

STATE OF CALIFORNIA  
**Budget Change Proposal - Cover Sheet**  
 DF-46 (REV 08/15)

Fiscal Year 2016-17	Business Unit <del>1110</del> 1111	Department Department of Consumer Affairs	Priority No. 1
Budget Request Name <del>1110-023-BCP-BR-2016-GB</del> 1111		Program 1210-Board of Pharmacy	Subprogram

Budget Request Description  
 Position Authority to extend 5.5 3-year limited-term positions to permanent

**Budget Request Summary**

The Board of Pharmacy (Board) is requesting a budget augmentation of \$1,088,000 to transition 5.5 limited-term positions to permanent in FY 2017-18 and ongoing in order to execute statutorily mandated inspections, investigations, process license and renewal applications, handle enforcement related workload and provide inspector support for the resident and nonresident sterile injectable compounding facilities, as required in Senate Bill (SB) 294.

The Board was authorized these positions in a FY 2014-15 BCP (1110-07L) as 3-year limited-term positions. However, due to CalHR policy, a person cannot be placed in a limited-term position for more than two years. Therefore, the Board will be unable to retain the current staff in these positions once their two-year limited-term appointments expire. The Board is requesting ongoing position authority in order to maintain its current service level. Since these positions were initially authorized as 3-year limited-term positions in FY 2014-15, the Board is not requesting funding for these positions until FY 2017-18.

Requires Legislation <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Code Section(s) to be Added/Amended/Repealed	
Does this BCP contain information technology (IT) components? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>If yes, departmental Chief Information Officer must sign.</i>	Department CIO	Date

For IT requests, specify the date a Special Project Report (SPR) or Feasibility Study Report (FSR) was approved by the Department of Technology, or previously by the Department of Finance.

FSR       SPR      Project No.      Date:

If proposal affects another department, does other department concur with proposal?  Yes       No  
*Attach comments of affected department, signed and dated by the department director or designee.*

Prepared By <i>V. Harold</i>	Date <i>12/9/15</i>	Reviewed By <i>Mark M. eto</i>	Date <i>12/9/15</i>
Department Director <i>Tom Carosone for</i>	Date <i>12.9.2015</i>	Agency Secretary <i>Bill Podst</i>	Date <i>12/15/15</i>

**Department of Finance Use Only**

Additional Review:  Capital Outlay     ITCU     FSCU     OSAE     CALSTARS     Dept. of Technology

BCP Type:       Policy       Workload Budget per Government Code 13308.05

PPBA      Original signed by *Jeff Carosone*      Date submitted to the Legislature *1-7-16*

# BCP Fiscal Detail Sheet

BCP Title: Pharmacy - Sterile Compounding Facilities

DP Name: 1111-023-BCP-DP-2016-GB

## Budget Request Summary

	FY16					
	CY	BY	BY+1	BY+2	BY+3	BY+4
Positions - Permanent	0.0	0.0	5.5	5.5	5.5	5.5
<b>Total Positions</b>	<b>0.0</b>	<b>0.0</b>	<b>5.5</b>	<b>5.5</b>	<b>5.5</b>	<b>5.5</b>
Salaries and Wages						
Earnings - Permanent	0	0	551	551	551	551
<b>Total Salaries and Wages</b>	<b>\$0</b>	<b>\$0</b>	<b>\$551</b>	<b>\$551</b>	<b>\$551</b>	<b>\$551</b>
Total Staff Benefits	0	0	218	218	218	218
<b>Total Personal Services</b>	<b>\$0</b>	<b>\$0</b>	<b>\$769</b>	<b>\$769</b>	<b>\$769</b>	<b>\$769</b>
Operating Expenses and Equipment						
5301 - General Expense	0	0	8	8	8	8
5302 - Printing	0	0	3	3	3	3
5304 - Communications	0	0	7	7	7	7
5306 - Postage	0	0	3	3	3	3
5320 - Travel: In-State	0	0	17	17	17	17
5320 - Travel: Out-of-State	0	0	225	225	225	225
5322 - Training	0	0	3	3	3	3
5340 - Consulting and Professional Services - Interdepartmental	0	0	50	50	50	50
5344 - Consolidated Data Centers	0	0	3	3	3	3
<b>Total Operating Expenses and Equipment</b>	<b>\$0</b>	<b>\$0</b>	<b>\$319</b>	<b>\$319</b>	<b>\$319</b>	<b>\$319</b>
<b>Total Budget Request</b>	<b>\$0</b>	<b>\$0</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>
<b>Fund Summary</b>						
Fund Source - State Operations						
0767 - Pharmacy Board Contingent Fund, Professions and Vocations Fund	0	0	1,088	1,088	1,088	1,088
<b>Total State Operations Expenditures</b>	<b>\$0</b>	<b>\$0</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>
<b>Total All Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>
<b>Program Summary</b>						
Program Funding						
1210 - California State Board of Pharmacy	0	0	1,088	1,088	1,088	1,088
<b>Total All Programs</b>	<b>\$0</b>	<b>\$0</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>	<b>\$1,088</b>

