Licensing Procedural Manual

Licensing Procedural Manual

Table of Contents

Communications:

The staff of the Board of Pharmacy works for the benefit of the Agency to achieve the mission of protecting the health, safety and welfare of all Oregonians through effective regulation of the practice of pharmacy and the sale and distribution of drugs in Oregon. Under the direction of the Executive Director (ED), agency staff implements policy decisions made collectively by the Board.

The ED, assisted by the Management Team, is responsible to the Board for the day-to-day management of the agency. The Management Team consists of the ED, the Administrative Director (AD), the Compliance Director, the Project Manager and the Office Manager.

Email Communications Protocols:

Email communications should not normally be used for confidential matters as they are public records and subject to subpoena and release under public records requests;

- Members of staff must include their supervisor and the ED as cc addressees on all emails they send to Board members;

- If a member of staff receives an email from a Board member that is not copied to the ED, they should forward it to the ED for information;

- Staff should not send an email addressed to "All Board members" or do a "Reply to all" on an email that includes all Board members as addressees without consulting the AD or the ED first, as there are Public Meetings Law implications in such exchanges.

- If a member of staff needs to send an email, which could be interpreted as stating a policy position, to an outside organization, they must get their supervisor's approval before the email is sent, and include the ED as a cc addressee.

Reporting:

The Executive Director is the only member of the agency who works directly for, and reports to, the Board. All members of staff work for the agency and as such, they report to their direct supervisor on all issues, not to members of the Board.

- Members of staff must report all contact with Board members to their direct supervisor as soon as possible. This includes contact resulting from work on a research council, committee or other working group of the Board.

- In the interests of full communications, any official contact with faculty or staff of a college of pharmacy, a professional association, another state agency, the Attorney General's office, a member of the state legislature, a consumer group or other significant organization must be reported to your direct supervisor as soon as possible except where such contact is a routine matter that your supervisor is aware of and has approved the contact.

Meetings:

- Whenever a member of staff plans to attend a meeting where they may be perceived as representing the Board, the Agency or the ED, they must advise their supervisor beforehand. As soon as possible following such a meeting, they must report to their supervisor.

- Whenever members of staff or Board members are responsible for arranging a meeting involving members of the public or outside organizations, they must notify the AD at least three weeks in advance so that all necessary requirements of the Public Meetings Law can be met.

- Members of staff may not commit themselves or another member of staff to speak at a meeting or conference without the prior approval of their supervisor and the proposed speaker.

- Staff are reminded that Board members may only accept commitments to attend or speak at meetings or conferences on behalf of the Board when the commitment is made by the Board as a body. Staff may not commit Board members to any engagements.

Phone Calls:

- Staff are expected to check voicemail daily and return phone calls within 24 hours.

Public Records Requests:

If information regarding a licensee is requested it is called a Public Records Request.

Available Information:

If requested <u>in writing</u> the Board may provide information regarding a licensee such as the licensee's employer, the officers of a corporation or a phone number. Other requests often come in for items relating to a Board Meeting. All public records requests go to the Administrative Director for review.

Fee:

If a public records request requires research the person requesting the information will need to pay a fee. The person requesting the information should be notified of the potential fee prior to conducting the research needed for the public records request.

Fees may be found in the Schedule of Administrative Fees.

Information that may <u>not</u> be Disclosed:

The following information may not be disclosed:

- Information such as applicant's Social Security Number or birth date may not be disclosed.

- Establishment information labeled as proprietary data may not be disclosed.

- *If you have any questions about public records requests ask Karen MacLean.*

Daily Deposits:

At this time the Board only accepts checks for new application payments. We cannot accept cash. Credit Card payments are limited to online renewals. All checks must be made payable to the Oregon Board of Pharmacy.

How to Enter a Daily Deposit Payment into the Database:

- Select "Accounting."

- Then "Receive Payment."

- Verify if you will be inputting the daily bank deposit or payment from lockbox (lockbox is for renewals only.) To change profile click the "Change Profile" button listed on the menu list on the right side.

Daily Bank Deposit New Applications:

If a new application is sent to the Board it must be verified whether or not the applicant already exists in the database.

- First select checklist.

- Then select "File" then "New."

- Select the appropriate license type that the applicant is applying for.

- In the "Obtained By" field select "Application"

- This will prompt a search option. For a person enter the applicant's Social Security Number and search. If no results are found, select clear, and then search by the applicant's name. For an establishment search by name, select clear, and then search by location only. Look at the application thoroughly to ensure that a license number is not already referenced. If the applicant is already in the database check with the appropriate Licensing Representative to determine where the payment should be applied.

- If the applicant is not in the database, select "New".

- Enter name, address, phone numbers, and email address in the "General" tab. For a person, below "Phone" is a field labeled "Other" in this field list the applicant's work phone number, if listed. For an establishment list the Fax number then type "FAX" after the number.

- In the "Licenses" tab enter the applicant's mailing address click the "Copy Address" button if the mailing address is the same as the physical address.

- Next take notice of the grey box in the upper right hand corner of the application and write the check number in red pen and circle the correct payment amount. Make sure that it matches the amount on the check. In the space that reads "Entered By" put your initials.

- In the database select the "$" symbol labeled "Accounts". For a new applicant the payment amount should already be populated. However for a set of Laws and Rules, or a Location or Owner Change the fee needs to be manually selected.

- To select a fee go to "Actions" then "New Fee".

- To enter the payment amount go to "Accounting" then "Receive Payments".

- Type in the payment amount and in the "Check #" field enter the check number.

- Next select "Generate," then select "Allocate" then "Search." Select the appropriate fee.

- A "Receipt Number" will appear. This number needs to be listed on the application for future reference. Write "R" followed by the receipt number.

Deposit Form:

Once all checks have been entered into the database and payment data has been listed on the applications a deposit form needs to be created.

- Go to "Reports" icon located on the left hand side.
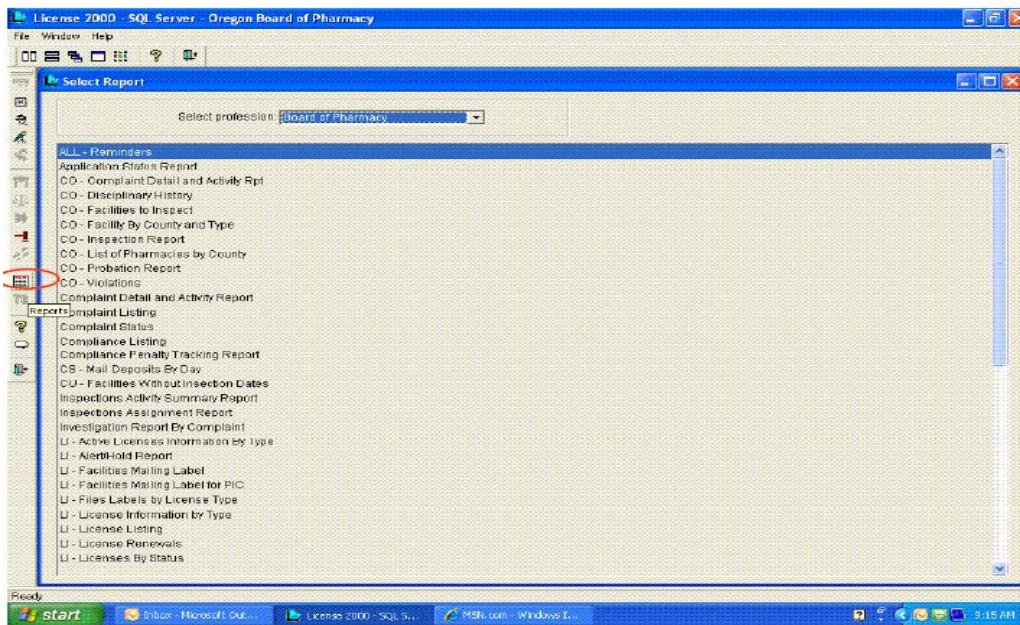
- Next select "CS Mail Deposit".
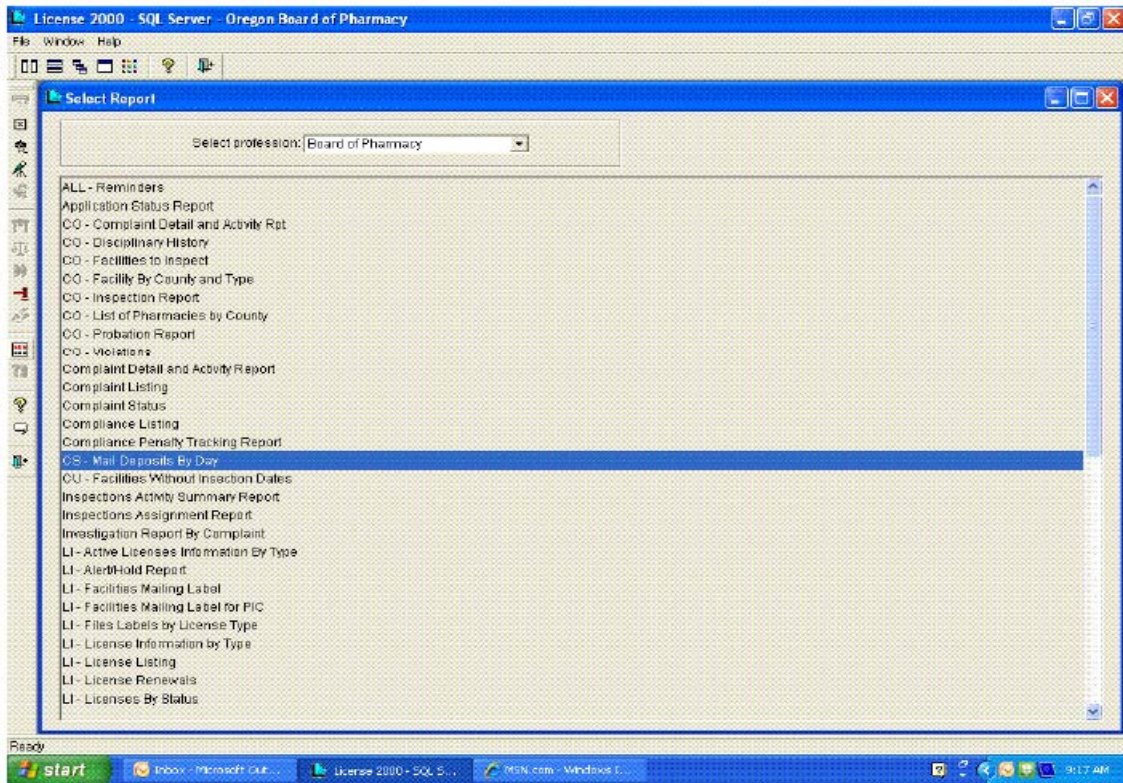
- Verify that the date is accurate then select "OK."

