

***Annual Report***  
***Fiscal Year 2014***

**BOARD OF PHARMACY**

***July 2014***



**DIVISION OF CORPORATIONS, BUSINESS  
AND PROFESSIONAL LICENSING**

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This Annual Performance Report is presented in accordance with Alaska Statute 08.01.070(1) and Alaska Statute 37.07.080(b). Its purpose is to report the accomplishments, activities, and the past and present needs of the licensing program.

**ALASKA STATE BOARD OF PHARMACY  
FY 2014 ANNUAL REPORT**

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**ALASKA STATE BOARD OF PHARMACY  
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IDENTIFICATION OF BOARD**

<b><u>Board Member</u></b>	<b><u>Date Appointed</u></b>	<b><u>Term Expires</u></b>
<b>Richard C. Holm RPh.</b>	<b>March 31, 2006</b>	<b>March 1, 2014</b>
<b>Dirk White RPh.</b>	<b>March 1, 2007</b>	<b>March 1, 2015</b>
<b>Christopher J. Kim RPh.</b>	<b>March 1, 2009</b>	<b>March 1, 2016</b>
<b>Lori DeVito RPh.</b>	<b>March 1, 2011</b>	<b>March 1, 2016</b>
<b>John Cotter RPh.</b>	<b>September 9, 2011</b>	<b>March 1, 2017</b>
<b>William Altland Rph.</b>	<b>March 1, 2014</b>	<b>March 1, 2018</b>
<b>Anne Gruening Public Member</b>	<b>March 1, 2010</b>	<b>March 1, 2014</b>
<b>Taryl Giessel Public Member</b>	<b>March 22, 2013</b>	<b>March 1, 2017</b>

**ALASKA STATE BOARD OF PHARMACY**  
**FY 2014 ANNUAL REPORT**  
**IDENTIFICATION OF STAFF**

**Donna Burns, Licensing Examiner**

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**Alvin Kennedy, Investigator**

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**ALASKA STATE BOARD OF PHARMACY**  
**FY 2014 ANNUAL REPORT**  
**NARRATIVE STATEMENT**

This narrative statement will describe the current activities and accomplishments of the Alaska Board of Pharmacy, composition of the Board in FY 2014, and the continuing efforts of the Board to regulate the practice of pharmacy in the State of Alaska.

The Board held four meetings during FY 2014 as follows:

- August 22-23, 2013, Anchorage
- November 21-22, 2013, Anchorage
- January 29-31, 2014, Juneau
- April 3<sup>rd</sup> – 4<sup>th</sup>, 2014, Anchorage

Board members during FY 2014:

- Anne F. Gruening, Public Member, Juneau (term expired March 2014, Reappointed through 3/18)
- Taryl Giessel, Public Member, Eagle River, (term expires March 2017)
- Richard Holm, Rph., Chair, North Pole, (term expired March 2014)
- William Altland, Rph., (appointed March 2014 and expires March 2018)
- Dirk White Rph., Chair, Sitka (term expires March 2015)
- Lori Devito, Rph., Vice-Chair, Soldotna, (term expires March 2016)
- John Cotter, Rph., Secretary, Fairbanks, (term expires March 2017)
- Christopher J. Kim, Rph., Anchorage, (term expires March 2017)

Sher Zinn is the Licensing Supervisor. Al Kennedy serves as the Board Investigator, based in Anchorage.

**Regulation Projects:** The board is currently working on regulations projects related to the Prescription Drug Monitoring Program. These include an exemption from report, pre-pack prescriptions dispensed to patients for short-term coverage not to exceed 72 hours, and a Regulation allowing healthcare professionals to delegate access of the PDMP, to their office staff.

The Board is also working on a regulation dealing with physical pharmacy inspections of high risk pharmacies, and when they would be required. Mandatory reporting by in-state pharmacy to the Board, when they obtain out-of-state licenses and a declared scope of practice. A regulation defining high risk pharmacy practice, and their requirements and inspection schedule.

