the type of result that you're looking for with those dollars. To have the drugs repackaged or if the health care system is large enough to self repacke.

Mr. Cacciatore stated that if this is part of the Departments legislative package the council could make a recommendation to support this.

Mr. Cacciatore stated that he had some comments from the audience that not all the suggestions sent from the industry are on the list.

Mr. Dixon stated that the Department will go through and update the list and make it available on the web-page.

Steve Miller of Air Liquide USA asked is there a formal decision making process of what will be approved to move forward through legislation?

Mr. Dixon stated one of the issues with medical gas is most of the requirements we have are in place based on the federal guidelines. We don't have and option of making a statutory change that fall below the federal guideline.

Mr. Ayotte asked when will the Department have the legislative packet available.

Mr. Dixon stated by the end of September.

4. Blood Establishment

Mr. Dixon gave a briefing on the Restricted Prescription Drug Distributor permit for Blood Establishments.

Mr. Dixon stated the Department will be working on rulemaking for 61N-1.023 to include this new permit. The Department will be working with the Blood Establishments on what
specific drugs fit the category of the language then bring it back to the council for review.

Mr. Dixon stated we may schedule a conference call to discuss this issue.

5. Centralized Repackaging

Mr. Dixon stated Florida Statutes 499.01 subsection 5 was recently amended. It allows restricted permit holders who have a health care entity permit to repack and distribute prescription drugs to other health care entities under common ownership. There was a question on how is the Department going to administer this.

Part of the new statute is you notify the department 30 days before you start this new practice.

The Department may need to perform and inspection of your facility. There will be a modifier added to your license number that has you repackaging.

When the department performs and inspection it will be for a repackager permit. The inspectors will be looking for policy and procedures and security requirements.

TAB 5: Other Business

Cancer Drug Donation Program

Ms. Skrnich thanked Mr. McQuone of the Florida Society of Health System Pharmacist for allowing the program to participate in their meeting.

Ms. Skrnich gave a review of the program and asked that the council keep the program in mind when they are destroying drugs and donate them to one of the participating hospitals.

Proposed Meeting Dates for 2013

Mr. Dixon stated these are proposed dates for the 2013 calendar year.

Mr. Cacciatore stated that the council had discussed having two face to face meetings. Change it from February 14, 2013 to February 12, 2013. Have the February 12 date and August date as the face to face meetings. The council agreed.

Senate Bill 517 - Mr. Barnes

Mr. Barnes stated at the last meeting we had talked about Senate Bill 517. Contract pharmacies being able to contract with covered entities. Is this transaction going to require a pedigree?
Mr. Barnes stated for example I am a covered entity and I want to partner with three community pharmacies to take care of my patients that don’t use my hospital. I have to buy the drug it is purchased from me it would then be shipped from the wholesaler to those contracted pharmacies. Does this require a pedigree transaction?

Mr. Jernigan stated the wholesaler would provide a pedigree regardless. They will pass a pedigree the bill to ship to the covered entity to the extent that you want to provide the drugs yourself as opposed to having them dropped shipped. You can get a Restricted Government entity permit if you have that permit the activities under that permit are and exception to the definition of wholesale distribution. If it’s not a wholesale distribution you don’t have to pass a pedigree.

Mr. Jernigan stated the covered entity can get a Restricted Prescription Drug Distributor permit for Government programs. It’s a special type of permit for 340B covered entities. That means you can take you’re inventory that you receive purchased 340B drugs and transfer them to contract pharmacies. You can also have the drugs in a different licensing scenario dropped shipped from the source to the contracted entities. The wholesaler is required to provide the pedigree to the recipient of the drugs. In the second example that’s not your hospital that’s the contracted pharmacy. They will be passing a pedigree to the recipient of the drugs.

Mr. Barnes stated that if we wanted to contract with pharmacies I need to get this permit.

Mr. Jernigan stated if you are serving 340B patients out of your hospital directly then you are not going to be operating solely on the drop shipment supply to your contract pharmacy. If you are not operating solely on the drop shipment model you can get the permit that would allow you to send the drugs to the contract pharmacy.

Mr. Cacciatore stated that would allow you to send drugs from your hospital to the contracted pharmacy without pedigree because it’s not a wholesale transaction.

Mr. Cacciatore asked if there was any further business to discuss. Hearing none a motion to adjourn was given.

Motion by: Mr. Barnes seconded by Mr. Mahoney. Meeting was adjourned.
TAB 2: CHAIR’S REPORT

1. FEDERAL PEDIGREE
**TAB 3: CONTROLLED SUBSTANCE REPORTING**
CSR
Controlled Substances Reporting System

Number of Registered Distributors That Are Reporting

Since 7/1/2011
Registered Distributors Who Have Reported = 434
Registered Distributors Who Have Not Reported = 125
Total Registered Distributors = 559

Number of Potential Reporting Distributors

Not Reported
22%

Reported
78%
Total of All Reports Submitted = 5051
Total of All Transactions = 11,604,262

Highest Reporter By Volume

- Cardinal Health
- McKesson
- AmerisourceBergen Drug Corp.
- CVS
- Henry Schein
- Publix Supermarkets, Inc.
- Walgreens Distribution Center
TAB 4: EXECUTIVE DIRECTOR’S REPORT

1. BORROW AND LOAN
2. CANCER DRUG DONATION PROGRAM
3. RULES
4. MENINGITIS
5. 2013 SESSION
6. CSR AUDITING
7. DDC 2013 LEGISLATIVE REPORT
TAB 4: EXECUTIVE DIRECTOR REPORT

1. BORROW AND LOAN
Florida Drugs, Devices and Cosmetics Program (Department of Business and Professional Regulation):
The Drug Wholesale Distributors Advisory Council met in Tallahassee on Thursday, August 16, 2012. The
DWDAC advises the DBPR / DDC on issues related to Chapter 499 FS and 61N-1 FAC. FSHP member
Patrick Barnes is the appointed Hospital Pharmacy representative to the DWDAC.

“Borrow and Loan”
Executive Director Reggie Dixon addressed the issue of “Borrow and Loan,” the traditional practice use
by pharmacies to obtain and then return a prescription drug that was not otherwise available. This
practice, while widespread in the industry, is “outdated” and is considered illegal as outlined in the
following scenario:

Hospital A has an immediate need for a prescription drug that is not in their inventory. They
contact Hospital B to arrange for the item. Shortly afterwards, Hospital A acquires a supply of
the item and returns an equivalent amount of the prescription drug to Hospital B.

The first transaction (Hospital A contacts Hospital B to obtain the needed item) is covered under 61N-
1.011(1) which lists the exceptions to the Whole Distribution of Prescription Drugs. Specifically this
situation is covered in the following: “(a) Transfers of a prescription drug between health care entities of
from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug
arising from delays in or interruption of regular distribution schedules, and should not occur between the
parties so as to amount to the health care entity regularly and systematically supplying that drug.”
Simply, Hospital B has supplied the prescription drug due to the “medical necessity” presented by
Hospital A.