- Select "Export" icon.
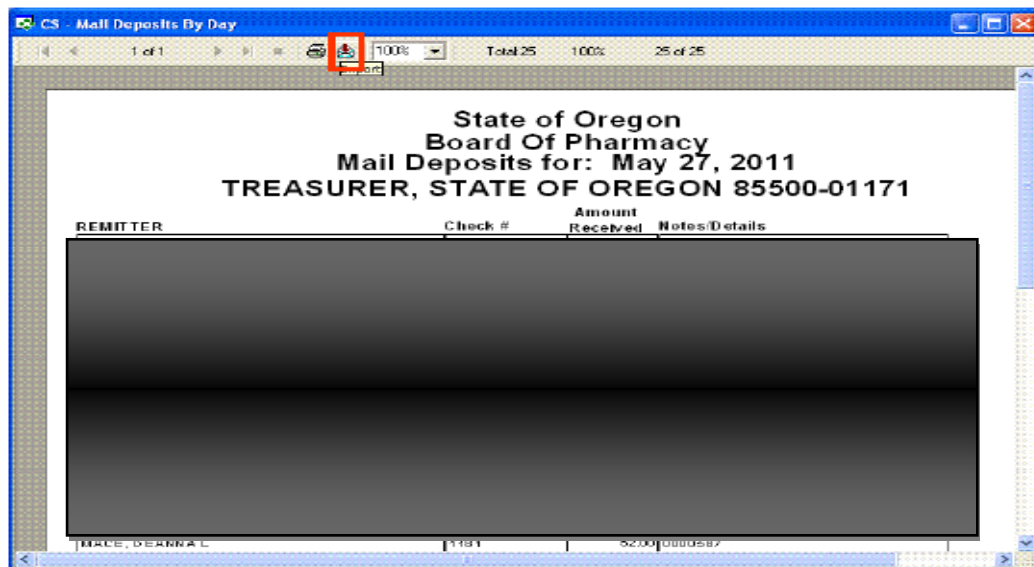
- Select **MS Excel 97-2000** and **Application** then Press **OK**
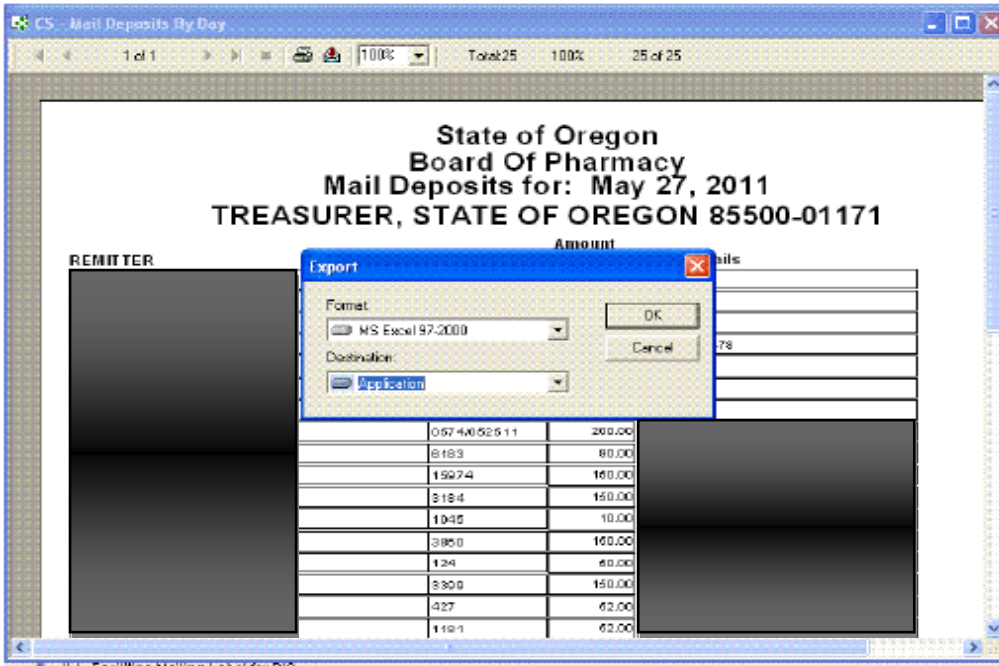
- Save the document in the file labeled "Licensing Shared," in the appropriate year and month folder. The file name will be the date of the deposit.

- If there are any reciprocity checks or civil penalties add them on to the deposit form manually. Then update the total of the checks.
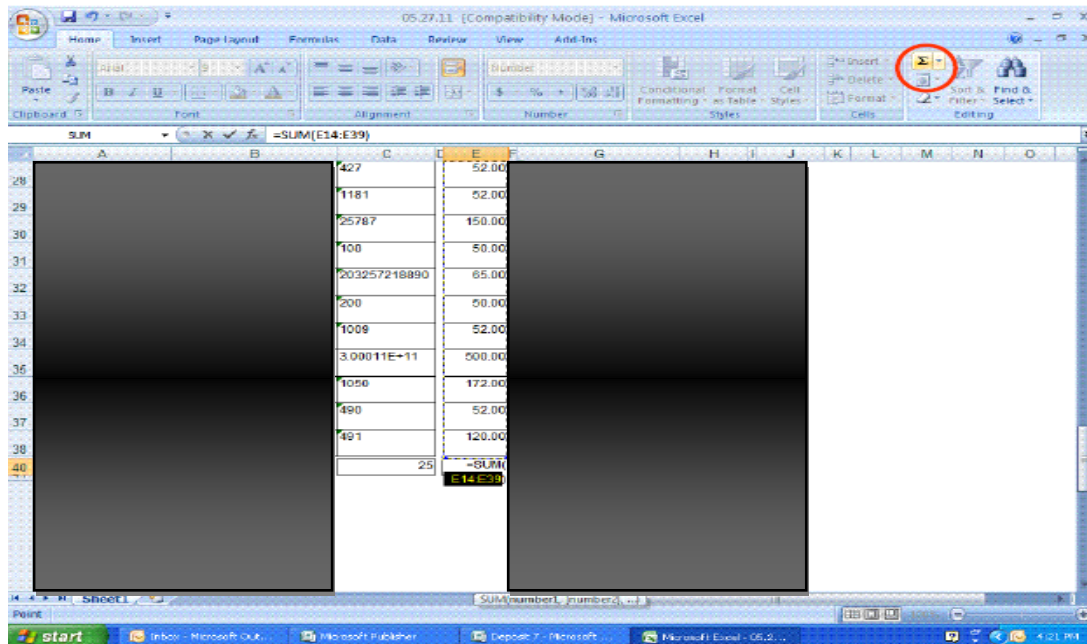
Verify Deposit:

The deposit form will automatically be formatted into alphabetical order.

- Put the checks in the same order as the deposit form.

- Run a total with a calculator and print the calculators print out. Initial and date the print out.

- Stamp the back of every check with the stamp labeled "US Bank."

- Distribute applications to the appropriate Licensing Representative for processing.

Return Payments:

- To return a payment, select the appropriate applicant. Next select "Accounts," go to "Payments" Then go to "Actions" and "Return Payment"

- A reason why the payment was returned must be selected.

Other Information:

- If you return a payment in the database it will appear twice or three times on the deposit form. Delete the extra payments and conduct an autosum of the total again.

- For reference purposes you may view the Board's fee schedule in Division 110 of the Board's rules. There is also a Schedule of Administrative Fees. This lists fees for items such as public records requests. You may view the schedule on the Board's website upon selecting the "Licensing, CE, Info and Forms" tab.

How to Process Multiple "Bulk" Renewals:

Preparing to Process "Bulk" Renewals:

As you look over the renewal forms, watch for deficiencies. Pull out any renewal with a deficiency or major change for further review.

A major change consists of a name change for a person or establishment. An employer change, an owner change, or address change.

Renewals with deficiencies or changes should not be processed via Bulk Renewals. They should be manually inputted into the database. Then provide the renewal to the appropriate Licensing Representative for review.

If there is a discrepancy on the bank transmittals highlight the discrepancy and review with the Office Manager. Sometimes a check will need to be requested from the bank to verify the amount paid.