**Personal Services Details**

Positions	Salary Information			CY	BY	BY+1	BY+2	BY+3	BY+4
	Min	Mid	Max						
5157 - Staff Svcs Analyst (Gen) (Eff. 07-01-2017)				0.0	0.0	0.5	0.5	0.5	0.5
5393 - Assoc Govtl Program Analyst (Eff. 07-01-2017)				0.0	0.0	1.0	1.0	1.0	1.0
8876 - Inspector (Eff. 07-01-2017)				0.0	0.0	4.0	4.0	4.0	4.0
<b>Total Positions</b>				<b>0.0</b>	<b>0.0</b>	<b>5.5</b>	<b>5.5</b>	<b>5.5</b>	<b>5.5</b>
Salaries and Wages	CY	BY	BY+1	BY+2	BY+3	BY+4			
5157 - Staff Svcs Analyst (Gen) (Eff. 07-01-2017)	0	0	22	22	22	22			
5393 - Assoc Govtl Program Analyst (Eff. 07-01-2017)	0	0	59	59	59	59			
8876 - Inspector (Eff. 07-01-2017)	0	0	470	470	470	470			
<b>Total Salaries and Wages</b>	<b>\$0</b>	<b>\$0</b>	<b>\$551</b>	<b>\$551</b>	<b>\$551</b>	<b>\$551</b>			
Staff Benefits									
5150350 - Health Insurance	0	0	61	61	61	61			
5150500 - OASDI	0	0	42	42	42	42			
5150600 - Retirement - General	0	0	97	97	97	97			
5150800 - Workers' Compensation	0	0	18	18	18	18			
<b>Total Staff Benefits</b>	<b>\$0</b>	<b>\$0</b>	<b>\$218</b>	<b>\$218</b>	<b>\$218</b>	<b>\$218</b>			
<b>Total Personal Services</b>	<b>\$0</b>	<b>\$0</b>	<b>\$769</b>	<b>\$769</b>	<b>\$769</b>	<b>\$769</b>			

## Analysis of Problem

### A. Budget Request Summary

The Board of Pharmacy (Board) is requesting a budget augmentation of \$1,088,000 to transition 5.5 limited-term positions to permanent in FY 2017-18 and ongoing in order to execute statutorily mandated inspections, investigations, process license and renewal applications, handle enforcement related workload and provide inspector support for the resident and nonresident sterile injectable compounding facilities, as required in Senate Bill (SB) 294.

The Board was authorized these positions in a FY 2014-15 BCP (1110-07L) as 3-year limited-term positions. However, due to CalHR policy, a person cannot be placed in a limited-term position for more than two years. Therefore, the Board will be unable to retain the current staff in these positions once their two-year limited-term appointments expire. The Board is requesting ongoing position authority in order to maintain its current service level. Since these positions were initially authorized as 3-year limited-term positions in FY 2014-15, the Board is not requesting funding for these positions until FY 2017-18.

### B. Background/History

In response to tragedies involving contaminated sterile injectable compounded drug products that were shipped into California and other states, SB 294 was drafted and approved to increase consumer protection. Under the new law both resident and nonresident sterile compounding pharmacies must be licensed with the Board. In addition a mandatory inspection of all resident and nonresident sterile compounding pharmacies prior to licensure and upon renewal every year is required. In addition to current pre-licensure and pre-renewal inspections, the pharmacy will be required to adhere to the following:

- 1) Provide the board with a list of all sterile drug products compounded;
- 2) Report any disciplinary actions taken by another state or suspension of any accreditation held by the pharmacy within 10 days; and
- 3) Notify the board of any recall notices issued by the pharmacy for sterile drug products compounded within 24 hours.

As a result of SB 294, the Board has an additional 666 new sterile compounding pharmacy licensees and the Board's Pharmacy Inspectors have performed an additional 866 resident and 122 nonresident sterile compounding pre-licensure and pre-renewal inspections.

To address the workload associated with the implementation of SB 294, the Board was granted authorization to hire seven (7) 3-year limited term positions; 4.0 Pharmacy Inspectors, 1.0 Associate Governmental Program Analyst (AGPA), 1.0 Staff Services Analyst (SSA), and 1.0 Office Technician (OT), effective July 1, 2014. The Board filled these positions between August – December 2014. These positions have been instrumental in the Board maintaining the additional ongoing workload associated with the implementation of SB 294. However, if the Board is not able to obtain the funding to retain these positions, the Board would not be able to maintain its current service level. This would not be consistent with the Board's mission of protecting the public.