The second transaction (Hospital A returns the prescription drug to Hospital B) is not in response to a
“medical necessity” and therefore not covered by 61N-1.011 as an exception to the definition of
wholesale distribution. If the second transaction were completed, Hospital A would be acting in violation
of Chapter 499 as an “un-registered wholesaler” and if Hospital B would accept the returned goods, they
risk a violation of Chapter 499 by accepting drugs from an unregistered / unlicensed source. Ouch! Two
nasty violations and all Hospital A was trying to do was be a “good neighbor” and return a borrowed
item! For a suggestion, read on:
Executive Director Dixon advises that the first transaction (Hospital B providing the prescription drug to
Hospital A) be handled as a “sale” (emphasizing that it is a “one-way” transaction) The statute and the
rule are silent on the terms of the sale, price of goods, etc. These decisions are between the parties.
Both parties are advised to maintain sufficient records of each transaction including, at minimum, the
name, address and permit numbers of both parties, product description and quantity. These records
will be subject to inspection and should follow the recordkeeping rules.

Centralized Repackaging:
Executive Director Dixon described that DBPR is in the process of developing guidelines for the
implementation of HB517. The application for Restricted Prescription Drug Distribution Permit will be
amended to capture the required information regarding the licensure authority of each of the facilities under common ownership, etc.

For additional information on any of these subjects, contact Mike McQuone muikemcquone@fshp.org
TAB 4: EXECUTIVE DIRECTOR REPORT

2. CANCER DRUG DONATION PROGRAM
# CANCER DRUG DONATION PROGRAM PARTICIPATION REPORT

<table>
<thead>
<tr>
<th>Hospital Participant</th>
<th>Date Hospital Approved</th>
<th>Contact</th>
<th>Phone</th>
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<tbody>
<tr>
<td>Moffitt Cancer Center</td>
<td>10/4/2012</td>
<td>Gene Weitzer</td>
<td>813-374-4644</td>
</tr>
<tr>
<td>12902 Magnolia Drive Tampa FL 33612</td>
<td></td>
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<tr>
<td>Shands Hospital at the University of Florida</td>
<td>10/4/2012</td>
<td>Alan Knudson</td>
<td>352-265-0404</td>
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<tr>
<td>1600 SW Archer Road Gainesville FL 32610</td>
<td></td>
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<tr>
<td>Sacred Heart Health</td>
<td>10/20/11</td>
<td>Debra Messer</td>
<td>860-416-7712</td>
</tr>
<tr>
<td>1545 Airport Blvd Pensacola FL 32504</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halifax Medical Center</td>
<td>11/13/2007</td>
<td>Jim Shepherd</td>
<td>386-254-4193</td>
</tr>
<tr>
<td>303 N Clyde Morris Blvd Daytona Beach FL 32114</td>
<td>11/13/2007</td>
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<tr>
<td>Adventist Health System/Sunbelt Health Care</td>
<td>2/7/2008</td>
<td>Rebecca R Preyster Robert Ingram</td>
<td>7407-303-4927</td>
</tr>
<tr>
<td>400 Celebration Place PH 15674</td>
<td></td>
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<tr>
<td>Tallahassee Memorial</td>
<td>6/30/2008</td>
<td>Bernadette Brown</td>
<td>850-431-5030</td>
</tr>
<tr>
<td>1300 Miccosukee Road Tallahassee FL 32308</td>
<td></td>
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<tr>
<td>Jackson Memorial Hospital</td>
<td>10/22/2012</td>
<td>Vanessa Pimental</td>
<td>305-585-7411</td>
</tr>
<tr>
<td>1611 NW 12th Avenue Miami FL 33186</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Hospital Name</td>
<td>Address</td>
<td>Date</td>
<td>Nurse Name</td>
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<tr>
<td>Indian River Medical Center</td>
<td>1000 36th Street Vero Beach, FL 32960</td>
<td>5/6/2012</td>
<td>Anna Heuer</td>
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<td></td>
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<td>Michael Briante</td>
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<tr>
<td>Baptist Medical Center</td>
<td>800 Prudential Drive Jacksonville, FL 32207</td>
<td>11/6/2012</td>
<td>Nicole Blackwelder</td>
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<tr>
<td>Lower Keys Medical Center</td>
<td>5500 College Road Key West, FL 33940</td>
<td>5/19/2012</td>
<td>David Ribanti</td>
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<tr>
<td>Sun City Hospital Inc</td>
<td>14016 Sun City Center Blvd, Sun City Center, FL 33356</td>
<td>11/12/2012</td>
<td>Agostina Eberstein</td>
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<tr>
<td>Mt. Sinai Medical Center</td>
<td>4500 Allen Road Miami Beach, FL 33140</td>
<td>11/19/2012</td>
<td>Mukesh Shah</td>
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<tr>
<td>Healthsouth Rehabilitation Hospital</td>
<td>Hospital of Spring Hill 12440 Cortez Blvd, Brooksville, FL 34613</td>
<td>11/19/2012</td>
<td>John Stevens</td>
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<tr>
<td>Baptist Hospital of Miami</td>
<td>6800 North Kendall Drive Kendall, FL 33176</td>
<td>11/20/2012</td>
<td>Anay Mosad</td>
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<tr>
<td>Palm Bay Hospital</td>
<td>1425 Malabar Road NE Palm Bay, FL 32907</td>
<td>11/28/2012</td>
<td>Karen Bills</td>
</tr>
</tbody>
</table>

Revised 12/28/2012
3. RULES
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUGS, DEVICES AND COSMETICS

RULE NO.: 61N-1.012
RULE TITLE: Records of Drugs, Cosmetics and Devices

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to amend the language to expand the return period of seven days for the exception to the pedigree documentation requirement for prescription drugs that are delivered in error to fourteen days.

SUMMARY: The proposed rule amends the language to expand the return period of seven days for the exception to the pedigree documentation requirement for prescription drugs that are delivered in error to fourteen days.

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: The Department conducted an analysis of the proposed rule's potential economic impact and determined that it did not exceed any of the criteria established in Section 120.541(2)(a), F.S.

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: 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS

LAW IMPLEMENTED: 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS.

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


THE FULL TEXT OF THE PROPOSED RULE IS:

61N-1.012 Records of Drugs, Cosmetics and Devices.

(1) through (2) No change.

(3) Pedigree Papers.

(a)(1) The pedigree papers required by Sections 499.01212, F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from
which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

2. A copy of the pedigree paper must be maintained by each wholesale distributor preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesale distributor preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesale distributor serves as the repository of its customer's pedigree, the wholesale distributor must specify on the customer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.

(b) If a wholesale distributor uses the statement contained in Section 499.01212, F.S., "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer" the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(c) Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," either Form DH 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2129 must be used to comply with the requirement in Section 499.01212, F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either "Prescription (legend) Drug Pedigree – Repackager" Form DH 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2135. A wholesale distributor that further distributes a repackaged prescription drug must include in the pedigree the information related to the repackaged drug contained in Form DH 2135 or the electronic record that contains all the elements of Form DH 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.01212, F.S., at the discretion of the wholesale distributor. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-
Rom or smart card or similar devices. Additional information to that required by forms DH 2129 and DH 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.

(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesales distributor providing the pedigree paper.

(e) Effective March 1, 2004, a pedigree paper under Section 499.01212, F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record. A prescription drug wholesales distributor that receives or prepares a pedigree paper under Section 499.01212, F.S., and this chapter that traces the previous distributions of a prescription drug back to a prescription drug wholesales distributor that is not listed on the department’s web site as an authorized distributor of record for the drug’s manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesales distributor is an authorized distributor of record in accordance with the criteria of Section 499.01212, F.S.