Processing Multiple "Bulk" Renewals:

- Utilize Lockbox to Enter Bulk Renewals by Selecting "Bulk" then "Renewals."

- Input your First Name in the "Batch Number" field.

- Select "Express Renewal"

- Enter the License Number i.e. NPC-0001234.

- Select "Tab."

- Save and Save Often.

- Enter the first Five Characters of the Establishment Name.

- "Tab" to the "Amount" field then enter the Amount.

- "Tab" to Detail, Enter 6-digit Date (no slashes or dashes) then "/" and check number up to 5 digits (last 5.) Example: 072312/55123.

- "Tab" to Enter Next Renewal.

- Note that the Amount will Auto-Fill on Consecutive Entries.

- When Finished with Specific License Type, select "Okay." Then Process Next License Type.

Renewing:

- To renew select "Bulk" then "Renewals"

- Select your Name under "Batch Number"

- Select "Renew"

How to Process Check Payments during Online Renewal Cycles:

When renewals are mailed to the Board's physical address, the Receptionist processes the payment (only) and then puts the paperwork in a common in-box on the cabinet by the Licensing printer to be processed by the Licensing Representatives.

When processing people renewals, (as opposed to facilities) the last 4 digits of the Social Security Number is required. The Receptionist usually writes this information on the renewals. Check to make sure this information is on all of the renewals. If not, look it up in L2K before beginning.

Open the L2K Connector. The icon should be on your desktop.

Select the correct license type either RPH, CPT, PI, NPA or NPB and the "Payment By Check" process to run in the connector. For example "2012 CPT Payment By Check."

The "Check Payment" box will appear next.

Enter data in the appropriate fields, then click the "Add Transaction" button.

The "Check Payment" window closes when the "Add Transaction" button is clicked. An image of the confirmation page will pop up on as an internet page. Close it.

**Oregon Board of Pharmacy
Online License Renewal**

**Your Electronic Renewal and Payment have been submitted.
Please Print this for your records.**

Licensee Name:	▮▮▮▮▮▮	**License Number:**	▮▮▮▮▮▮
Payment Status:	COMPLETE		

Payment Info

Date Payment Received:	7/10/2012		
Payment was:	CHECK	**Confirmation #:**	▮▮▮▮▮▮
Total Payment:	$$52.50	**Paid For:**	Certified Pharmacy Technician License Renewal

Mandatory Renewal Response Questions

Question #1: Within the last five years, have you been arrested, charged with, convicted of or been sentenced for any violation of the law, or any crime in any state or by the federal government whether or not sentence was imposed, suspended, or whether you were pardoned from any such offense?

Answer: **NO**

Question #2: Within the last five years, have any disciplinary actions been taken against, or are any pending against, your Certified Pharmacy Technician license or registration in any state other than Oregon?

Answer: **NO**

Certification of Continuing Education

CE Question #1: I have completed the required 1 hour of Oregon pharmacy law in the previous 12 months (September 1, 2011 to August 31, 2012.)

Answer: **Yes. I have completed the CE required to renew my license.**
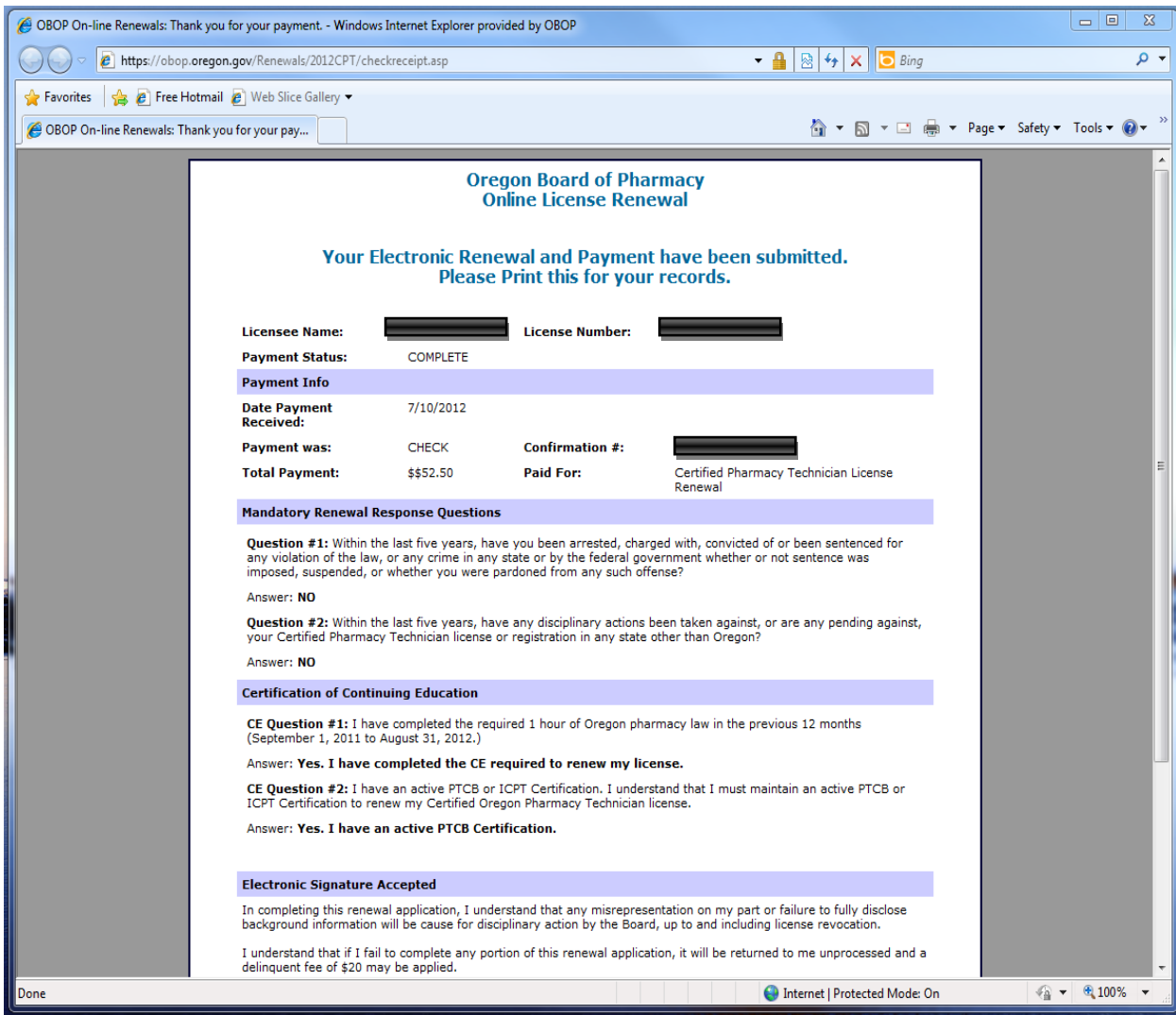
CE Question #2: I have an active PTCB or ICPT Certification. I understand that I must maintain an active PTCB or ICPT Certification to renew my Certified Oregon Pharmacy Technician license.

Answer: **Yes. I have an active PTCB Certification.**

Electronic Signature Accepted

In completing this renewal application, I understand that any misrepresentation on my part or failure to fully disclose background information will be cause for disciplinary action by the Board, up to and including license revocation.

I understand that if I fail to complete any portion of this renewal application, it will be returned to me unprocessed and a delinquent fee of $20 may be applied.
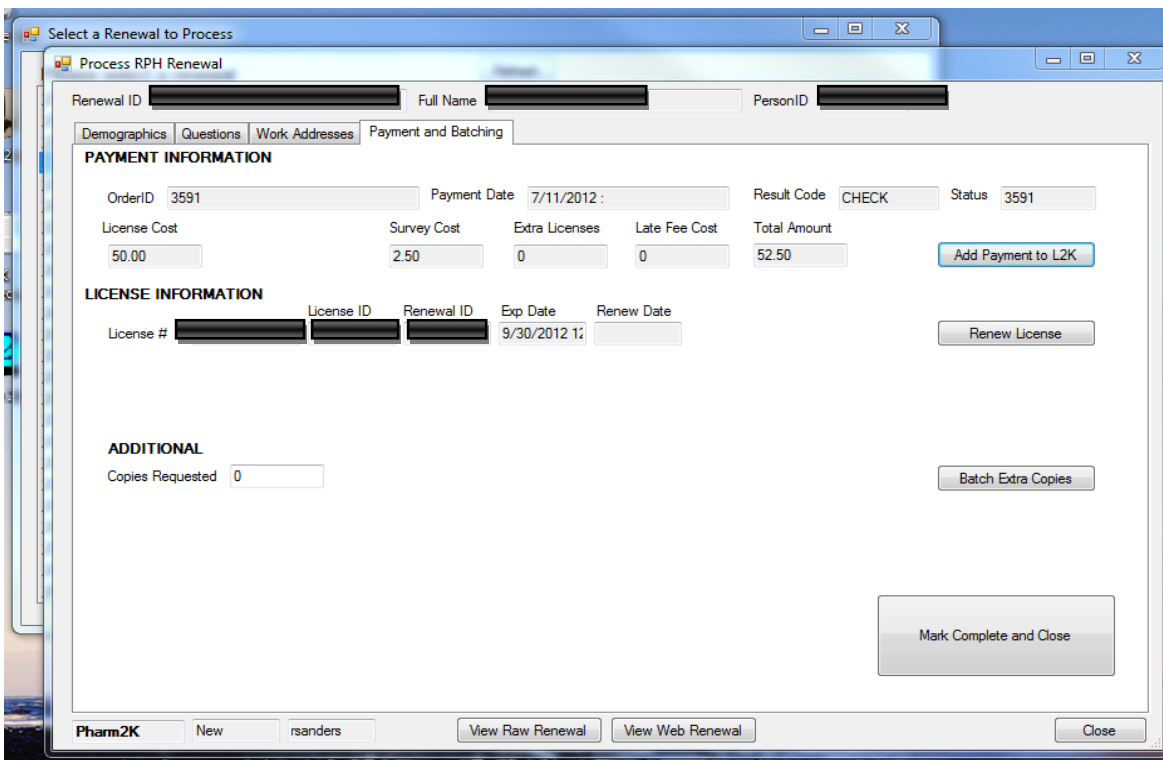
Repeat this process for each check renewal.