## Analysis of Problem

### Resource History (Dollars in thousands)

Program Budget	FY 10-11	FY 11-12	FY 12-13	FY 13-14	FY14-15	FY 15-16
Authorized Expenditures	\$13,056	\$14,521	\$15,057	\$18,155	\$20,850	\$19,770
Actual Expenditures	\$11,233	\$13,545	\$14,990	\$17,468	\$19,766	\$19,770
Revenues	\$12,232	\$12,863	\$14,697	\$15,331	\$19,324	\$16,632
Authorized Positions	79.2	83.5	79.8	80.8	100.8	100.7
Filled Positions	60.2	72.0	73.8	80.8	96.8	97.7
Vacancies	10	11.5	6.0	0	4.0	3.0

### Workload History

Workload Measure	FY 10-11	FY 11-12	FY 12-13	FY 13-14	FY 14-15	FY 15-16
Applications Received – Licensed Sterile Compounding	39	55	63	771	167	175
Applications Received – Non-resident Sterile Compounding	24	13	19	16	22	23
Renewals Received – Licensed Sterile Compounding	244	243	238	260	824	865
Renewal Received- Non-resident Sterile Compounding	69	73	63	71	79	83
Total Sterile Compounding Investigations Opened	0	2	8	12	99	109

### C. State Level Considerations

The Board will not require additional space or equipment to support this proposal because the permanent staffing granted herein would be replacing the limited-term staffing that already exist and are being funded within existing resources. This request will enable the Board to align its permanent position authority with its ongoing permanent workload.

This proposal is consistent with The Board's mandate to make public protection its first priority. This mandate is articulated in Business and Professions Code section 4001.1 which states:

“Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”

### D. Justification

The Board is requesting position authority to transition the 4.0 Limited-Term Pharmacy Inspector positions to permanent positions to allow the Board to perform the mandatory pre-renewal inspections of the 936 current resident and 91 current nonresident sterile compounding facilities. The Board's licensed pharmacy inspectors work in the field conducting pre-licensure, post-licensure and routine inspections and investigations in addition to inspections and investigations as a result of a complaint filed by a consumer.

In addition, the Board is requesting position authority to transition the 1.0 Limited-Term AGPA, and a 0.5 Limited-Term SSA position to permanent positions so they can continue to process license applications, handle enforcement related workload and provide inspector support.

The Board was authorized these positions in a FY 2014-15 BCP as 3-year limited-term positions. However, due to CalHR policy, a person cannot be placed in a limited-term position for more than two years. Therefore, the Board will be unable to retain its current staff in these positions once their two-

## Analysis of Problem

year limited-term appointments expire. Transitioning these existing staff members who have received extensive training in order to enforce the regulations and procedures of sterile compounding will eliminate the additional workload and expense of recruiting for the positions and training new staff.

If the Board does not receive the requested position authority to make the current limited-term positions permanent, it will be forced to make the difficult decision to redirect staff from other areas of critical need. This will cause statutorily mandated inspections to be delayed and investigations of complaints to be postponed causing undue risk to California citizens who have a reasonable expectation that their drug supply is safe and those providing it are monitored. Failure to provide these inspections means failure to uphold the Board's mandate that protection of the public should be its first priority.

### E. Outcomes and Accountability

If granted the permanent staffing in this proposal, the Board would be utilizing existing staff that have received extensive training on current regulations and procedures giving them the knowledge and skill to conduct inspections and investigations, process license applications, handle enforcement related workload and provide inspector support. With the existing staff in position, the Board will be able to meet the demand of the ongoing workload as a result of SB 294, conduct the mandated inspections and investigate complaints, thus ensuring that the protection of the public should be its first priority.

#### Projected Outcomes

Workload Measure	FY 14/15	FY 15/16	FY 16/17	FY 17/18	FY 18/19	FY 19/20
Applications Received – LSC	167	175	184	193	203	213
Applications Received - NSC	22	23	24	25	27	28
Renewals Received – LSC	824	865	908	954	1002	1052
Renewal Received- NSC	79	83	87	91	96	101
Total Sterile Compounding Investigations Opened	99	109	114	120	126	132

### F. Analysis of All Feasible Alternatives

**Alternative 1** – Approve \$1,088,000 in FY 2017-18 and ongoing to fund 5.5 positions to transition 4.0 Limited-Term Pharmacy Inspectors, 1.0 Limited-Term AGPA, and a 0.5 Limited-Term SSA to permanent positions.

Pro: Approval of this alternative would be the most cost efficient for the Board and would allow the Board to continue to regulate the sterile compounding industry.

Con: If the Board does not receive the requested position authority to make the current limited-term positions permanent, it will be forced to make the difficult decision to redirect staff from other areas of critical need. This will cause statutorily mandated inspections to be delayed and investigations of complaints to be postponed causing undue risk to California citizens who have a reasonable expectation that their drug supply is safe and those providing it are monitored.

**Alternative 2** – Approve \$1,088,000 in FY 2017-18 and \$1,063,000 in FY 2018-19 and ongoing to fund 5.5 positions to transition the 4.0 Limited Term Pharmacy Inspector positions and a 1.0 Limited-Term AGPA position to permanent positions, and extend a 0.5 Limited Term Staff Services Analyst position for an additional two years.

Pro: Approval of this alternative would be the most cost efficient for the Board and would allow the Board to continue to regulate the sterile compounding industry.