(f) Returns.

1. When a distribution of a prescription drug by a wholesales distributor to an authorized recipient pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that shipment prescription drug by the authorized recipient to the wholesales distributor need not be reflected in a the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within fourteen seven calendar days after the date of receipt of the original shipment:

   a. The authorized recipient ships the specific unit of the prescription drug back to the wholesales distributor from which that specific unit was purchased; or

   b. The authorized recipient transmits a documented communication to the wholesales distributor from which the prescription drug was purchased stating the authorized recipient’s intent to return the shipment in accordance with the wholesales distributor’s wholesales prescribed written policies and procedures and the wholesales distributor communicates authorization for return of the product.

2. Any returns to a wholesales distributor by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in a the pedigree paper trail for any subsequent wholesales further distributions of the returned drug product to the extent required by Section 499.01212, F.S.
3. An authorized recipient that returns a prescription drug shipment to the wholesale distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.325(2), F.S., a written document submitted with the returned product,

   a. That the specific unit (exact unit) being returned was purchased from the receiving wholesale distributor (including the corresponding sales invoice number and the date of the sale from that wholesale distributor to the authorized recipient); and

   b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

   c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

   (g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization code.

   (h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesale distributor consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., (and that wholesale distributor provides a pedigree to its customer consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., the wholesale distributor must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesale distributor provides to its customer.

   (i) A wholesale distributor that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives those units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesale distributor prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (h) above.

   (j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.01212, F.S., to provide a pedigree paper upon distribution of the manufacturer's
prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets
the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on
its relationship with the manufacturer.

(k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care
practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree
that complies with Section 499.01212, F.S., is not available, when the prescription drug is required immediately to
treat a specific patient with a life-threatening medical condition or a medical condition that will result in serious
bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to
the supplying wholesale distributor(s) that the emergency meets this rule paragraph's requirements and the
supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section
499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable
provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.

(4) through (11) No change.

(12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business
shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or
business. A person permitted under Chapter 499, F.S., that also conducts other business activities not permitted
under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct
from the other business activities. For the purpose of this rule, those operational systems required to be kept separate
and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and
manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A
Retail Pharmacy Drug Wholesale Distributor wholesaler however, is not required to maintain its stock of
prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription
drugs which may be dispensed by a retail pharmacy.

(13) through (15) No change.

(16) Establishing an ongoing relationship pursuant to Sections 499.01212, F.S. A wholesale distributor that is
not listed as an authorized distributor of record on the list submitted to the department by a prescription drug
manufacturer may request the department add the wholesale distributor to the department's web site of authorized
distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.01212,
F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.

(a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesale distributor establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:
   a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR
   b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR
   c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales, excluding customer returns. AND

2. For each manufacturer for whom the wholesale distributor claims authorized distributor of record status, submit both subparagraphs a. and b. to document that the wholesaler distributor annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer’s prescription drug products directly from that manufacturer.
   a. A computerized listing of all of a manufacturer’s prescription drugs purchased by the wholesaler distributor during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled. AND
   b. A computerized listing of all purchases of a manufacturer’s prescription drugs directly from the
manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesaler distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

ii. Copies of the manufacturer’s sales invoices of prescription drugs to the wholesaler distributor. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesaler distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

3. Each wholesaler distributor establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group’s ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesaler distributor establishment, must submit the names and address of all member wholesaler distributor establishments of the affiliated group. In addition, each wholesaler distributor establishment must either:

a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as the affiliated group upon which the eligibility criteria for the affiliated group was met, or

b. Hold a valid prescription drug wholesaler distributor permit or out-of-state prescription drug wholesaler distributor permit issued under Chapter 499, F.S.

(b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:

a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR

b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR

c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-
month period based on the most recent calendar quarter, of at least $100 million. This report must be totaled. The
detail should include the invoice number, invoice date, customer name, and total invoice amount related to
prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug
sales, excluding customer returns.

2. For each manufacturer for whom the wholesaler distributor claims authorized distributor of record status,
submit a., b., or c. to document that the wholesaler distributor has a verifiable account number issued by the
manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the
verifiable account number.

a. If the wholesaler distributor is a member of an affiliated group and all purchases from that manufacturer are
made at a central location for the wholesaler distributor, copies of at least 12 invoices dated during the previous 12
months from the date the information is submitted, which invoices document purchases of prescription drugs, at
least one unit of which on each invoice was not returned, under that central account number but shipped to the
wholesaler distributor's address for whom the authorized distributor of record status is claimed. A statement must be
provided that the invoices document purchases of prescription drugs for the wholesaler distributor for whom the
authorized distributor of record status is claimed and that the wholesaler distributor did not return to the
manufacturer at least one unit of the prescription drugs on each invoice.

b. If the wholesaler distributor is a member of an affiliated group and all purchases from that manufacturer are
made at a central location and received at a central location for the wholesaler distributor, copies of at least 12
invoices dated during the previous 12 months from the date the information was submitted, under the same account
number which is clearly assigned to the wholesaler distributor at the permitted address. Each invoice must document
the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement
must be provided that the invoices document purchases of prescription drugs by that central location and that the
central location or wholesaler distributor for which the drugs were obtained did not return to the manufacturer at
least one unit of the prescription drugs on each invoice, and that the central location shipped at least 12 times to the
individual wholesaler distributor for whom the authorized distributor of record status is claimed during the 12
months based on the fiscal year or designated timeframe.

c. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from
the date the information was submitted, under the same account number that is clearly assigned to the wholesales
distributor at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that wholesaler distributor and that the wholesaler distributor did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

Rulemaking Authority 499.003, 499.005, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS. History—New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-05, 8-6-06, Formerly 64F-12.012, Amended _________.

NAME OF PERSON ORIGINATING PROPOSED RULE: R. Kathleen Brown-Blake, Assistant General Counsel, Office of the General Counsel, 1940 North Monroe Street, Suite 42, Tallahassee, Florida 32399, (850)717-1244

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 1, 2012

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: August 3, 2012
4. MENINGITIS
Via Hand Delivery

GULF COAST SURGERY CENTER
411 2ND STREET EAST
BRADENTON, FL 34208

RE: Facility Inspection

To Whom It May Concern:

This agency (DBPR) and the Florida Department of Health are conducting onsite reviews at all 257 facilities in Florida believed to have received recalled prescription drugs from the New England Compounding Center ("NECC") of Framingham, Massachusetts since January 1, 2012.

The department employees designated to conduct these reviews will carry and present department-issued credentials, including photographic identification, indicating employment with the Division of Regulation or the Division of Drugs, Devices, and Cosmetics. Our personnel will attempt to complete this task with minimal disruption. The review will include brief interviews of key personnel, a walk-through of all parts of the facility, a thorough examination of all drug storage areas, and review and possible copying of NECC-related records.