**Controlled Substance Prescription Database** (aka Prescription Drug Monitoring Program or PDMP) (12 AAC 52.855 – 12 AAC 52.895) – The PDMP was mandated by the Alaska Legislature in 2008. The primary purpose of the PDMP is to create a database that records all dispensed controlled substances. This will allow prescribers and pharmacists to identify, through secure methods, patients who are “doctor shopping” and/or prescribers who are over-prescribing. This program has proved very valuable to many prescribers and pharmacists within Alaska. Doctors working out of hospital emergency rooms have been particularly vocal on its merits. Interim funding was obtained through FY 2013 and into FY 2014 from the help of HHS. The PDMP remains in jeopardy without further funding from the legislature. This is a public health and safety issue which should be publicly funded.

**Automatic Dispensing Systems:** The Board continues to investigate Automatic Dispensing Systems and how they can and should be regulated in Alaska. There are currently a number of these systems in our state, mostly in physician offices and out of the purview of the Board of Pharmacy. Their benefits and safety of use have not yet been determined.

#### **RECOMMENDATIONS FOR PROPOSED LEGISLATION:**

**Out-of-State Wholesale Distributors** – Alaska remains one of only two states which do not license out-of-state wholesale drug distributors. This shortcoming has become an important concern, especially since the Federal Government's passage of the DQSA (Drug Quality Security Act) in November of 2013.

DQSA now allows an entity that compounds sterile drugs to register as a 503b outsourcing facility. If a facility registers with the FDA they can compound sterile drugs in bulk without individualized prescriptions.

Oversight of distributors shipping drugs and devices into Alaska is a primary concern due to the increase of prescription drug counterfeiting and the utilization of Automatic Dispensing Systems, which are currently unregulated and are often serviced from outside the state. Currently the board has no authority to regulate these wholesalers, and is asking the legislature to add a new section AS 08.80.159, Registration of Wholesale Distributors. This legislation would have not have any negative cost issues and would help assure the safe delivery of controlled, non-counterfeit medications to Alaska residents, and prevent other parties from circumventing Alaska law to obtain products they currently are not licensed to handle or prescribe. A bill was introduced this past legislative session, but did not pass. The Board will re-introduce draft legislation for the upcoming legislative session.

#### **Inclusion of Pharmacists to the State's Anti-Discrimination Law: (House Keeping Legislation)**

The states' Insurance Code AS 21.36.090(d) needs to include pharmacists and pharmacies in its list of healthcare entities which "cannot be discriminated against in group policies that extend coverage on an Expense-incurred basis, or under group service, or indemnity-type contract, issued by an HMO, or non-profit corporation, if the service is within the scope of provider's occupational license". Currently they are not listed, an oversight which needs correction soon as possible. The parallel federal law in the Public Health Service Act 42 U.S.C. 1320d of the Social Security Act does not include pharmacists. There appears to be no valid reasons not to have pharmacists included. This is house-keeping, but it is very important in terms of protection for the pharmacy community.

**Regulation of Medical Marijuana Growing and Dispensing** – The Board of Pharmacy remains committed to identifying friendly legislators who are willing to sponsor a bill to provide safe, clean, reliable means of medical marijuana to Alaskan residents holding valid prescriptions for the same. The Board is following how the other states who have passed this or similar legislation to avoid the same issues

**Pharmacy Audit Bill:** Pharmacy Audit Bills before the State House and Senate did not pass. The board will rewrite and introduce again for the upcoming legislative session. The Alaska Board of Pharmacy strongly supports this legislation, and would encourage the Legislature for its passage in the next session. A majority of other states already have a similar law on their books.

#### **RECOMMENDATIONS FOR REGULATION PROJECTS, FY 2015:**

**Automatic Dispensing Systems (ADS)** – Automatic dispensing systems are vending machines for prescription medications, many of which contain narcotics. For the safety of the public, there are multiple reasons the board is opposed to their use in facilities where the system is not fully managed by a pharmacist.

**In-State School of Pharmacy:** The University of Idaho - School of Pharmacy, is currently setting up an in-state school of pharmacy in Alaska, in conjunction with the University of Alaska. This is currently scheduled to be operational in the fall of 2015 and would benefit Alaska students wishing to enter the field of pharmacy as well as the benefitting the public in general. The Board of Pharmacy has assured the Universities that they will work closely with them to provide any regulations necessary to assure a smooth

program for the students. Creighton University in Omaha, Nebraska holds four seats for Alaska applicants.