Once all the check payments have been entered select the correct license type and then select the "Process Renewals" button. For example, "Process 2012 CPT Renewals."

The check renewal will be in the list within 60 seconds. Process as you would renewals that were paid online, until you reach the Payment and Batching tab.

These renewals were mailed to the Board's physical address, which means that the Receptionist has already entered the payment. When you get to the Payment and Batching tab, skip the "Add Payment to L2K" button and start with "Renew License."

Online Renewals - Downloading Payments

This procedure requires a login and password which must be obtained for you by the Office Manager. Online payments typically occur during renewal periods for pharmacists, technicians and interns.

- Go to the Secure US Bank Admin Website and Log in:
  https://admin.epymtservice.com/admin/index.jhtml

- Click on "Download Remittance File." *This takes a moment to complete.*

- A List of Links Appears for Each Business Day.

- The file names appears in the following format:

  o phr_mcy_v4_0_2012_03_16.csv and phr_mcy_v4_0_2012_03_16.xml, with the numbers preceding the file extension (.csv or .xml) being the date in yyyy_mm_dd format.

- Click on the .cvs file for the date you wish to work on.

- Open the File. It will open in Excel.

- Save the File as an Excel Workbook. This File is the Archive Copy.

- Use the Default File Name that Appears when you Select "Save As."

- Delete the "(1)" at the end of the Default File Name. Parentheses are not allowed in File Names.

- Save the file to U://Licensing Shared Folder/Online Payments/… Select the correct year and month folder to save it in.

- Save the file again to the same location, removing the "(1)" and adding "_A" to the end of the file name. This file is your working copy.

- Once the files are saved, log off the bank website and close the window.

Formatting the Online Renewal Payment Spreadsheet

After the bank download with "_A" at the end of the default file name has been saved, you may begin formatting the spreadsheet to a usable style for processing the renewals.

- In Box 1A, enter the bank business date (from the file name) in mm/dd/yyyy format.

- In Box 1B, enter the total amount of all transactions. This can be found at the bottom of the spreadsheet. There are 5 items, "CreditCardSummary," "ATMSummary," "ACHSummary," and "DetailSummary," and "Trailer." "DetailSummary" is the grand total, and is the figure you want to enter in Box 1B.

- Format Box 1B for US Dollars by selecting the Box, then clicking on the "$" icon. This can be found on the "Home" tab of the ribbon, in the "Number" section.

- Clear the contents of the rest of Line 1. Click on Box 1C and drag to contain the rest of the boxes with text. Right click and select "Clear Contents."

- Scroll to the bottom, and insert a row between the final transaction and the balances section. The balances begin with the row that has "CreditCardSummary" in Column A. Click on the number of the row with "CreditCardSummary" in Column A, then right click and select "Insert". You must click on the number of the row, or you will only insert 1 cell. By clicking on the number, you insert an entire row.

- Delete the row that has "Trailer" in Column A. Click on the number of the row that has "Trailer" in Column A. Right click, then select "Delete."

- Scroll back to the top of the spreadsheet. Cut and paste Column B to Column C. Click on Cell 2B, and drag to the bottom of the transactions. Hold down the "Ctrl" key and press "X." The selection area border will appear to flash. Click on Cell 2C, then press "Enter".

- Delete Column E. Click on the "E", to hi-lite the column, then right-click, and select "Delete." Format the new Column E to US Dollars by clicking on the "$" icon in the ribbon.

- Delete Columns F, G, and H. Then delete columns G, H, and I.

- Make Column G smaller so that the text "ACH" just fits in it. Click on the line between Rows G and H. Drag the line to the left until the cells are the right size.

- Delete Columns H, I, and J. Then delete columns K through AC. Delete Column L.

- Select Cells 2K and 2L and drag to the bottom of the transactions. Cut and paste these 2 columns of data into Columns A and B, at Row 2.

- Make Column B bigger so that you can see all of the names. Make Column C bigger so that you can see all of the numbers.

- Delete Columns M, N, and O.

- Cut and paste the data beginning in Cell 2M to the end of the transactions into Column D beginning in Cell 2D.
- Make Column D bigger so that you can see all of the contents.

- Change the page setup to Landscape. Click on "Page Layout" at the top of the ribbon. Click "Orientation," then "Landscape."

- Set the print area for the spreadsheet. Select your entire data area, from Cell 1A to ?G. Click "Print Area," then click "Set Print Area."

- Add a header with the date and total dollar amount. Click on the box with the arrow in the "Page Setup" section of the ribbon. A dialog box opens. Click the "Header/Footer" tab. Click "Custom Header." In the "Left Section" area, type in the date from Box 1A, space over 5 spaces, then type in the dollars from Box 1B. Include a $. Click the box with the "A" to format the font. Set "Font style" to "Bold" and "Size" to "14." Click "OK." Click "OK" on each of the next 2 boxes as well.

- Sort the transaction data by License Number. Click on "Data" at the top of the ribbon. Select the entire transaction data, from Cell 2A to _G. Click "Sort." A small screen pops up. In the "Sort by" drop-down, choose "Column A." Click "OK."

- Highlight groups of transactions to make processing easier. Click "Home" at the top of the ribbon. Select the data in Rows 2 and 3. Click on the paint bucket in the "Font" section of the ribbon. Choose a light grey hi-lite and click it. Select the data in Rows 2, 3, and 4. Click on the paintbrush labeled "Format Painter" in the "Clipboard" section of the ribbon. Click in Box 5A, drag to 5G, and drag down to the end of the transaction. Release.

- Click the cell in Column E below the final transaction. Click the Sigma sign marked "AutoSum" in the "Editing" section of the ribbon. It should default to "=SUM(E2:E_)" with the _ being the final row of the transaction. If not, change it to encompass that data. Hit the "Enter" key. Make the font Bold. (Click on the "B" in the "Font" section of the ribbon.) Make sure this figure matches the the total in the "DetailSummary" row.

- The data in the print area should be no more than 1 page wide. If it is wider, shrink the font of some of the longer data in rows B and/or D to 10 point, and make the columns smaller. Do this until your data is only 1 page wide.

- Look for any payments that include additional certified license copy fees. Make the entire row Bold font for any such transactions. (This is because the L2K Connector does not add the certified copy fees, and thus leaves money unallocated. We have to add the fee manually, unallocate, then reallocate the fees in this case. If the L2K Connector is able to accomplish this task in the future, this step may be eliminated.)

- Print 2 copies of the spreadsheet.

Online Renewals - Processing

- Obtain the oldest bank spreadsheet from the Licensing Shared Inbox located next to the Licensing printer.

- Open L2K Connector

- Click "Import Latest Renewals and Print Worksheets."

- Click "OK" and wait for the next screen to appear.

- Click "OK" and wait for the next screen to appear.

- Close the printout screen.

- Click on "E-Process Renewal on Production by License #."

- Click it again.

- Enter the license number, numbers only, starting with the first whole number (after "zero".)

- Select "Enter" twice.

- Proof the address screen, make changes if necessary, and Enter.

- Check for correct answers to the questions. If there is an "incorrect" answer, complete the download process, but **do not renew** the license.

- Select "Enter".

- Check for matching birth date, then Enter.

- If work address is different, manually update L2K, then Enter. Otherwise, Enter.

- Check second work address, if any. Make any updates needed, then Enter.

- Select "Enter" three times to add the payment to L2K.

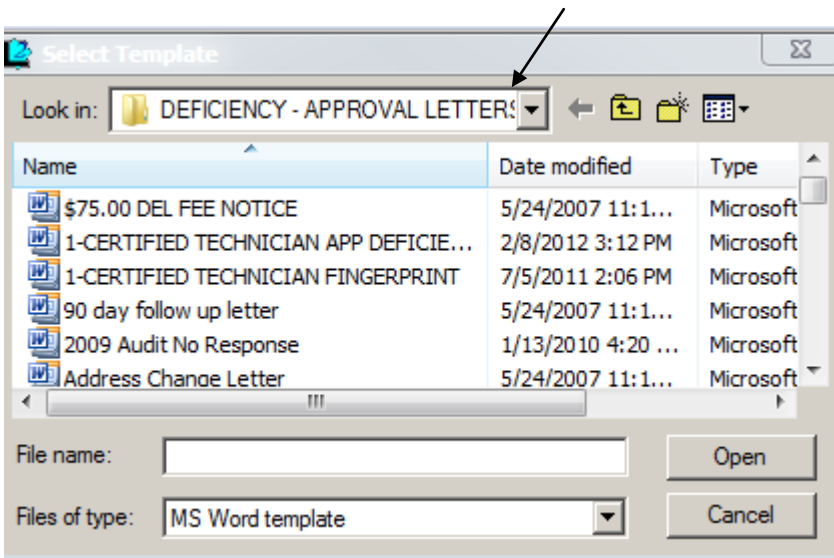- If everything is correct, renew the license.