We will also conduct a detailed inventory of any NECC products still on hand. Your facility will receive a copy of the results that may assist in responding to NECC’s recall. The recall is not mandatory, but the department strongly encourages all facilities to comply with the procedures established by NECC and the U.S. Food and Drug Administration.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorizes a covered entity to disclose protected health information without the written authorization of an individual or without the opportunity for an individual to agree or object, when such disclosure is to a health oversight agency for oversight activities authorized by law. DBPR is an agency of the State of Florida authorized to administer and enforce Chapter 499, Florida Statutes, to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices or cosmetics. Chapter 499, Florida Statutes is intended to safeguard the public health and promote the public welfare by protecting the public from injury by product use and merchandising deceit involving drugs, devices, and cosmetics.

We appreciate your cooperation. Feel free to contact the Division of Drugs, Devices, and Cosmetics with questions or concerns.

Sincerely,

Reginald D. Dixon

Reginald D. Dixon
Director

LICENSE EFFICIENTLY. REGULATE FAIRLY.
WWW.MYFLORIDALICENSE.COM
November 21, 2012

All Children's Hospital
501 6th Avenue South
Saint Petersburg, FL 33701

RE: URGENT Product Recall – Ameridose, LLC

To Whom It May Concern:

DBPR understands that your facility has received prescription drugs from Ameridose, LLC ("Ameridose"), a Florida-licensed, non-resident prescription drug manufacturer located in Massachusetts. Ameridose’s management is associated with the New England Compounding Center ("NECC"), the compounding pharmacy linked to the ongoing outbreak of fungal meningitis from contaminated medications.

On October 31, 2012, Ameridose issued a voluntary recall of its unexpired products in circulation. Health care professionals should cease using any products from Ameridose at this time and should return the products to the company. A complete list of recalled products subject to this recall, as well as instruction on how to return the recalled products, is available at Ameridose’s website: http://www.ameridose.com/news/. The U.S. Food and Drug Administration ("FDA") has conducted an inspection of the Ameridose facilities and has published its initial findings on its website at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm326331.htm.

DBPR strongly urges you to segregate all Ameridose products from other stock, secure the medications, and contact Ameridose at 1-888-820-0622 for instructions on how to return the products. For the most up-to-date information you can call the FDA’s Drug Information Line at 1-855-543-DRUG (3784).

Respectfully,

Reginald D. Dixon

Reginald D. Dixon
Director
TAB 4: EXECUTIVE DIRECTOR’S REPORT

5. 2013 Legislative Session-Discussion
6. CSR Auditing-Discussion
TAB 4: EXECUTIVE DIRECTOR’S REPORT

7. 2013 Legislative Report
Message from the Secretary

Dear Fellow Floridians,

Fiscal Year 2011/2012 was a great year at the Department of Business and Professional Regulation, and I hope a great year for you as well. Last year, I pledged that our Department was committed to increasing the Department's efficiency and making our processes easier for those that matter: our customers. Over the past 12 months, we've made several improvements which I believe are helping us achieve that goal.

The first improvement we have made and continue to work toward is reducing the license processing times. In October 2008, the average license processing time was 41 days, and as of the end of July 2012, the average had decreased to less than two days. This success can be attributed to three main principles: using technology to maximize use of employees, focusing on core business functions to guide improvements and regularly measuring and evaluating our performance.

Additionally, during the last Legislative Session, the Department proposed a bill to waive initial licensure fees for military veterans who have been honorably discharged within the past 24 months. The new law went into effect July 1, 2012. I am so glad we are able to pass along this small token of appreciation to our military heroes who have sacrificed so much to protect and defend our nation.

Lastly, through our ApplyNow! project, we have reviewed and revised our licensing applications to ensure they make more sense for each respective profession and our customers. We are now monitoring the application deficiency rates to determine if our applications need further revisions.

Through these improvements, I am certain we are on the right track to helping Florida's professionals and businesses get to work. I appreciate all of the feedback I have received from licensees across the state this past year, and I am always open to hearing more. We are committed to serving the people of this great state, and I appreciate the opportunity to do so. Thank you for doing business with us, and I look forward to many more improvements over the next Fiscal Year!

Sincerely,

Ken Lawson, Secretary
Department of Business and Professional Regulation
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Executive Summary

This report, prepared at the expressed directive of the Florida Legislature pursuant to House Bill 5001, enacted in April 2012, details the department’s options and recommendations pertaining to the Drugs, Devices and Cosmetics (DDC) program area regarding the following: 1) eliminating the program deficit by operational changes or efficiencies without fee increases; 2) how to cost effectively align the licensure renewal with other professions; and, 3) bringing the program under the provisions of Chapter 455, Florida Statutes (F.S.). The report includes historical data and estimates of revenues, expenditures, cash balances and performance statistics for the next five years.

On October 1, 2011, the DDC program area transferred to the department from the Department of Health; at the time of the transfer the program area was operating at a deficit and projecting an ending fiscal year trust fund deficit of nearly $3 million. Department staff took immediate measures to reduce daily operating expenses and to shore up the financial stability of the program area. In April 2012, as a result of the passage of HB 5001, the Secretary created a special DDC workgroup to review the DDC regulatory program area; the workgroup was directed to “develop legislative, budgetary, and organizational recommendations to streamline the Drugs, Devices, and Cosmetics unit without raising fees and/or costs for our licensees.” The workgroup has made the following recommendations:

1. The DDC program area should be operationally moved under chapter 455, Florida Statutes;

2. The DDC program area should pursue legislative changes to increase the efficiency and effectiveness of the unit; and

3. Other than the move under Chapter 455, F.S., no other significant organizational changes should be made.

The workgroup’s recommendations are incorporated into the department’s recommendations discussed below.
Division of Drugs, Devices, and Cosmetics

The Division of Drugs, Devices, and Cosmetics (DDC) is responsible for licensing, inspecting and regulating Florida's drugs (prescription and over-the-counter), medical devices, and cosmetics manufacturers and distributors. The mission of the division is to safeguard the health, safety, and welfare of the citizens of the state of Florida from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients, and cosmetics by administering the provisions of the Florida Drug and Cosmetic Act (Chapter 499, F.S.) in a manner that is consistent with the mission, vision, and values of the Department.

The division is organized into four main units:

• the Director's Office
• the Licensing Office
• the Compliance and Enforcement Office
• the Legal Office

The division is funded by application, examination and renewal fees, plus fines, settlements and administrative costs collected in the course of licensure and disciplinary enforcement actions. The division has 30.5 full time employees, including 10 Florida-licensed pharmacists.

OFFICE OF THE DIRECTOR
Reginald D. Dixon, Director

The Office of the Director oversees the day-to-day activities of the division. The director supervises the administration of the Cancer Drug Donation Program; supervises the administration of the Drug Wholesale Distributor Advisory Council; oversees the preparation of the division's annual legislative budget requests; ensures that appropriated funds are properly disbursed; and is responsible for implementing legislative changes to Chapter 499, Florida Statutes, as well as promulgating rules and regulations pertaining to the division's programs. The director works closely with the department's legal staff regarding matters of enforcement and compliance, as well as immediate suspension of licensees or permittees posing an immediate health or safety threat to the public.

LICENSING
Rebecca Burnett, Regulatory Supervisor Consultant

The six-person licensing unit processes all licenses for drug (prescription and over-the-counter) manufacturers and wholesale distributors, cosmetic manufacturers, certified designated representatives, health care clinic establishments, drug and cosmetic
product registrations and certificates of free sales. Staff also enters new licenses and changes of ownership, reconciles license fees, resolves licensing problems and provides information to the public and the division’s field staff. They coordinate division’s annual and biennial license renewals. The Staff works closely with the department’s information technology unit to ensure the department’s single licensing (LicenseEase) and electronic data management (OnBase) systems support the division’s functions according to current business practices and legal requirements. During the 2011–2012 fiscal year, the licensing unit processed 2,275 new license applications, resulting in the issuance of 1,273 licenses.