Con: Approval of this alternative would result in the clerical functions being absorbed into the current workload and would undermine the Standard Auditing principles that require a separation of functions relating to handling money and issuing licenses. The additional workload will also significantly impact

## Analysis of Problem

the Board's ability to complete statutorily mandated inspections and investigations resulting in undue risk to Californians.

**Alternative 3** – Approve \$1,041,000 in FY 2017-18 and ongoing to transition the 4.0 Limited-Term Pharmacy Inspector positions to permanent; and allow the 3.0 other Limited-Term positions to expire.

Pro: Approval of this alternative would give the Board a sufficient amount of pharmacy inspectors to regulate the sterile compounding industry.

Con: This alternative would result in the Board's current staff absorbing the workload of processing paperwork for the over 650 additional pharmacies that have resulted as a result of the commencement of SB 294. This alternative does not meet the Board's needs and fails to uphold the Board's mandate that protection of the public should be its first priority.

**Alternative 4** – Status Quo – Do nothing and allow the limited term positions to end.

Pro: This alternative will not require a funding and personnel augmentation to handle the workload associated with regulation of the sterile compounding industry.

Con: This alternative would result in the Board's current staff absorbing the workload of processing paperwork and performing inspections for the over 650 additional pharmacies that have resulted as a result of the commencement of SB 294. This alternative does not meet the Board's needs and fails to uphold the Board's mandate that protection of the public should be its first priority.

## G. Implementation Plan

The Board will transition the 4.0 Limited-Term Pharmacy Inspectors positions, the 1.0 Limited-Term AGPA position, and a 0.5 Limited-Term SSA position to permanent positions, effective July 1, 2016.

## H. Supplemental Information

None

## I. Recommendation

The Board recommends alternative 1. If this request is not granted, the Board will not be able to meet its mandate of protecting the public.

SB 294 Sterile Compounding  
Workload Chart

<b>Staff Services Analyst (0.5) Workload FY 14/15</b>	<b># TIMES TASK PERFORMED</b>	<b>HOURS TO PEFORM TASK</b>	<b>TOTAL TIME/HOURS ANNUALLY*</b>
Process Applications and Renewals <sup>1</sup>	496	1.25	620
Process Deficient Mail <sup>1</sup>	300	0.17	51
Process Temporary Permits <sup>1</sup>	33	0.50	16
Sort and Process Incoming Mail <sup>1</sup>	45	2.00	90
Respond to Status Inquiry Emails <sup>1</sup>	150	0.25	38
Respond to Status Inquiry Phone Calls <sup>1</sup>	98	0.25	25
Admin Functions (filling, mail, general correspondence) <sup>1</sup>	25	2.25	56
Training <sup>1</sup>	4	8.00	32
Meetings <sup>1</sup>	12	3.00	36
<b>Total Time</b>			<b>964</b>

\*As of 6/30/15

1 – This denotes 0.5 of the PY SSA Workload. The board will have to absorb the remaining workload.

<b>Associate Governmental Program Analyst (1.0) Workload FY 14/15</b>	<b># TIMES TASK PERFORMED</b>	<b>HOURS TO PEFORM TASK</b>	<b>TOTAL TIME/HOURS ANNUALLY*</b>
Review Applications, Approve and Issue Licenses	147	1.50	221
Process Renewal Applications	903	0.25	226
Issue Replacement licenses	280	0.08	22
Admin Functions (filling, mail, general correspondence)	52	3.00	156
Training	4	8.00	32
Meetings	12	3.00	36
Inspector Support	52	5.00	260
Travel Arrangements	83	.75	63
Travel Claims	869	1.00	869
<b>Total Time</b>			<b>1885</b>

\*As of 6/30/15

SB 294 Sterile Compounding  
Workload Chart

<b>Inspectors (4.0) Workload FY 14/15</b>	<b># TIMES TASK PERFORMED</b>	<b>HOURS TO PERFORM TASK</b>	<b>TOTAL TIME/HOURS ANNUALLY*</b>
Resident (LSC/LSE) Inspections**	306	6.50	1989
Nonresident (NSC) Inspections**	122	18.0	2196
Resident (LSC/LSE) Investigations***	89	34.0	3026
Nonresident (NSC) Investigations***	10	30.0	300
<b>Total Time</b>			<b>7,511 (1,878 per inspector)</b>