Deficiency Letters for Outlets and Technicians:

An application that is not complete requires a deficiency letter. A deficiency letter may be generated by performing the following:

- Select applicant from L2K and go to the "Licenses" tab.

- Select the Merge Licenses Icon.
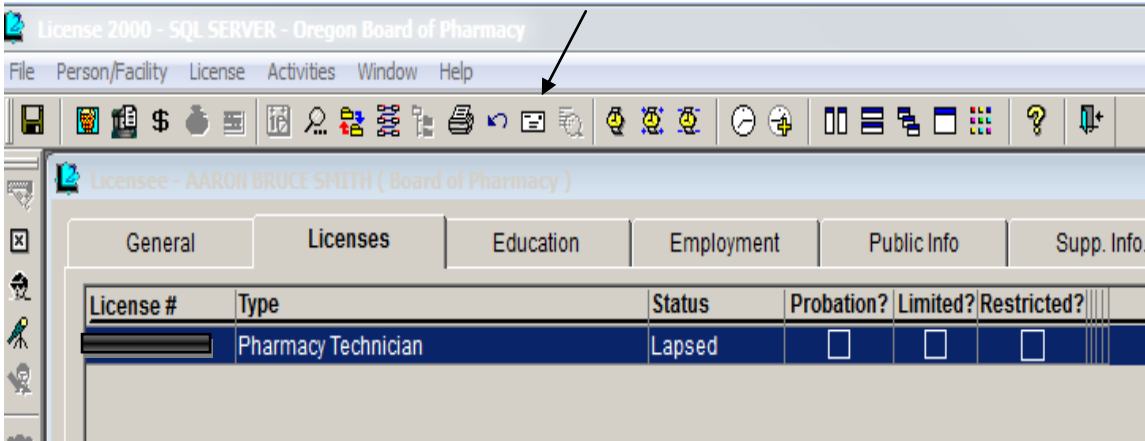
 o Select the "Deficiency –Approval Letters" file.

  o Select the appropriate Deficiency Letter.

  o This process will generate a Deficiency Letter that may be edited.

  o Save the letter by into the appropriate directory.

  o Sign the letter and make a copy of it to attach to the application.

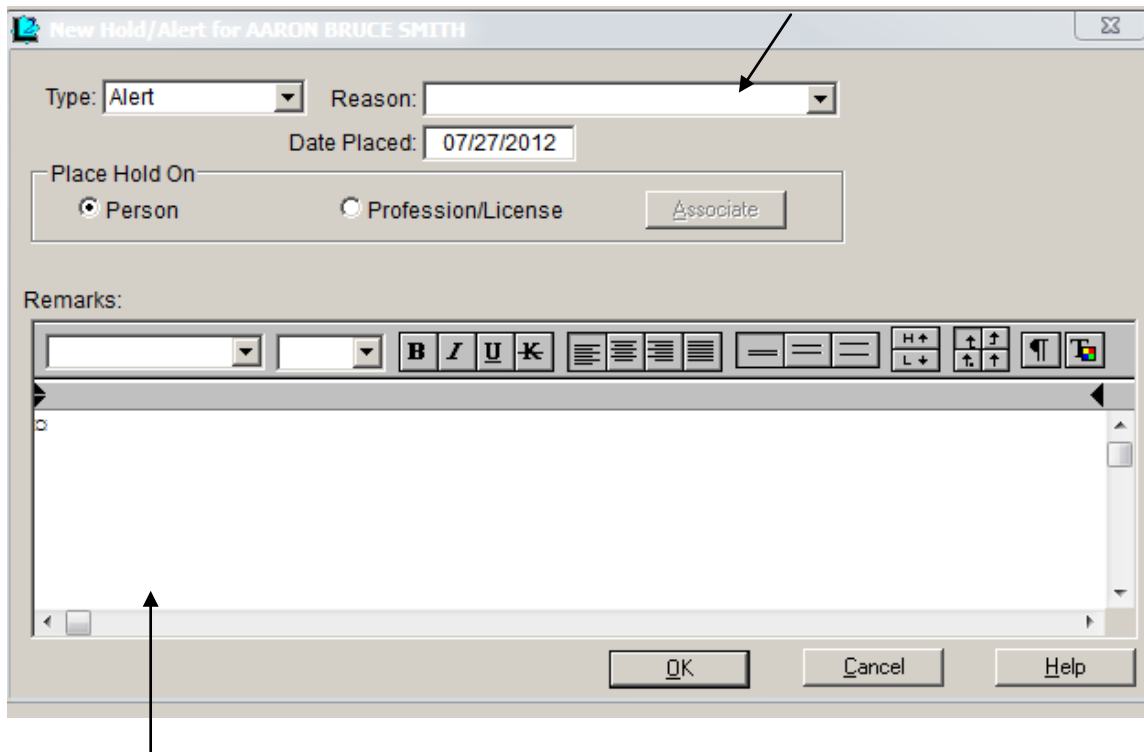 o File Application in Incomplete Applications File.

- If Applicant has an unexpired, "Null and Void" Background Check, note the expiration date on the application. These applications will not go to the Background Check Specialist.

How to Enter an Alert:

- Click on the New Hold icon (middle yellow watch)
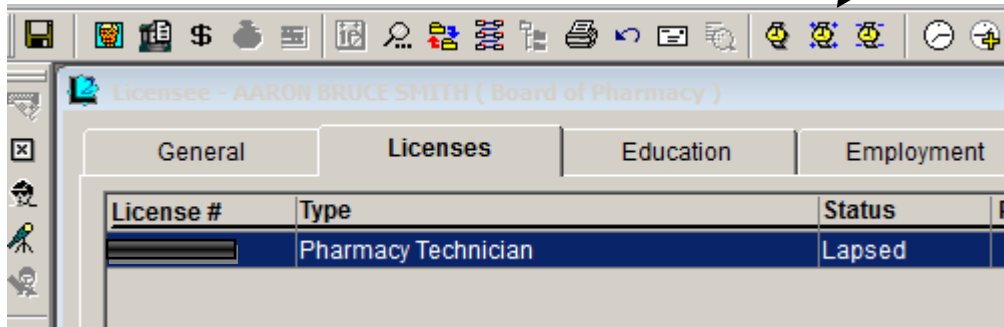
- Select the reason from the drop-down menu.

- In the Remarks Section, make note of what is missing from Application

- Click Okay.

- Create a reminder by clicking the clock with a "+" sign on the far right.
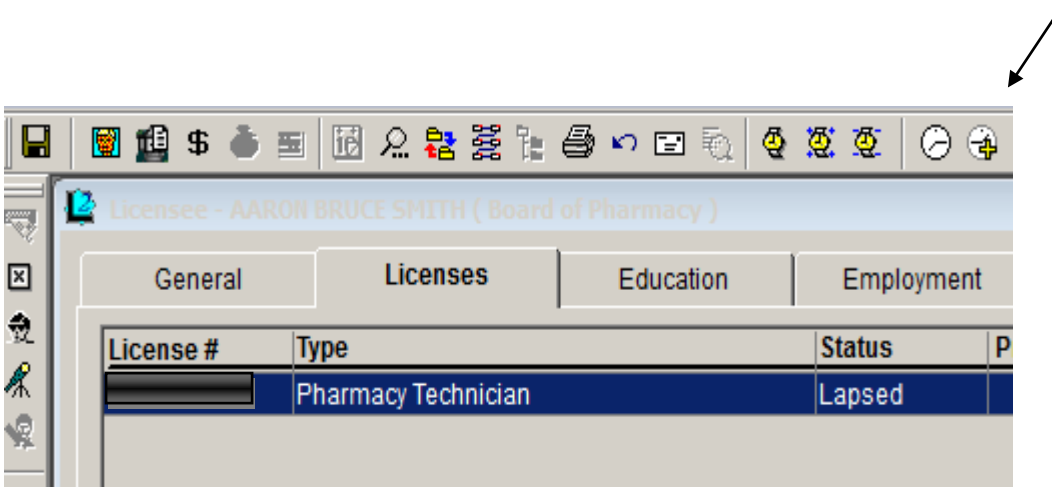
- Set Due Date 22 days ahead.
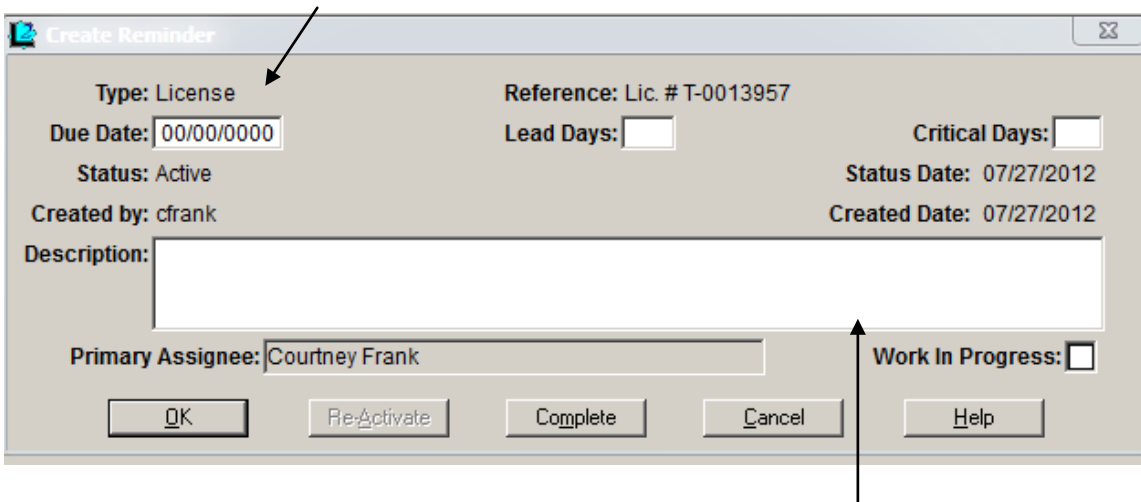
- Write a short description of what is needed, and click "Okay

Checklist and Remarks:

- Open Checklist and add remarks to the relevant items not checked off.