COMPLIANCE AND ENFORCEMENT
Robert F. Jernigan, Chief of Compliance and Enforcement

The Compliance and Enforcement Office advances the division’s core mission — safeguarding the health, safety, and welfare of the citizens of the state of Florida — by continuously working to ensure compliance with state and federal law governing the manufacturing and distribution of drugs and cosmetics into and within the state.

This 13.5-FTE unit\(^1\) works closely with the division’s Licensing unit by conducting application-driven inspections in a manner calculated to maximize potential for long-term success in new and expanding businesses. Field personnel also guide existing permit holders through routine — and increasingly risk-based — onsite compliance inspections and desk audits.

As the division’s principal point of contact with the industry, the unit devotes considerable effort to encouraging voluntary compliance through education and feedback communication. In the first two quarters of the 2012–2013 fiscal year, the Compliance and Enforcement Office issued 47 Notices of Inspection Results, a new initiative intended to provide an education-based alternative to fine assessments and other disciplinary action.

During the 2011–2012 fiscal year, the Compliance and Enforcement Office conducted 1,283 investigations, many with criminal implications under state and federal drug laws, and more recently was instrumental in the state’s rapid and thorough response to the national fungal meningitis outbreak associated with contaminated products produced by the New England Compounding Center (NECC). The division’s pharmacist Drug Inspectors also work closely with federal, state and local regulatory and law enforcement partners in efforts to address significant and timely issues of public

\(^1\) In FY 2012–2013 this unit experienced a 16.67% reduction-in-force: 2.5 FTEs, including 2 pharmacist Drug Inspector positions and now employs 9 Drug Inspectors, 1.5 Medical Gas Inspectors, 2 manager/supervisor inspectors, and 1 administrative assistant.
concern: controlled substance diversion, drug counterfeiting, Medicare/Medicaid fraud, and other drug-related crimes.

LEGAL
Kathryn E. Price, Chief Attorney

The 6 FTE (3 Attorneys; 2 Assistants and 1 Senior Legal Assistant) Legal unit provides legal services to and representation of the division. This unit works closely with the program office (Director, Licensing, and Compliance and Enforcement collectively) to ensure that all the division's legal needs are met. This unit is essential to the achievement of the division’s licensing and regulatory goals.

Over the last twelve months, the Legal unit reduced its pending disciplinary caseload by 46% (from 341 to 183). The unit's work led to the filing of 120 disciplinary final orders and the assessment of disciplinary fines and settlements totaling over 1 million dollars. In accordance with the division's compliance-based approach, the Legal unit also closed approximately 136 disciplinary files where the violations were minor, corrected, or could be addressed with a letter of warning and where the evidence was stale and the likelihood of a successful prosecution was remote.

The Legal unit instituted weekly meeting with the program office. These meetings facilitate effective, efficient communication within the division. Although this unit is organizationally within the division, the unit is supervised by the Office of the General Counsel.

DBPR Recommendations

At the time of the October 1, 2011, transfer, the DDC program area was projected to have an ending trust fund balance of nearly $3 million for the fiscal year ending July 1, 2012. Prior to the transfer, the department had reviewed the program with the goal of implementing operational and structural changes upon effective date of the transfer. Out of concern for the continued efficient operation of the regulatory unit, the Legislature enacted House Bill 5001 (2012), which directed the department to:

"...submit a report regarding the Drugs, Devices and Cosmetics Regulatory Program that provides detailed options and recommendations regarding the following: 1) eliminating the program deficit by operational changes or efficiencies without fee increases; 2) how to cost effectively align the licensure renewal with other professions; and, 3) bringing the program under the provisions of chapter 455, Florida Statutes...."

In response to this directive, the Secretary created a workgroup to review the DDC regulatory program area. The workgroup consisted of representatives from multiple areas across the department, including, DDC, Administration, Budget, Finance &
Accounting, Service Operations, Technology, Legislative Affairs, and General Counsel. The workgroup's recommendations were taken into consideration during the formulation of the department's recommendations to the Legislature set forth below.

The current five-year projections for the division (See Tab 5 below) have the division operating at an annual projected deficit of approximately $160,000. At this rate, the projected deficit at the end of FY 2017 is $40,000. The projections are based on expected annual divisional expenses and conservative estimates of income from fines and costs, which reflect the department's business-friendly approach to licensing and regulating. The Department of Health (DOH) had significantly higher projections based on very aggressive prosecutions, even where it has been determined that a less intrusive method would suffice. The division will continue to seek to reduce its expenditures, and increase its revenues, without increasing fees and costs to our licensees.

Effective July 1, 2012, the DDC regulatory program became a division within the department. Effective November 1, 2012, the Drugs, Devices and Cosmetics Trust Fund was eliminated and all remaining balances transferred to the Professional Regulation Trust Fund (PRTF). Organizationally, the division falls under the professional regulation side of the department.

Move to Chapter 455, F.S.

The department examined moving the DDC regulatory program to bring the program under the jurisdiction of Chapter 455, F.S. The department considered the following:

1. Minimal statutory and administrative rule revisions would be necessary to place this regulatory program under the provisions of Chapter 455, F.S.;
2. Administratively, Chapter 455, F.S., provides operational tools that are currently lacking under Chapter 499, F.S., for example:
   a. Chapter 455, F.S., provides for the closing of deficient applications that have been pending for more than two years; DDC applicants have no expiration under Chapter 499, F.S.;
   b. Chapter 455, F.S., provides for the development of long-range policy planning and monitoring; Chapter 499, F.S. does not (it should be noted that DBPR would perform this analysis even without the move to Chapter 455, F.S.);
   c. Chapter 455, F.S., provides for an annual report to the Legislature regarding finances, disciplinary actions, and any administrative or

---

2 DBPR only has 9 months of actual data upon which to base the 5 year projections. The lack of actual data regarding past expenses led to projections reflecting an annual increase in expenses of approximately 33% in most non-fixed re-occurring expenses.
statutory changes the department believes are necessary to cost-effectively operate; Chapter 499, F.S., does not have this requirement;

d. Chapter 455, F.S., allows for the one-time assessment against licensees to eliminate cash deficits or to maintain the financial integrity of the profession; Chapter 499, F.S. does not have such a provision; and

e. Chapter 455, F.S., provides for the issuance of Notices of Non-compliance and citations, in lieu of discipline; Chapter 499, F.S. does not provide for these options.

Recommendation: It is recommended by the department that the DDC division be moved under the provisions of Chapter 455, F.S.