### **NATIONAL ASSOCIATION OF BOARDS OF PHARMACY:**

The Board of Pharmacy continues to participate in the process of keeping current the pools of questions for the law exam given to pharmacists prior to licensing in Alaska. This is a formal exam called the Multi-State Pharmacy Jurisprudence Examination (MPJE), operated by NABP, which requires an Alaska pool of questions to be reviewed annually and new questions added. Each year two board members are required to travel to NABP in Illinois, to review test questions, and then approve or delete them and add others. This past year due to scheduling conflicts a board member participated remotely. The board will determine which two members will attend during FY 2015.

### **LICENSING ACTIONS:**

The Board conducted reviews of licensing issues as presented by the board investigator and paralegal and actions were passed as warranted. Continuing education audits were reviewed by and acted on as warranted. FY 2014 was a year for all license renewals in our biennial cycle and efficiencies continue to improve with each renewal cycle.

### **BUDGET RECOMMENDATIONS FY 2014:**

1. Maintain the frequency of full board meetings at four per year.
2. Travel and per diem for 2 board members to attend (MPJE) (Multi-State Jurisprudence Exam) Review Meeting and two to attend the MPJE Question Writing Meeting.
3. Travel and per diem for one board member to travel and attend Annual NABP meeting.
4. Travel and per diem for one board member to travel and attend Region 7 District NABP meeting.
5. Training budget for investigator and selected board members to train for physical inspections of in-state pharmacies.
6. Travel and per diem for investigator and/or board members to conduct on-site pharmacy inspections in-state.
7. Full-time office assistant or examiner to assist current Licensing Examiner due to increased applications over the last 5 years.
8. Research for cost of tablets (i.e. Kindle, Samsun Galaxy) for use by board members at board meetings.

Respectfully submitted

Dirk White, Rph.  
Chair, Alaska Board of Pharmacy

**ALASKA STATE BOARD OF PHARMACY  
FY 2014 ANNUAL REPORT  
BUDGET RECOMMENDATIONS FOR FY 2015**

**TRAVEL REQUESTS:** ranked in order of the board's priority. Provide the best estimates based on past actuals and seasonal trends in travel, such as summer hotel rooms or increased fuel costs. Calculate on full costs and note any third-party fiscal offsets. Expand the tables below as needed.

**Board Meetings**

Date	Location	# of Board Members	# of Staff	Total Estimated Cost (total of airline, hotel, mileage, M&IE, parking, rental car, taxi, etc.)
8/7-8/2014	Anchorage	7	1	\$6,500.00
11/20-11/2014	Anchorage	7	1	\$6,500.00
Jan 2015 (tbd)	Juneau	7	1	\$6,500.00
May 2015 (tbd)	Anchorage	7	1	\$6,500.00

**Travel Required to Perform Examinations**

Date	Location	# of Board Members	# of Staff	Total Estimated Cost (total of airline, hotel, mileage, M&IE, parking, rental car, taxi, etc.)
	N/A			
Description of meeting and its role in supporting the mission of the board:				

**Out-Of-State Meetings and Additional In-State Travel**

Rank in order of the board's priority. "Reimbursement" refers to payment to cover travel costs. "Direct" refers to an offer by a company to secure travel arrangements on behalf of the board member.

Rank	Date	Location	# of Board Members	# of Staff	Total Estimated Cost		Total Potential Third-Party Offset
					(total of airline, hotel, mileage, M&IE, parking, rental car, taxi, etc.)	Conference Fee	<input checked="" type="checkbox"/> reimbursement <input type="checkbox"/> Direct
1	3/19-20/2015	NABP Headquarters- Mt. Prospect, IL	1	0	\$4,200.00	\$400.00 (not reimbursed)	Up to \$1500.00 reimbursement from NABP
Description of meeting and its role in supporting the mission of the board: MPJE Question Writing Meeting. Board participation required.							
2	5/16-19/2015	111 <sup>th</sup> Annual NABP Meeting New Orleans, LA	1	0	\$4,200.00		<input checked="" type="checkbox"/> Reimbursement \$1500.00
Description of meeting and its role in supporting the mission of the board: This meeting allows the board to participate and remain proactive on national issues in pharmacy							
3	TBD	2015 Region 7 District Meeting TBD	1	0	\$4,200.00		<input checked="" type="checkbox"/> Reimbursement \$1500.00
Description of meeting and its role in supporting the mission of the board:							