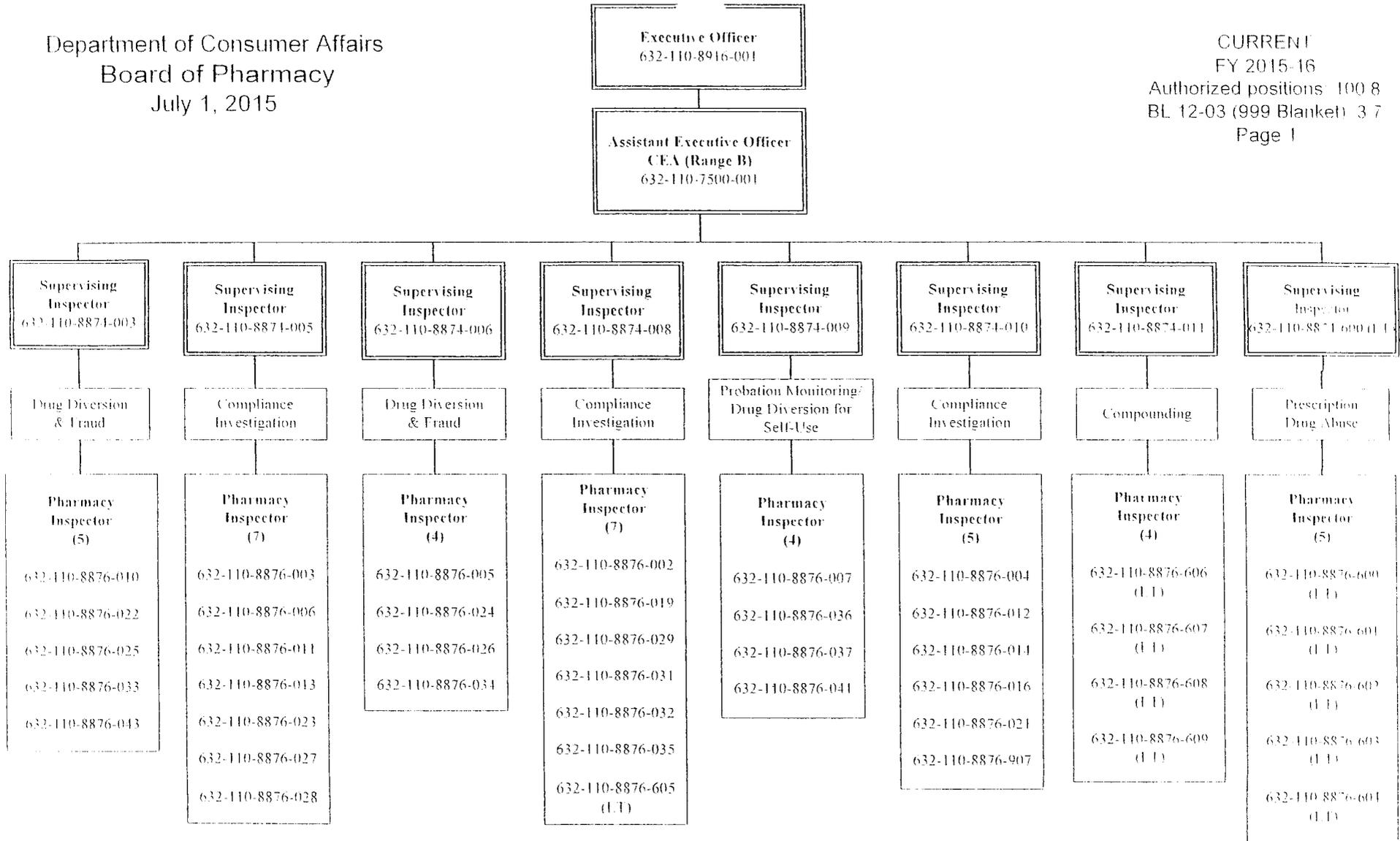
\*As of 6/30/15

\*\*The inspectors travel both statewide and out of state to perform annual state mandated inspections of licensed premises and premises applying for new sterile compounding licensure to ensure the compliance with operational requirement and pharmacy laws and regulations. The inspection process includes review of each compounding pharmacy policies and procedures, review of the quantity and type of preparations compounded, evidence collection, report writing, interviewing staff, education of staff and issuance of orders of correction as appropriate.

\*\*\*The inspectors investigate and/or mediate complaints alleging violations of the pharmacy practice act, specifically laws related to sterile compounding. The investigation process includes collecting evidence, conducting interviews, preparing correspondence, performing drug audits, report writing, assisting other governmental or law enforcement agencies and providing testimony during administrative or criminal hearings.

Department of Consumer Affairs  
 Board of Pharmacy  
 July 1, 2015

CURRENT  
 FY 2015-16  
 Authorized positions: 100.8  
 BL 12-03 (999 Blanket) 3.7  
 Page 1