Re-alignment of DDC Renewal Schedules

The department examined the option of re-alignment of DDC renewal schedules to move the renewals from a monthly rolling renewal cycle, to a set annual or biennial renewal period similar to the other licenses and permits administered by the department. The workgroup considered the following:

1. Significant statutory and administrative rule revisions would be necessary to re-align the renewal cycles of the DDC licensees;
2. DDC licensees do not “renew” their licenses, but rather “re-apply” for their licenses, which re-application process includes more than the simple filing of a one-page renewal and application fee;
3. The DDC licensing application and re-application process involves significant document review, including documentation pertaining to ownership percentages, criminal history, and prior licensure history;
4. The DDC licensing unit is insufficiently staffed to timely handle the increased workload associated with having major portions of the DDC licensee base “re-applying” for licenses at a single point, e.g., ¼ of the permits re-applying in January 2013; and
5. The cost benefit analysis of re-aligning DDC renewal schedules did not result in a positive financial benefit to the department.

Recommendation: It is recommended that the department not re-align the DDC renewal schedules at this time, but continue review of DDC’s re-application process for efficiencies.

Elimination of Projected Deficit

Prior to the transfer of the DDC regulatory program from DOH, DBPR conducted a thorough analysis of the structure of the program with an eye towards gaining efficiencies wherever possible. The table below summarizes the efficiency efforts initially undertaken by DBPR upon the transfer of the DDC program area:
<table>
<thead>
<tr>
<th>Category</th>
<th>DOH</th>
<th>DBPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positions</td>
<td>- 33 positions transferred (but initial analysis of DOH's structure revealed significantly more personnel involved in DDC than transferred)</td>
<td>- 30.5 positions; 2.5 positions were eliminated, including 2 pharmacist inspector positions and a half time administrative position.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting</td>
<td>- Program staff reported to Pharmacy Exec. Dir. (ED) who had significant, non-DDC duties w/in DOH.</td>
<td>- Program staff report directly to DDC Exec. Dir. (ED), whose primary responsibility (95%) is DDC.</td>
</tr>
<tr>
<td>Structure</td>
<td>- Inspectors reported to Division of Medical Quality Assurance (MQA) field supervisors, who reported up to MQA Investigations Services Unit, but not to Compliance Manager</td>
<td>- Inspectors fall directly under the supervision of the Compliance Manager</td>
</tr>
<tr>
<td></td>
<td>- Legal Staff was housed in the Office of General Counsel (OGC) and physically located in separate building</td>
<td>- Legal Staff housed with DDC staff and part of DDC program organizationally, but supervised by OGC</td>
</tr>
<tr>
<td></td>
<td>- Complaint/Intake analyst housed in 3rd building separate from OGC and program office and reported to MQA Consumer Services Unit, not program staff or Compliance Manager</td>
<td>- Complaint/Intake function transferred to administrative position housed in DDC program office and reporting directly to Compliance Manager</td>
</tr>
<tr>
<td></td>
<td>- No data steward</td>
<td>- Converted complaint analyst position to create data steward to run &amp; analyze DDC specific performance reports and to assist with DDC specific technological troubleshooting</td>
</tr>
<tr>
<td></td>
<td>- Significant overhead w/DOH, including at least 3 layers of supervision between lowest level employees and Pharmacy ED</td>
<td>- Significant reduction in overhead and supervisory personnel on all levels</td>
</tr>
<tr>
<td>Efficiency</td>
<td>- Inspectors used both PDAs and laptop/tablet computers to perform inspections and write investigative reports.</td>
<td>- Developed and implemented new inspection program utilizing the latest technology (iPads) and interfacing with the department's electronic document management system (OnBase)</td>
</tr>
<tr>
<td></td>
<td>- Inspectors had two credit cards / payment methods that were used to pay for gas, vehicle repairs and maintenance, etc.</td>
<td>- Streamlined use of payment method used by field inspectors by use of a single WEX card.</td>
</tr>
<tr>
<td></td>
<td>- Met infrequently with OGC without a regular reserved time or agenda.</td>
<td>- Scheduled weekly meetings w/OGC and program office to discuss legal issues affecting program</td>
</tr>
<tr>
<td></td>
<td>- Conducted last minute meetings to make decisions regarding application denials, resulting in hurried orders being signed &amp; filed with the Agency Clerk.</td>
<td>- Schedule &quot;as needed&quot; meeting in program office to consider application denials; allowing earlier decisions on applications and significantly reducing the last minute filing of DDC orders with the Agency Clerk.</td>
</tr>
</tbody>
</table>
In addition to the efforts set forth in the table above, the management team of the division has taken additional steps to increase efficiencies, including:
1. Reducing/eliminating all non-essential travel by division staff;
2. Reducing/eliminating administrative overhead associated with the operation of the division;
3. Implementing a risk-based inspection program, which, in addition to focusing on inspecting those licensees which pose a greater health threat while relaxing inspections on the other licensees, reduces expenses associated with divisional enforcement activities;
4. Re-aligning inspector territories, thereby increasing division responsiveness and reducing unnecessary travel expenses;
5. Working cooperatively with licensees to provide increased education and feedback regarding regulatory matters, thereby encouraging increased voluntary compliance and reducing the expenses associated with regulatory actions taken by the division;
6. Streamlining the DDC licensure applications, thereby reducing the collection of unnecessary information, simplifying and streamlining the application process and reducing operational costs associated with processing applications;
7. Soliciting ideas from stakeholders, industry groups, and the Drug Wholesale Distributors Advisory Council concerning rule and statutory revisions calculated to reduce regulatory burden on industry without compromising the division’s mission to protect the public health, safety and welfare; many of these ideas will result in savings to the department by reducing the licensing and enforcement activities of the division.

DDC has adopted a compliance-oriented, as opposed to enforcement-oriented, approach to dealing with the regulation of the industry. At DOH, DDC routinely “held” an establishment’s pending application because of an ongoing investigation or disciplinary matter involving a separate, but related or affiliated establishment. This approach allowed DDC to leverage the applicant for larger fines and costs associated with the pending application. This practice resulted in the receipt of significant fines and costs by DDC leading DOH to project $800,000 in annual revenues attributable to fines and costs. Under the compliance approach, the holding of applications in the manner described above has decreased significantly and is only used where a risk to public health is indicated. DDC has worked hand-in-hand with applicants to obtain compliance with laws and rules, resulting in fewer denied permit applications, and a reduction in the projected annual revenues attributable to fines and costs. DDC is conservatively projecting approximately $400,000 in annual revenues from fines and costs.

During the last nine months of fiscal year 2011–2012 (See Tab 3 below), the DDC unit realized total revenues of $3,075,385; this amount includes approximately $524,000 collected from licensing and disciplinary fines and settlements and a one-time transfer of $563,752 from DOH. The division’s expenditures over this same period totaled $2,327,186, resulting in an ending trust fund balance of $748,198. Even without the
one-time transfer from DOH, the DDC unit’s revenues exceeded its expenses by $184,446.

During the first quarter of fiscal year 2012 – 2013 (see Tab 4 below), the DDC unit realized total revenues of $894,220; this amount includes approximately $367,680 collected from licensing and disciplinary fines and settlements. The division’s expenditures over this same period totaled $601,829, resulting in an ending trust fund balance of approximately $1,096,191 at the end of the first quarter. The Legislature appropriated $900,000 in General Revenue funding for use by the DDC unit this fiscal year if needed. Based on the first quarter actual revenues and expenditures, it is unlikely that it will be necessary for the DDC unit to expend this additional funding.