**ALASKA STATE BOARD OF PHARMACY  
FY 2014 ANNUAL REPORT  
BUDGET RECOMMENDATIONS FOR FY 2015 CONTINUED**

**NON-TRAVEL BUDGET REQUESTS**

**Dues/Memberships/Resources/Online Training/Teleconferences/Examination Contracts**

Provide details of the budgetary request. Break down into specific events, where applicable.

<b>Product or service:</b> <b>Alaska BOP Newsletter</b>	<b>Provider:</b> <b>NABP</b>	<b>Cost per event:</b> <b>\$465.00</b>
Description of item and its role in supporting the mission of the board: AK State newsletter is the primary way of communicating with licensees and colleagues, regarding regulation changes, current board activity, and other related matters that are important and need to be communicated to AK state NABP members.		
<b>Product or service:</b> <b>NABP Annual Membership</b>	<b>Provider:</b> <b>NABP</b>	<b>Cost per event:</b> <b>\$250.00</b>
Description of item and its role in supporting the mission of the board: NABP provides national information about regulations and protocols in other states. NABP responds to requests for information from the Licensing Examiner and the AK BOP. NABP also maintains the electronic database for continuing education units.		

**Other Items with a Fiscal Impact:**

<b>Product or service:</b> <b>Training budget for investigator and selected board member for inspection of in-state pharmacies</b>	<b>Provider:</b> <b>BOP and Investigator</b>	<b>Cost per event:</b> <b>Unknown at this time</b>
Description of item and its role in supporting the mission of the board: Training for on-site physical inspections for in-state pharmacies		
<b>Product or service:</b> <b>Travel and per diem pay for investigator and/or board members</b>	<b>Provider:</b> <b>BOP and Investigator</b>	<b>Cost per event:</b> <b>Unknown at this time</b>
Description of item and its role in supporting the mission of the board: To conduct on-site pharmacy inspections for in-state pharmacies		

**Summary of FY15 Fiscal Requests**

Board Meetings	<b>\$26,000</b>
Travel for Exams	<b>N/A</b>
Out-Of-State and Additional In-State Travel	<b>\$12,600</b>
Dues/Memberships/Resources/Online Training/Teleconferences	<b>\$815.00</b>
Total Potential Third-Party Offset	<b>(\$4,500.00)</b>
Other:	
<b>Total Requested:</b>	<b>\$34,915.00</b>

**Additional information:**

**ALASKA STATE BOARD OF PHARMACY**  
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**RECOMMENDATIONS FOR PROPOSED LEGISLATION FOR FY 2015**

**Focus Area (Check all that apply)**

- Economic Development
- Government Within Our Means
- National Regulatory/Industry Changes
- Enhance Public Protection

**1. Subject and Proposed Language (include intent and statutory reference)**

Reintroduce legislation that would license out-of-state wholesale drug distributors and medical equipment suppliers. This will also include entities that register with the FDA as a 503b facility.

**2. Explain the benefits the proposed legislation would provide.**

- Create statutory authority for the Board of Pharmacy to regulate and monitor medications and medical devices being provided to facilities and residents of Alaska from out-of-state wholesalers of the same and 503b facilities that can ship in bulk.
- Provide a means by which the State of Alaska has recourse to combat increased frequency of counterfeit medications being produced and distributed by out-of-state vendors.
- Resolve the issue of acquisitions of prescription medications from out-of-state wholesalers by those without adequate prescriptive authority.
- Create a revenue source from the application and licensing fees for this new BOP licensing category
- Create authority for the Board of Pharmacy to regulate the inventory management of Automatic Dispensing Systems in high risk environments.