Executive Officer or Designee

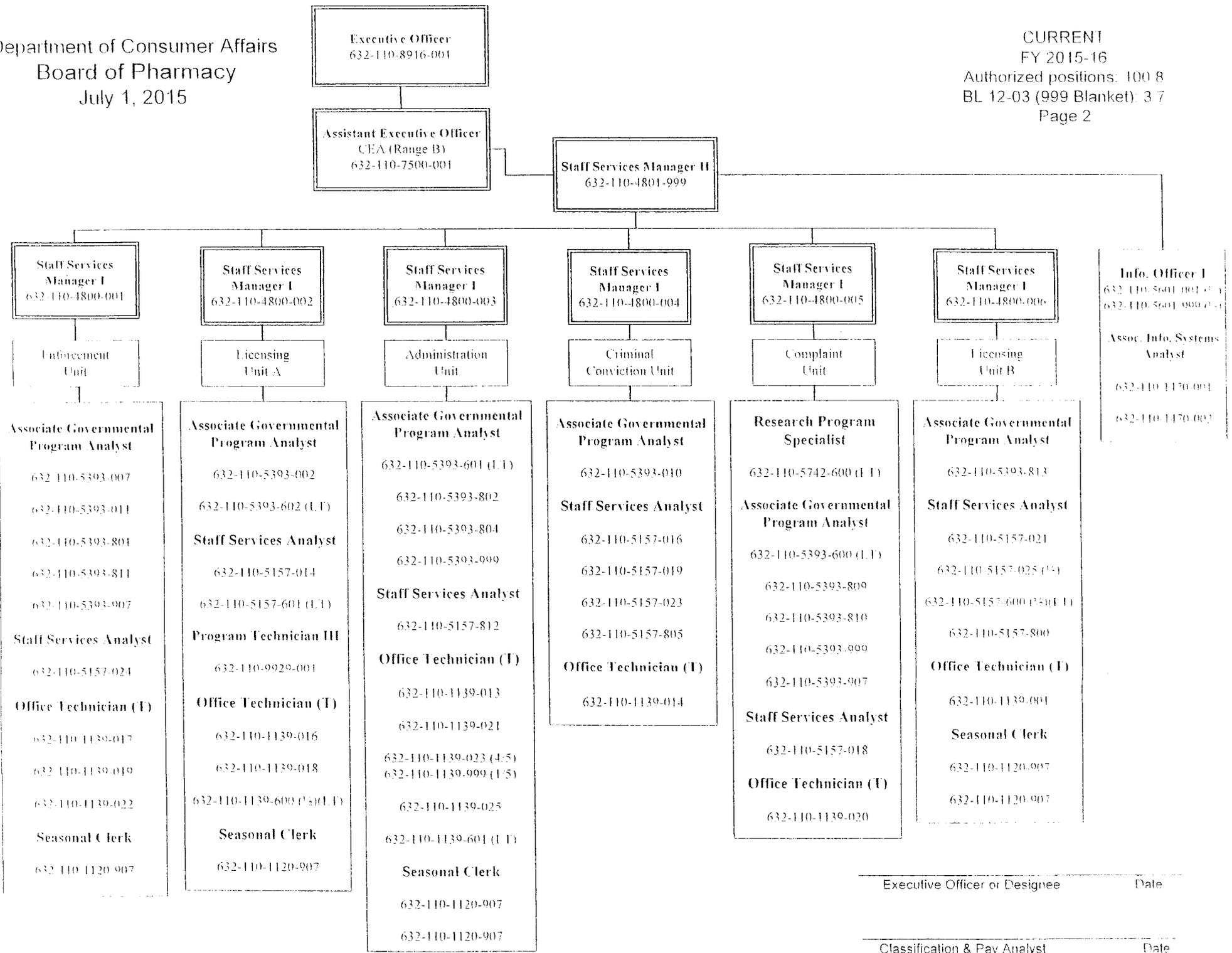
Date

Classification & Pay Analyst

Date

Department of Consumer Affairs  
Board of Pharmacy  
July 1, 2015

CURRENT  
FY 2015-16  
Authorized positions: 100 8  
BL 12-03 (999 Blanket): 3 7  
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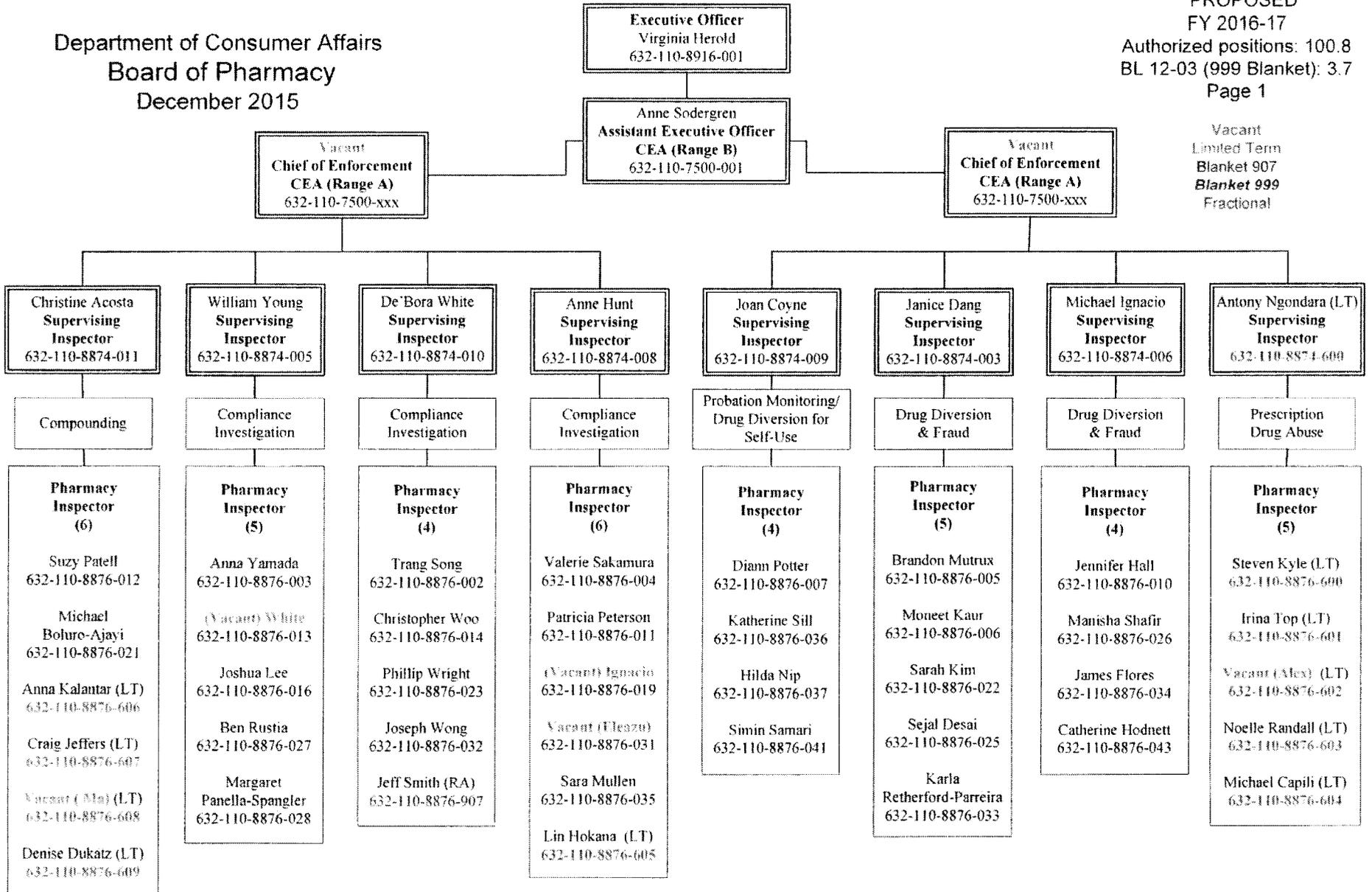
Executive Officer or Designee \_\_\_\_\_ Date \_\_\_\_\_

Classification & Pay Analyst \_\_\_\_\_ Date \_\_\_\_\_

Department of Consumer Affairs  
Board of Pharmacy  
December 2015

PROPOSED  
FY 2016-17  
Authorized positions: 100.8  
BL 12-03 (999 Blanket): 3.7  
Page 1

Vacant  
Limited Term  
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Fractional