- Search for Applicant.

- Select item, such as "Legal Identification."

- Click the "Remarks" button.

- Type in a brief description, such as "NO ID" or NO BACK OF ID" in all capital letters.
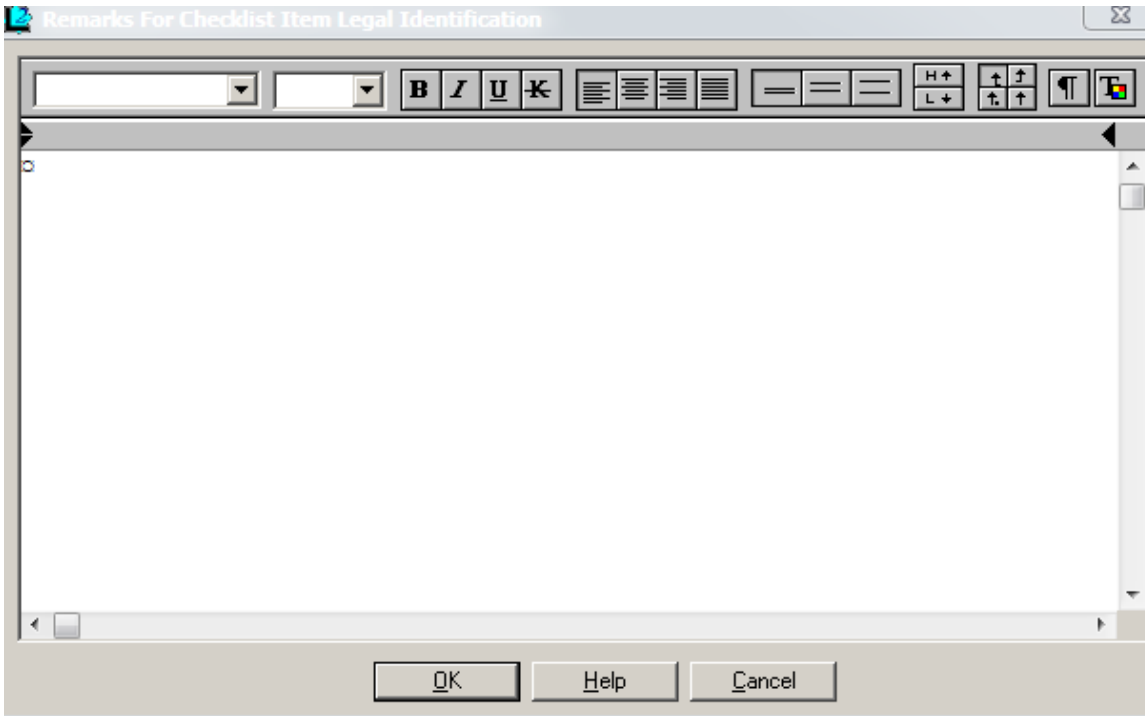
- Click "OK."

- If a fingerprint packet has not yet been mailed or picked up, include letter with application to go to Background Check Specialist, who will mail it out with the fingerprint packet.

- If a fingerprint packet has already been mailed or picked up, mail the letter directly to the applicant.

- If applicant has an unexpired, "Null and Void" Background Check, note the expiration date on the application. These applications will NOT go to the Background Check Specialist.

- Close Cool Dude.

Fingerprint Background Checks:

Effective February 1, 2011, all new Pharmacy Technician, Certified Pharmacy Technician, Intern & Pharmacist applicants, as well as applicants for reinstatement are required to undergo a national (FBI) fingerprint-based background check. This includes:

- Pharmacy Technician/Certified Pharmacy Technician Applicants
    - Residing in Oregon or outside of Oregon.

- Intern Applicants
    - Attending an Oregon Pharmacy School.
    - Attending an out-of-state Pharmacy School.
    - Foreign Pharmacy Graduates who require an Oregon Intern License.

- Pharmacist Applicants Applying for Licensure via
    - Exam
    - Score transfer
    - Reciprocity
    - FPGEC

Fingerprint background checks are not being conducted for Corporate Officers of establishments at this time.

Requesting a Fingerprint Background Check Application:

- An applicant may request a fingerprint background check application by making a request in writing. The request may be submitting via email, fax or mail. An electronic request form is also available on the Board's website.

- Additionally, once an applicant applies for a license by submitting a complete application and the appropriate fee, they will be sent a fingerprint instruction packet, if not already requested. The Receptionist is responsible for sending these out.

Fingerprint Background Check Application Requirements:

- The following items must be returned to the Board office:
    - A completed fingerprint card issued by the Board.
    - A completed verification form issued by the Board.
    - Payment of $52.00 payable by check or money order only.
      Note: The Board will not process generic fingerprint cards or verification forms from other agencies.

Upon receipt, the Receptionist will enter the payment into the system and the application will be forwarded to the Background Check Specialist. If the application and verification form are complete the fingerprint card will be forwarded to the Oregon State Police (OSP).

OSP will process the request and conduct a nationwide background check through the FBI, and return the results to the Board office. The Fingerprint Background Specialist will review the results and either return it to the appropriate Licensing Representative for processing or submit it to the Compliance Department for further evaluation.

Rejected Fingerprint Cards:

- Occasionally, an applicant's fingerprint card may be rejected because of poor quality fingerprints, and they will have to get fingerprinted again. The applicant will not need to pay the $52.00 processing fee again. However, they may need to pay to have their fingerprints retaken. A new Verification Form must also be completed and submitted with the fingerprint card.

Background Check Validity:

- The background check is valid for 15 months.

- The 15 month validity policy applies to any license application. Regardless of any existing license type. Note that a new fingerprint background application also requires a new fee of $52.00 for processing.

Other Information:

- An applicant may have their fingerprints taken in any State. If they are an out-of-state resident they do not need to come to Oregon to have their fingerprints taken.

- Fingerprints submitted to other State or Federal agencies are not available for use by the Oregon Board of Pharmacy, nor are Oregon Board of Pharmacy fingerprint results available to other entities.

- OSP may take up to 21 days or longer to return the results.

LICENSING
Technicians and Certified Pharmacy Technicians

Pharmacy Technicians:

A licensed Pharmacy Technician, supervised by a Pharmacist may assist in the practice of pharmacy by the following:

- Packing any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Pouring any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Placing in a Container for Dispensing any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Sale of any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Distribution of any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Transfer Possession of any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Other items listed in OAR 855-025-0040.

Registration Requirements Include:

- Submission of a complete **Pharmacy Technician Application.**

- One passport photograph.

- Copy of Government issued photo identification card i.e. drivers license, State ID card. Copy must also show signature.

- Detailed explanation of criminal history if applicable. Each criminal incident also requires the following:

- o Police Report
- o Court Documents Revealing the Final Outcome of the Case.

- Submission of **Fingerprint Background Check Application** and **Processing Fee** of **$52.00**.

- Submission of **Pharmacy Technician Application Fee** of **$50.00**.

Renewal Information:

- The **Pharmacy Technician License** is a **One Year non renewable License** with the **Exception** of those under the age of **18**.

- For those **over** the age of **18**, they must apply for a **Certified Pharmacy Technician Registration** in order to continue to work as a Technician.

Other Information:

- This License Expires after One Year from the Date of Issuance.

Applicable Rules:

- **Oregon Administrative Rules 855-025-0001**

Certified Pharmacy Technicians:

A licensed Certified Pharmacy Technician, supervised by a Pharmacist may assist in the practice of pharmacy by the following:

- Packing any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Pouring any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Placing in a Container for Dispensing any drug, medicine, poison or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Sale of any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Distribution of any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Transfer Possession of any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

- Other items listed in OAR 855-025-0040.

Registration Requirements Include:

- Submission of a complete **Certified Pharmacy Technician Application.**

- A copy of applicant's National Certification.

- One passport photograph.

- Copy of Government issued photo identification card i.e. drivers license, State ID card. Copy must also show signature.

- Detailed explanation of criminal history if applicable. Each criminal incident also requires the following:

    o Police Report
    o Court Documents Revealing the Final Outcome of the Case.

- Submission of **Fingerprint Background Check Application** and **Processing Fee** of **$52.00**.

- Submission of **Certified Pharmacy Technician Application Fee** of $50.00.

Renewal Information:

- Registration expires **September 30th annually**.

- **Renewal notices** are mailed in early **July**.

- The **renewal fee** is **$52.50.**

- If a **renewal application** paid by a check is received after the **postmark deadline** of **August 31st** a **$20.00 delinquent fee** is required. The delinquent fee is automatically added to online payments at midnight on September 1st.

Other Information:

- National Certification must be maintained and current in order to renew a Certified Pharmacy Technician License.