**3. Explain the consequences, if any, of not implementing the proposed statutory change.**

- Increased frequency of counterfeit medications being provided to Alaska residents.
- Increased acquisition and distribution of prescription medications by those who are unqualified to do so.
- Increased liability to the board and the state due to inadequate safeguards.

**4. Describe any potential negative impacts of this legislation and how they would be minimized.**

None

**5. Who do you anticipate will support the bill and why? Include municipalities, groups, etc...**

- Alaska Pharmacist Association: Assures the quality and safety of medications coming into the state; reduces liability in the pharmacy profession; provides better quality of patient care.
- National Association of Boards of Pharmacy: As above, on a national vs. state level; plus improve consistency in the practice of pharmacy among states.
- Law Enforcement: Decrease the frequency of counterfeit drugs entering the state.
- Medical Professionals: Assures the safety of medications; improves patient outcomes; improves compliance with scope of practice among medical license holders.

- National Pharmacy and Medical Supplier Organizations: Creates consistency in regulation among all states; improves operational procedures and efficiencies.
- FDA: Would bring Alaska into compliance with the DQSA.

**6. Who do anticipate will oppose the bill and why?**

The board is not aware of any opposition

**7. What other state departments will be affected by this legislation? Have you discussed the impact with the affected departments, and if so who and do they support this bill?**

The board is not aware that this legislation would impact other department within the state.

**8. Identify and describe any previous state or federal legislation or similar efforts in other states which affect or relate to this proposal.**

- Alaska is now only one of two states in the U.S. who do not already license Out-of-State Wholesale Drug Distributors.
- The Alaska Board of Pharmacy has been regulating In-State Wholesale Drug Distributors and Out-of-State Pharmacies nearly since the creation of the Board. Over time, the practice of pharmacy has become a National profession which now demands the oversight of Out-of-State Wholesale Distributors.

**9. Has this bill topic been previously introduced in the legislature? If so, what was the final outcome and why?**

Yes, HB 324 was introduced this past legislative session and did not pass. This was due to other items being tacked onto this bill and bogged the bill down. The BOP will work to rewrite the bill and reintroduce it for the upcoming 2015 Legislative session.

**10. In the event questions should be raised during review of this request, please indicate below which board member should be contacted:**

Dirk White, R.Ph. Board Chair – Sitka, AK.

**ALASKA STATE BOARD OF PHARMACY**  
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**REGULATION RECOMMENDATIONS FOR FY 2015**

**Out-of-State Wholesale Distributors** – The board will re-write legislation for licensing of out-of-state wholesale drug distributors a bill for the upcoming legislative season.

The board will also determine if the out-of-state wholesale drug distributor license would include facilities that have registered with the FDA as a 503b facility or if it should be a separate license.

At the upcoming August 2014 BOP meeting, the board will review regulations disapproved from Regulation Project JU2013200469 from Department of Law in June. The board will then determine how best to proceed.

**ALASKA STATE BOARD OF PHARMACY  
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GOALS AND OBJECTIVES FOR FY 2015**

**List the board's FY14 goals and objectives and how they were met:**

- 1.) The board will continue to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.
- 2.) The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.
- 3.) The board will continue to promote effective patient counseling by licensees.
- 4.) The board will continue to assess and evaluate the Multi-State Pharmacy Jurisprudence Examination (MPJE).
- 5.) The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
- 6.) The board will continue to assess and evaluate the licensing of Pharmacy Technicians.
- 7.) The board will continue its affiliation with NABP and send one member to the District 7 NABP meeting, and two members to the annual NABP meeting.
- 8.) The board will continue to evaluate the impact of current regulations and the need for new regulations.
- 9.) The board will continue to evaluate regulations regarding collaborative practice, and established procedures for reviewing/approving appropriate protocols for collaborative practice.
- 10.) The board will assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and continue enhancement for the Prescription Drug Monitoring Program.
- 11.) The board will monitor, assess, evaluate and modify the Alaska Prescription Drug Monitoring Program based on the best interest of the public and the profession.

The Board of Pharmacy goals and objectives remain fluid, and the board tries to meet its goals and objectives in a proactive manner. Case in point, in early 2013 a national crisis occurred and the board recognized it early on, and took a proactive approach to address the problem and update current regulations to the address it.