Over the first twelve calendar months that the DDC unit has been with the department, the unit has collected approximately $891,680 from licensing and disciplinary fines and settlements. At the time of the transfer from DOH to the department, there were a significant number of enforcement and disciplinary cases pending. Over the past twelve months, the DDC unit has worked diligently to reduce the pending enforcement and disciplinary matters, resulting in the collection of unexpectedly high, unsustainable revenue from fines and costs. It is expected (see Table 2 below) that the number of complaints and investigations, and therefore enforcement actions, over the coming fiscal years will be significantly lower than in the prior fiscal years. As such, the department is conservatively projecting approximately $400,000 in annual revenues from licensing and disciplinary fines and costs.

The difficulty with making fiscal projections relating to the DDC unit is attributable to the lack of actual reliable fiscal data for the preceding fiscal years. The department’s fiscal projections for its other divisions are based on the actual revenues collected and expenses incurred over a set period (usually the preceding four to six fiscal years). Without the actual data from the prior fiscal years, the department has taken a conservative approach of projecting relatively flat revenues and expenses over the next five fiscal years (See Tab 5 below). The unit is self-sufficient at this point. As more actual data is collected by the department, the fiscal projections should be adjusted accordingly.

Recommendation: It is recommended that the department not make any additional significant changes, other than possibly transferring the division under Chapter 455, F.S., at this time. The implemented changes should be monitored and refined for an additional year to allow the opportunity to determine the impact of the changes.
### Tab 1: Licensing Statistics

<table>
<thead>
<tr>
<th></th>
<th>FY 2007-08</th>
<th>FY 2008-09</th>
<th>FY 2009-10</th>
<th>FY 2010-11</th>
<th>FY 2011-12**</th>
<th>FY 2012-13 1st Half</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applications Received**</td>
<td>506</td>
<td>1553</td>
<td>2614</td>
<td>2112</td>
<td>2275</td>
<td>1289</td>
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<tr>
<td>Licenses Issued</td>
<td>118</td>
<td>1013</td>
<td>2424</td>
<td>1355</td>
<td>1273</td>
<td>525</td>
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</tbody>
</table>

* Pertains to new applications; Excludes license renewals.
** Includes DOH data from the 1st quarter of the 2011-2012 fiscal year.
Tab 2: Compliance and Enforcement Statistics

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Complaints Received</td>
<td>616</td>
<td>443</td>
<td>346</td>
<td>294</td>
<td>179</td>
<td>115</td>
</tr>
<tr>
<td>Investigations Conducted</td>
<td>559</td>
<td>424</td>
<td>306</td>
<td>284</td>
<td>83</td>
<td>46</td>
</tr>
<tr>
<td>Inspections Conducted</td>
<td>1678</td>
<td>1699</td>
<td>993</td>
<td>1104</td>
<td>1283</td>
<td>475</td>
</tr>
</tbody>
</table>

* Includes DOH data from the 1st quarter of the 2011-2012 fiscal year.

![Complaints & Investigations](image)

![Inspections](image)
## FLORIDA DRUG, DEVICE, & COSMETIC TRUST FUND
### STATEMENT OF REVENUE AND EXPENDITURES
#### JUNE 30, 2012

<table>
<thead>
<tr>
<th>REVENUES</th>
<th>2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees</td>
<td>$32,370.00</td>
</tr>
<tr>
<td>Licenses</td>
<td>$1,910,702.00</td>
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<tr>
<td>Miscellaneous</td>
<td>$2,014.00</td>
</tr>
<tr>
<td>Refunds</td>
<td>$15,082.00</td>
</tr>
<tr>
<td>Fines</td>
<td>$417,407.75</td>
</tr>
<tr>
<td>Settlement</td>
<td>$107,000.00</td>
</tr>
<tr>
<td>Transfer from DOH</td>
<td>$563,752.00</td>
</tr>
<tr>
<td>Unassigned</td>
<td>$27,059.00</td>
</tr>
<tr>
<td><strong>Total Revenues</strong></td>
<td><strong>$3,075,304.65</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>EXPENDITURES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries &amp; Benefits</td>
<td>$1,651,054.17</td>
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<tr>
<td>OGS</td>
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<td>Cellular</td>
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<td>Technology Supplies</td>
<td>$7,585.23</td>
</tr>
<tr>
<td>Postage</td>
<td>$6,696.00</td>
</tr>
<tr>
<td>Freight</td>
<td>$4,50</td>
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<td>Printing</td>
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<td>Technology Supplies</td>
<td>$2,900.30</td>
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<tr>
<td>Technology Training</td>
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</tr>
<tr>
<td>Software</td>
<td>$434.70</td>
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<td>Rent</td>
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<tr>
<td>Storage Rental</td>
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<td>Vehicle Tags</td>
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<td>Other Expense</td>
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<tr>
<td>Notary Bonds</td>
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<td>Legal Contract</td>
<td>$354.38</td>
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<td>Security</td>
<td>$8.01</td>
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<tr>
<td>Mailing Service</td>
<td>$134.70</td>
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<td>Fingerprints</td>
<td>$12,575.00</td>
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<td>Moving Office Expense</td>
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<tr>
<td>Other Service</td>
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<tr>
<td>Repairs &amp; Maintenance</td>
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</tr>
<tr>
<td>Gas &amp; Vehicle Expense</td>
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<tr>
<td>Personnel Assessment</td>
<td>$8,450.00</td>
</tr>
<tr>
<td>Refunds</td>
<td>$12,863.00</td>
</tr>
<tr>
<td>Service Charge</td>
<td>$199,702.55</td>
</tr>
<tr>
<td><strong>Total Expenditures</strong></td>
<td><strong>2,327,186.25</strong></td>
</tr>
</tbody>
</table>

Excess (Deficiency) of Revenues
Over (Under) Expenses

CHANGE IN ACCOUNT BALANCE

ACCOUNT BALANCE, Beginning of Period

ACCOUNT BALANCE, End of Period

$748,198.40

* DDC transferred to DBPR 10/1/11; Data represents last 3 quarters of FY 2011-2012.
Tab 4: 1st Quarter Fiscal Year 2012 - 2013