- **National Certification** has its own **Continuing Education (CE) requirements.** It is the licensees responsibility to be aware of the CE requirements and to satisfy them.

Applicable Rules:

- **Oregon Administrative Rules 855-025-0001**

Application Processing for Technicians and Certified Technicians:

Review and Verify Information:

- Open Cool Dude in L2K.

- For Person Search by Social Security Number or name.

- Select Appropriate Applicant.

- Verify information in the "General" and "Licenses" Tabs match information listed on the Application. For Establishments that have a Location or Owner Change Changes cannot be made to the database until Application is complete. Any changes to a Manufacturer, Wholesaler or Drug Distribution Agent require approval from a Supervisor.

- Add any missing information in General, License, Employment, and Supplemental tab.

  o For Certified Pharmacy Technicians, verify national certification online. You may obtain the username and password for the PTCB or NHA from a supervisor. This information is confidential. Once information is verified include the PTCB or NHA number in "Supp. Info" under the "Licenses" tab.

    - PTCB: www.ptcb.org
    - NHA: www.nhanow.com/employers.aspx

Open Checkbox:

- Search for Applicant by name.

- Select correct Applicant and verify correct License Type.
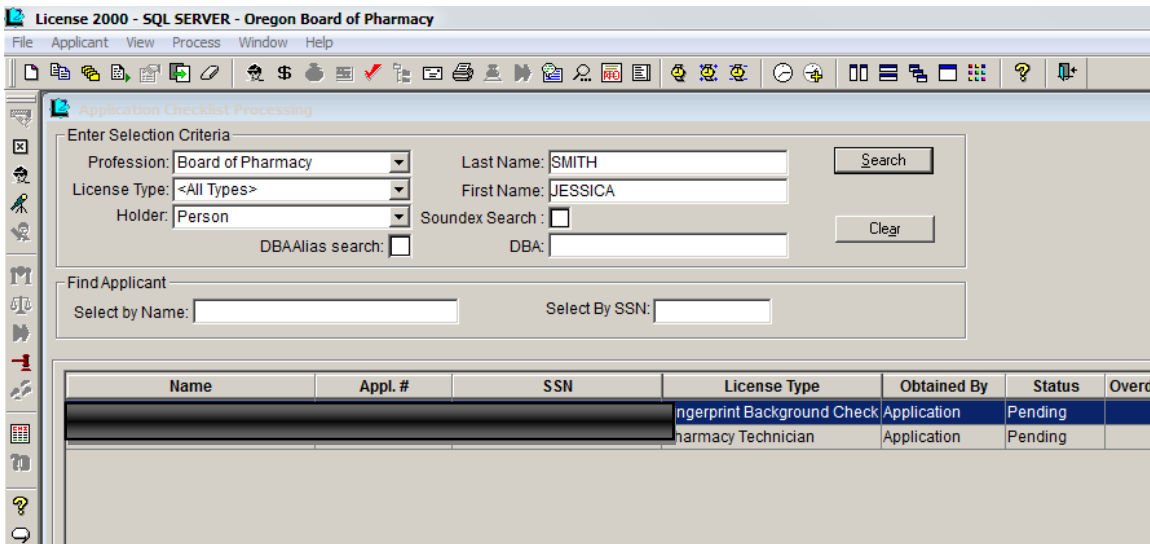
- Bring all applicable items in Checklist over to "Completed Items" once documents have been received.
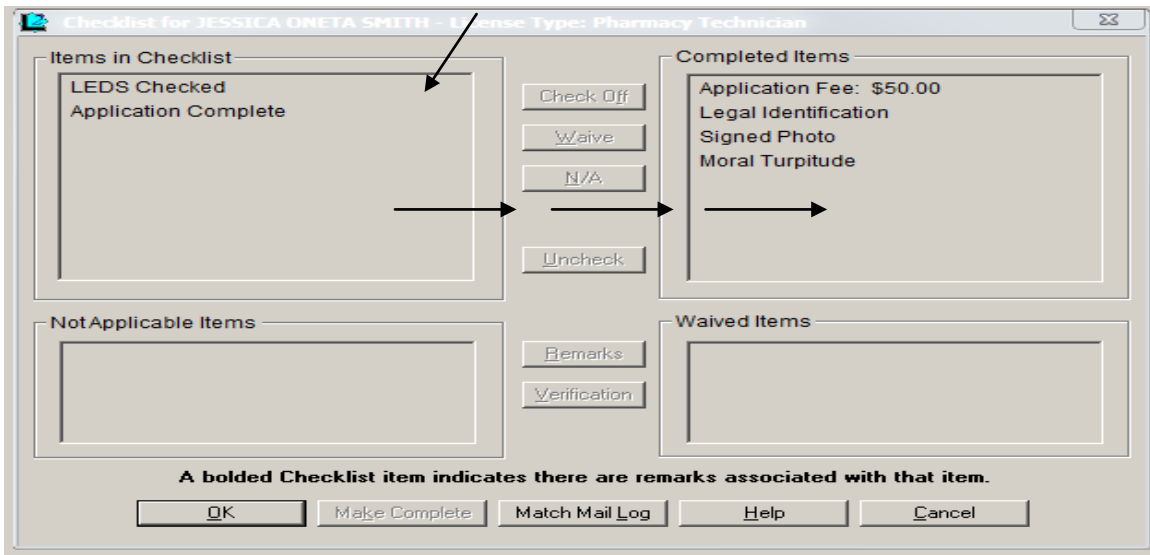
- On any item that is under the "Completed Items" section you may place a remark. This can be done by highlighting the selected item and pressing the "Remarks" button. Remarks may also be added to "Items in Checklist" too.

- Then select **"Okay."**

- Select item, such as "Legal Identification."
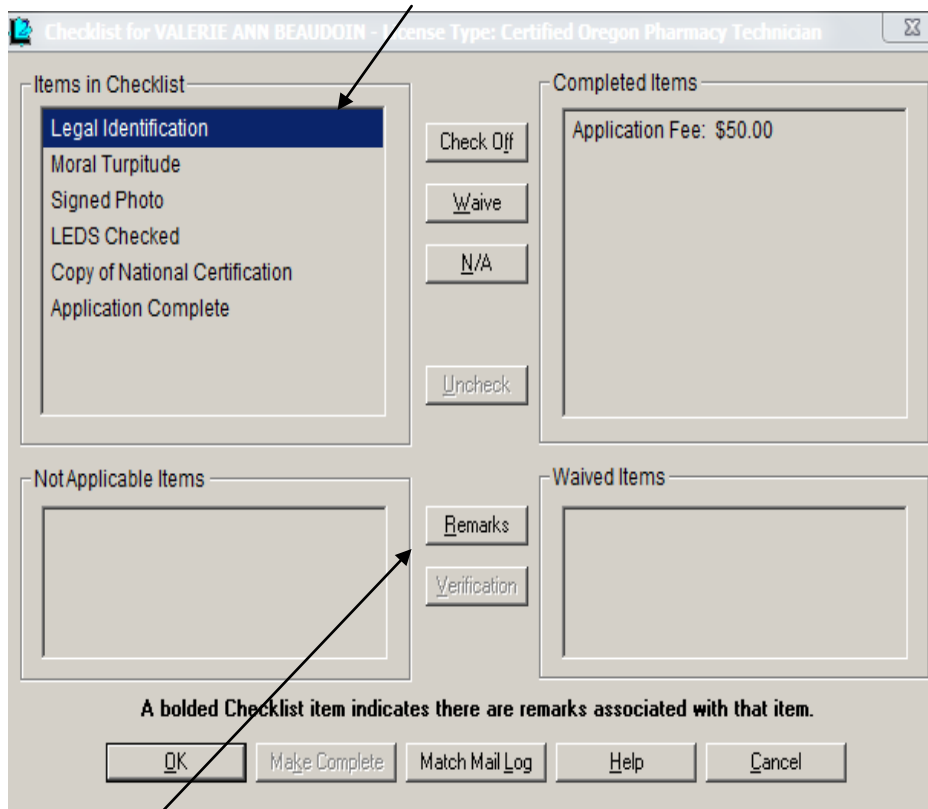
- Click the "Remarks" button.