Executive Officer or Designee

Date

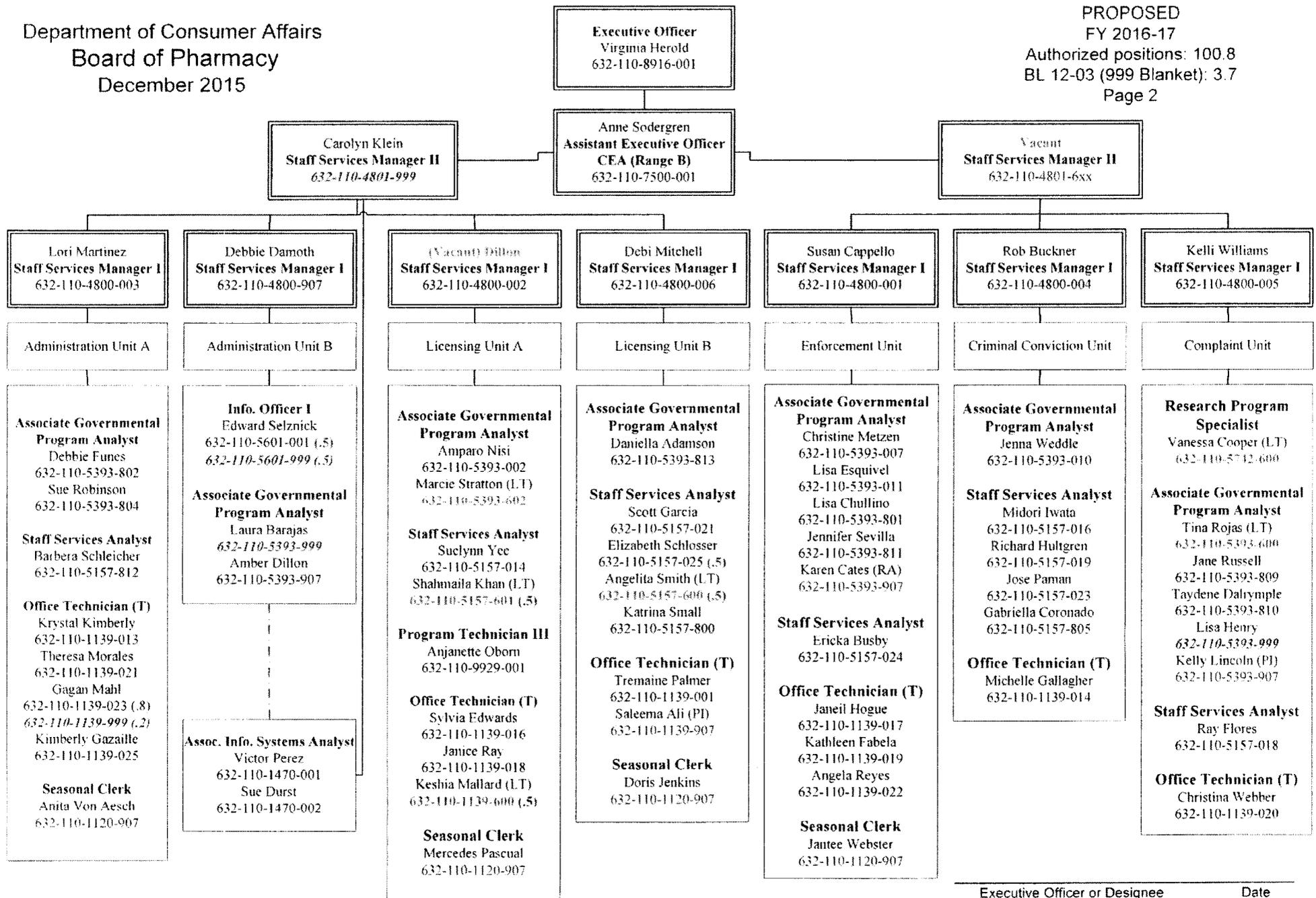
December 4, 2015

Classification & Pay Analyst

Date

Department of Consumer Affairs  
Board of Pharmacy  
December 2015

PROPOSED  
FY 2016-17  
Authorized positions: 100.8  
BL 12-03 (999 Blanket): 3.7  
Page 2



Executive Officer or Designee

Date

Classification & Pay Analyst

Date

# 0767 - State Board of Pharmacy

## Analysis of Fund Condition

1.4.16

(Dollars in Thousands)

2015-16 Budget Act w/ Sterile Compounding and Prescription Drug Abuse BCPs	Budget Act			
	ACTUAL 2014-15	CY 2015-16	BY 2016-17	BY +1 2017-18
<b>BEGINNING BALANCE</b>	\$ 12,769	\$ 11,741	\$ 8,227	\$ 4,412
Prior Year Adjustment	\$ 109	\$ -	\$ -	\$ -
Adjusted Beginning Balance	\$ 12,878	\$ 11,741	\$ 8,227	\$ 4,412
<b>REVENUES AND TRANSFERS</b>				
Revenues:				
125600 Other regulatory fees	\$ 2,074	\$ 863	\$ 863	\$ 863
125700 Other regulatory licenses and permits	\$ 3,865	\$ 3,508	\$ 3,508	\$ 3,508
125800 Renewal fees	\$ 11,774	\$ 11,723	\$ 11,723	\$ 11,723
125900 Delinquent fees	\$ 184	\$ 172	\$ 172	\$ 172
131700 Misc. revenue from local agencies	\$ 262	\$ -	\$ -	\$ -
141200 Sales of documents	\$ -	\$ -	\$ -	\$ -
142500 Miscellaneous services to the public	\$ 1	\$ -	\$ -	\$ -
150300 Income from surplus money investments	\$ 33	\$ 25	\$ 13	\$ -
150500 Interest Income From Interfund Loans	\$ 4	\$ -	\$ -	\$ -
160400 Sale of fixed assets	\$ -	\$ -	\$ -	\$ -
161000 Escheat of unclaimed checks and warrants	\$ 21	\$ -	\$ -	\$ -
161400 Miscellaneous revenues	\$ 9	\$ -	\$ -	\$ -
Totals, Revenues	\$ 18,227	\$ 16,291	\$ 16,279	\$ 16,266
Transfers from Other Funds:				
FO0001 GF loan repay per item 1110-011-0767, BA of 2008				
Transfers to Other Funds:				
Totals, Revenues and Transfers	\$ 18,227	\$ 16,291	\$ 16,279	\$ 16,266
Totals, Resources	\$ 31,105	\$ 28,032	\$ 24,506	\$ 20,678
<b>EXPENDITURES</b>				
Disbursements:				
0840 State Operations	\$ 1	\$ -	\$ -	\$ -
1110 Program Expenditures (State Operations)	\$ 19,350	\$ 19,770	\$ 20,094	\$ 20,496
Sterile Compounding BCP	\$ -	\$ -	\$ -	\$ 1,088
Prescription Drug Abuse BCP	\$ -	\$ -	\$ -	\$ 1,261
8880 FISC (State Operations)	\$ 13	\$ 35	\$ -	\$ -
Total Disbursements	\$ 19,364	\$ 19,805	\$ 20,094	\$ 22,845
<b>FUND BALANCE</b>				
Reserve for economic uncertainties	\$ 11,741	\$ 8,227	\$ 4,412	\$ -2,167
<b>Months in Reserve</b>	7.1	4.9	2.3	-1.2