FLORIDA DRUG, DEVICE, & COSMETIC TRUST FUND
STATEMENT OF REVENUE AND EXPENDITURES
SEPTEMBER 30, 2012

<table>
<thead>
<tr>
<th>REVENUES</th>
<th>2012-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees</td>
<td>$9,730.13</td>
</tr>
<tr>
<td>Licenses</td>
<td>404,345.00</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>28,345.52</td>
</tr>
<tr>
<td>Fines</td>
<td>367,880.00</td>
</tr>
<tr>
<td>Investment Interest</td>
<td>4,119.55</td>
</tr>
<tr>
<td>Total Revenues</td>
<td>894,220.20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EXPENDITURES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries &amp; Benefits</td>
<td>415,093.23</td>
</tr>
<tr>
<td>OPS</td>
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</tr>
<tr>
<td>Telephone</td>
<td>1,406.64</td>
</tr>
<tr>
<td>Cellular</td>
<td>326.38</td>
</tr>
<tr>
<td>Technology Supplies</td>
<td>1,143.40</td>
</tr>
<tr>
<td>Postage</td>
<td>1,497.00</td>
</tr>
<tr>
<td>Freight</td>
<td>0.87</td>
</tr>
<tr>
<td>Printing</td>
<td>347.72</td>
</tr>
<tr>
<td>Travel</td>
<td>1,096.52</td>
</tr>
<tr>
<td>Office Supplies</td>
<td>3,220.96</td>
</tr>
<tr>
<td>Software</td>
<td>6.20</td>
</tr>
<tr>
<td>Rent</td>
<td>27,975.55</td>
</tr>
<tr>
<td>Dues</td>
<td>530.00</td>
</tr>
<tr>
<td>Copying</td>
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<tr>
<td>Legal Contract</td>
<td>21.08</td>
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<tr>
<td>Security</td>
<td>2.67</td>
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<tr>
<td>Mailing Service</td>
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</tr>
<tr>
<td>Fingerprints</td>
<td>3,564.00</td>
</tr>
<tr>
<td>Gas &amp; Vehicle Expense</td>
<td>5,326.75</td>
</tr>
<tr>
<td>Refunds</td>
<td>8,668.60</td>
</tr>
<tr>
<td>Service Charge</td>
<td>62,911.92</td>
</tr>
<tr>
<td>Education &amp; Testing</td>
<td>3,080.65</td>
</tr>
<tr>
<td>Departmental Administration</td>
<td>22,355.84</td>
</tr>
<tr>
<td>Departmental Technology</td>
<td>29,221.50</td>
</tr>
<tr>
<td>Service Operations - Central Intake</td>
<td>11,386.23</td>
</tr>
<tr>
<td>Service Operations - Bank Charges</td>
<td>52.19</td>
</tr>
<tr>
<td>Total Expenditures</td>
<td>601,828.60</td>
</tr>
</tbody>
</table>

Excess (Deficiency) of Revenues
Over (Under) Expenses 292,391.60

CHANGE IN ACCOUNT BALANCE

292,391.60

ACCOUNT BALANCE, Beginning of Period 748,198.40

Prior Year Adjustments to Receivables & Incurred Obligations In DDCTF 55,600.76

ACCOUNT BALANCE, End of Period $1,096,190.76

Note: $803,799.15 cash balance for 2012 transferred from DDCTF to PRTF.
Tab 5: Five year Projections

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics Trust Fund

OPERATING ACCOUNT

ACTUAL AND PROJECTED REVENUES, EXPENSES
AND CHANGES IN ACCOUNT BALANCES

FISCAL YEARS ENDING JUNE 30, 2012 THROUGH JUNE 30, 2017 effective 10-1-2011

<table>
<thead>
<tr>
<th>Month</th>
<th>Actual</th>
<th>Projected</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUNE 30</td>
<td>2012</td>
<td>2013</td>
</tr>
<tr>
<td>REVENUES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Licenses</td>
<td>1,910,702</td>
<td>2,547,603</td>
</tr>
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<td>Miscellaneous</td>
<td>2,014</td>
<td>2,685</td>
</tr>
<tr>
<td>Transfer in DOD</td>
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<td></td>
</tr>
<tr>
<td>Interest on Investments</td>
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<td>17,989</td>
</tr>
<tr>
<td>Settlement</td>
<td>107,000</td>
<td>15,082</td>
</tr>
<tr>
<td>Refunds</td>
<td>27,058</td>
<td>400,000</td>
</tr>
<tr>
<td>Total Revenues</td>
<td>3,075,384</td>
<td>3,030,676</td>
</tr>
</tbody>
</table>

EXPENSES

<table>
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<tr>
<th>Category</th>
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<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries and Benefits</td>
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<td>2,242,851</td>
<td>2,242,851</td>
<td>2,242,851</td>
<td>2,242,851</td>
<td>2,242,851</td>
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<tr>
<td>Telephone</td>
<td>6,654</td>
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<td>6,605</td>
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<tr>
<td>Cellular</td>
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<td>8,928</td>
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<tr>
<td>Freight</td>
<td>7,712</td>
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<td>850</td>
<td>850</td>
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<tr>
<td>Vehicle Tags</td>
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<td>Registration</td>
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<td>400</td>
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<tr>
<td>Other Expense</td>
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<td>Maintaining Service</td>
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<td>180</td>
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<td>16,767</td>
<td>16,767</td>
<td>16,767</td>
<td>16,767</td>
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<tr>
<td>Moving Office Expense</td>
<td>504</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Repairs and Maintenance</td>
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<td>8,017</td>
<td>8,017</td>
<td>8,017</td>
<td>8,017</td>
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<td>O &amp; M Vehicle Expenses</td>
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<tr>
<td>Service Charge to General Revenues</td>
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<td>240,913</td>
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<td>240,913</td>
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<td>OHS Transfer HK Services</td>
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<td>15,031</td>
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<tr>
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<tr>
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<td>243,321</td>
<td>243,321</td>
<td>243,321</td>
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</tr>
<tr>
<td>Total Expenses</td>
<td>2,377,195</td>
<td>3,180,138</td>
<td>3,179,839</td>
<td>3,179,839</td>
<td>3,179,839</td>
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Excess (Deficiency) of Revenues

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<th>Category</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over (Under) Expenses</td>
<td>748,199</td>
<td>(149,222)</td>
<td>(153,340)</td>
<td>(157,572)</td>
<td>(161,921)</td>
<td>(166,360)</td>
</tr>
</tbody>
</table>

TRANSFERS

<table>
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<tr>
<th>Category</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Balance</td>
<td>748,199</td>
<td>(149,222)</td>
<td>(153,340)</td>
<td>(157,572)</td>
<td>(161,921)</td>
<td>(166,360)</td>
</tr>
</tbody>
</table>

Account Balance, End of Period

<table>
<thead>
<tr>
<th>Category</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Balance, End of Period</td>
<td>748,199</td>
<td>(149,222)</td>
<td>(153,340)</td>
<td>(157,572)</td>
<td>(161,921)</td>
<td>(166,360)</td>
</tr>
</tbody>
</table>

Drugs, Devices & Cosmetics – Legislative Report

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Key Contacts

For more information, contact the Office of Communications at 850.922.8981 or the Office of Legislative Affairs at 850.487.4827.

The Honorable Rick Scott, Governor of Florida
Ken Lawson, Secretary
Tim Vaccaio, Deputy Secretary of Professional Regulation
Reginald Dixon, Director of Drugs, Devices & Cosmetics
J. Layne Smith, General Counsel
Sam Verghese, Director of Legislative Affairs
Sandi Poreda, Director of Communications
TAB 5: COMPOUNDING UPDATE

Mark Whitten, Executive Director-Board of Pharmacy
TAB 6: HB 517- PATRICK BARNES
HB 517 Communication

1. Hospitals under common control are allowed to repack container drug products under HB 517.
2. This includes repackaging bulk products to unit dose from Examples are bulk tablets to unit dose and liquids to unit dose.
3. HB 517 also allows hospitals under common control to pick automated dispensing refills for the other hospitals.
4. The hospital that is repackaging or filling the automated dispensing refills must have a Restricted Prescription Drug Distributors Permit.
5. A letter must be sent to the Department giving a 30 day notice of the start date.
TAB 7: FINALIZE 2013 MEETING DATES
Proposed Drug Wholesale Advisory Council Meeting Dates for 2013

February 12, 2013 – In person meeting - Tallahassee

May 16, 2013 – Conference Call

August 15, 2013 – In person meeting - Tallahassee

December 5, 2013 – Conference Call