It is always the board's goal of getting legislation introduced, and it is our continued hope that the legislative work done in 2013 will be introduced and move forward in 2014.

**List the board's FY15 goals and objectives. Include any strengths, weaknesses, opportunities, and threats, as well as any resources needed:**

- 1.) The board will continue to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.
- 2.) The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.
- 3.) The board will continue to promote effective patient counseling by licensees.
- 4.) The board will continue to assess and evaluate the Multi-State Pharmacy Jurisprudence Examination (MPJE).
- 5.) The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
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- 11.) The board will monitor, assess, evaluate and modify the Alaska Prescription Drug Monitoring Program based on the best interest of the public and the profession.

**ALASKA STATE BOARD OF PHARMACY  
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SUNSET AUDIT RECOMMENDATIONS**

Date of last Legislative Audit: November 9, 2012

Board sunset date: June 30, 2018

<b>Audit Recommendation #1: The Board of Pharmacy should improve Collaborative Practice Agreements in accordance with regulations.</b>
Action taken: The process for review and approval was modified to include a checklist for each agreement submitted. The check list is based on the Collaborative Practice regulations.
Next Steps: The board reviewed the checklist and concurred that its implementation has helped insure ongoing compliance.
Date completed:

<b>Audit Recommendation #2: DCCED's Professional Licensing Administrative Officer should improve administrative support.</b>
Action taken: This recommendation has been addressed internally.
Next Steps:
Date completed:

<b>Audit Recommendation #3: Board of Pharmacy and staff, with the office of the Governor, should work together to increase the pool of qualified applicants available for board appointments to ensure full representation.</b>
Action taken: Since the recommendation has been made, the Board of Pharmacy has been a full board until the resignation of a public member in April of 2012. The vacancy has been filled and the board has seven members, five pharmacists and two public members.
Next Steps:
Date completed:

# FISCAL YEAR 20\_\_\_\_ STATISTICAL OVERVIEW

Program: \_\_\_\_\_

AS 08. \_\_\_\_\_

12 AAC \_\_\_\_\_

Name of Individual Completing Report: \_\_\_\_\_

Date: \_\_\_\_\_

FY13 LICENSEES	NEW-ISSUED FY 20____	TOTAL AS OF 6/30/____

**A. Current Active Licenses, Endorsements, Permits**

List type and if issued by examination or credential, as applicable.

LICENSE TYPE & PROGRAM CODE	Lic. Type Code	Status Code	NEW-ISSUED FY 20____	TOTAL AS OF 6/30/____	LICENSURE BASIS
Example: Civil Engineer - AEL	C	AA	10	250	Exam: 6 Credentials: 4
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
<b>TOTAL</b>					

**B. Temporary Licenses**

LICENSE TYPE & PROGRAM CODE	Lic. Type Code	Status Code	NEW-ISSUED FY 20____	TOTAL AS OF 6/30/____	NOTES
Example: Physical Therapist - PHY	R	AA	4	24	
1. N/A					
2.					
3.					
<b>TOTAL</b>					

**C. Current Licenses Issued as Inactive (not lapsed licenses)**  
 (Only Medical, Chiropractic, CPA, and Real Estate)

LICENSE TYPE & PROGRAM CODE	Lic. Type Code	Status Code	TOTAL AS OF 6/30/____
Example: Salesperson - REC	S	II	64
1.			
2.			
3.			
4.			
<b>TOTAL</b>			

**D. Retired Licenses**

CATEGORY & PROGRAM CODE	Lic. Type Code	Status Code	RETIRED DURING FY 20____	TOTAL AS OF 6/30/____	NOTES
Example: Osteopath - MED	O	RR	1	8	
1.					
2.					
3.					
<b>TOTAL</b>					

**E. Examination Detail**

(List each examination administration separately. Write "See Attached" and attach a separate sheet if necessary.)

EXAM TYPE	LOCATION	DATE	CANDIDATES	NO. PASSED	NO. FAILED
<b>Number of Postponed Exams</b>					
<b>Number of Exam Reviews</b>					