- Type in a brief description, such as "NO ID" or "NO BACK OF ID" in all capital letters.
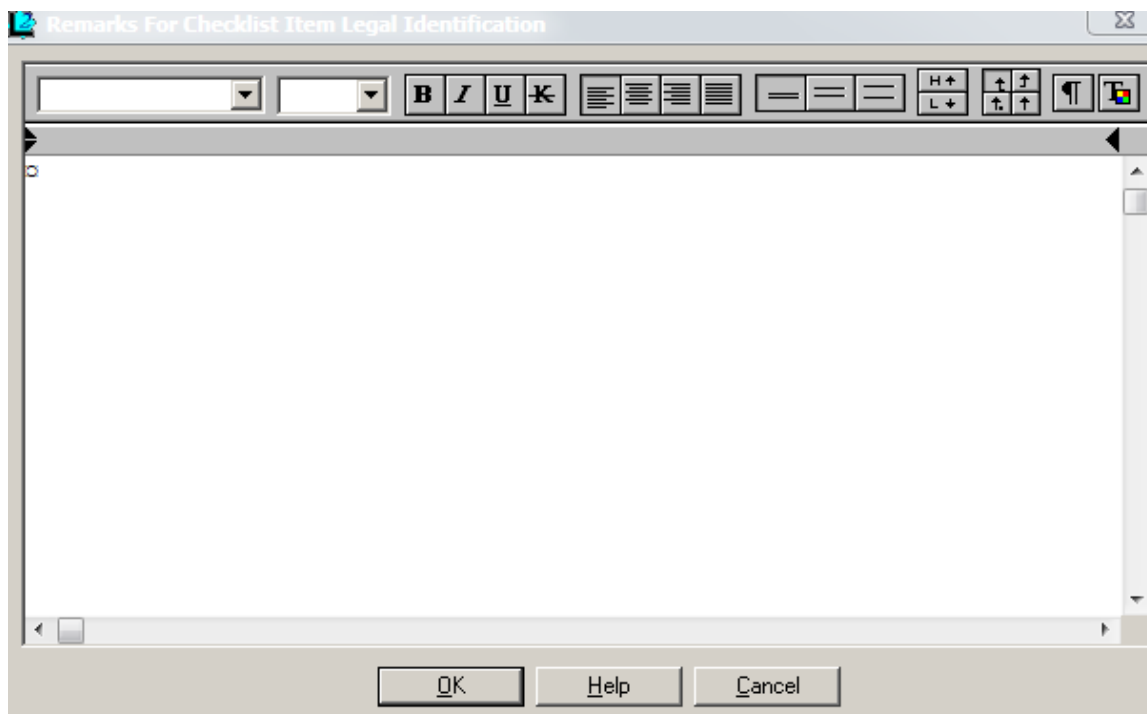
- Click "OK."

- If a deficiency letter is needed include letter with application to go to Background Check Specialist, who will mail it out with the fingerprint packet.

- If a fingerprint packet has already been mailed or picked up, mail the letter directly to the applicant.

- If applicant has an unexpired, "Null and Void" Background Check, note the expiration date on the application. These applications will NOT go to the Background Check Specialist.

- Close Cool Dude.

Issuing a License:

Once all of the application requirements have been fulfilled, the license is ready to issue.

- Open Checkbox.

- Select the "License Type from the drop-down menu.

- Enter the name of the applicant for whom you want to issue the license; then click "Search".

- Click the red checkmark. Check off any items remaining on the checklist, then click "Make Complete."
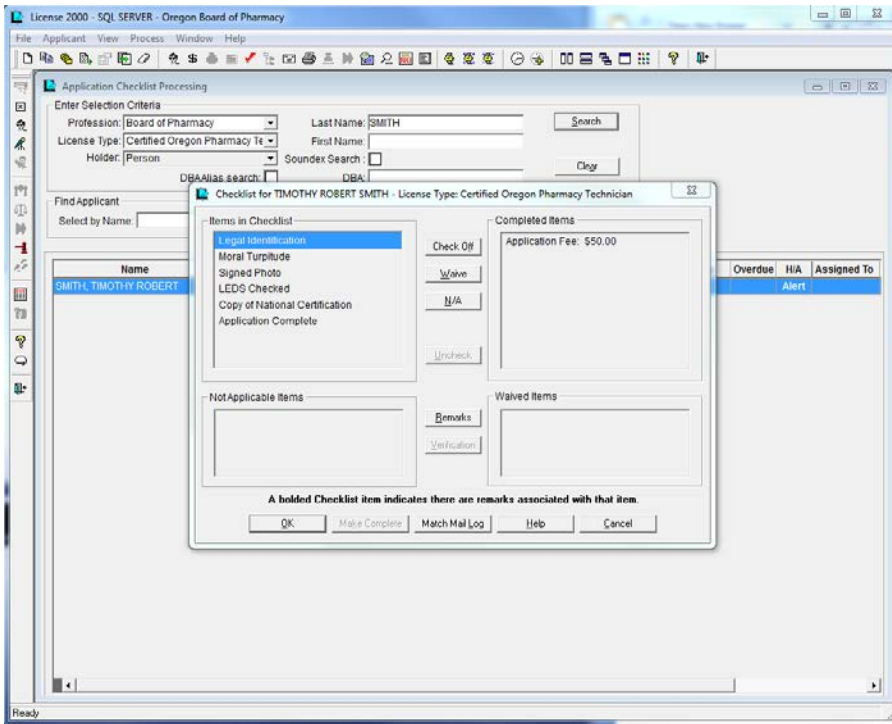
- The "Approve" icon becomes active.
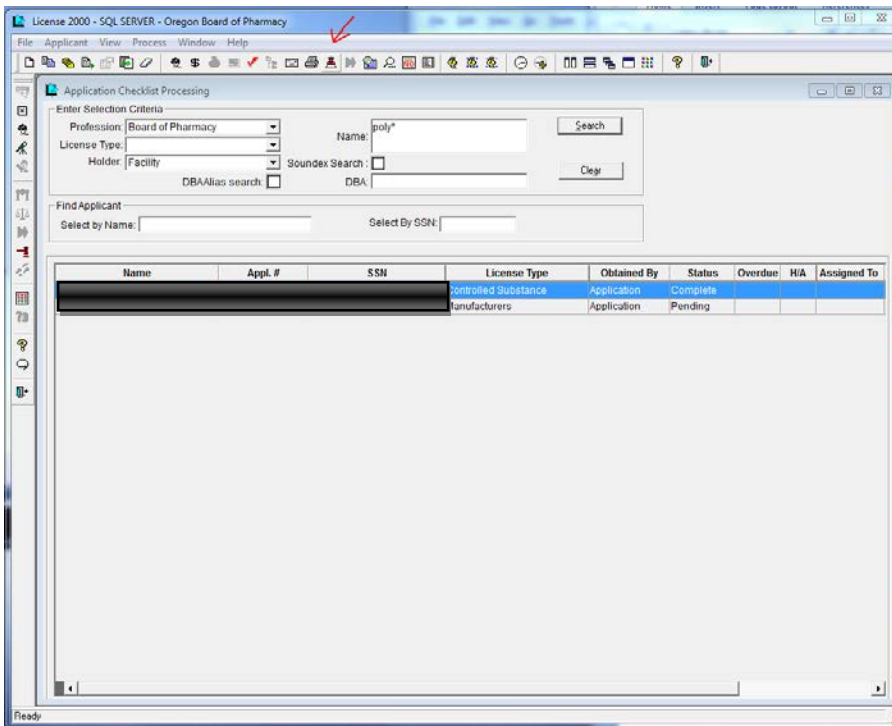
- Click the "Approve" icon. Click "OK" when appropriate. Write the license number on the application below the gray payment box. Once the license is issued, it will appear in the print queue.

Issuing a License for a Future Date:
During a renewal cycle, applicants are given the choice of having their license issued "now", or on the first of the month following the expiration date for that license type. (Ex. Certified Pharmacy Technicians could have their license issued in August or September, or could choose to have it issued on October 1st.) If they choose the 1st of the month, they may NOT work (and facilities may not operate) in Oregon until they are licensed.

To issue licenses with an effective date in the future, follow the instructions for issuing licenses up to clicking the "Approve" button. When you click the "Approve" button, you can set the issue date in the first pop-up window. Continue with issuing the license, write the number on the application and the license will appear in the print queue. Typically, we mail future-dated licenses one week prior to the effective date, so the licensee will have it once it becomes effective.

On the effective date, the licenses must actually be "Issued".

- In checkbox, search by the license type you are issuing. All "Approved" licenses that had a future issue date will show up.

- The "Issue" icon will be active. The "Issue" icon is a Green Arrow, facing to your right, next to the red "Approve" icon.

- Select the licenses to be issued. Hold down the "Ctrl" key to select more than one individual license, or hold down the "Shift" key and click the top and bottom licenses to select a range of licenses.

- Click the green arrow.

- The Issued licenses will now show "Active" in Cool Dude.

Note: This activity may only be performed on or after the due date previously selected when the license(s) was/were Approved.

LICENSING
Interns and Pharmacists

Intern Application Information:

Intern license applications can be found on the Oregon Board of Pharmacy website:

http://www.oregon.gov/pharmacy/Imports/Intern_Application.pdf

To be eligible to hold and Intern license in Oregon, you must be a student who will be attending either Oregon State University or Pacific University; a student who will attending a University or School of Pharmacy in another state which is ACPE accredited; or an individual who is a Foreign Pharmacy Graduate who has obtained an FPGEE/FPGEC Certificate.

For those individuals who will be attending Oregon State University or Pacific University, they must fill out and application and submit the following items to the Oregon Board of Pharmacy:

- $50.00 License Fee;
- An original passport/visa style photograph (2x2 inches in size) taken within the past 6 months;
- A copy of their state issued driver's license or state issued ID card (both front and back).
- Fingerprinting Requirements (stated elsewhere in this manual.)

Once the above items have been received they will be kept at the Oregon Board of Pharmacy waiting for confirmation of their enrollment. When the status of their admission has been confirmed with the School of Pharmacy, the Oregon Board of Pharmacy will process the Intern application and provide the Intern license to the School or College of Pharmacy. The School or College of Pharmacy will provide the student with their Intern license when they are physically attending classes.

For those individuals who will be attending a University or College of Pharmacy outside the State of Oregon, in addition to the above required items, the individual will need to contact their University or College of Pharmacy. The Oregon Board of Pharmacy must have received a letter from the University or College of Pharmacy a verification letter indicating that the individual is currently enrolled in a PharmD program.

Once the above items have been received, the Oregon Board of Pharmacy will process the Intern application and provide the Intern license to the individual at the address they used when filling out the application.

If a student does not have a social security number, or are attending their University / College of Pharmacy under a student visa, they must provide the Oregon Board of Pharmacy with a copy of their F1 Visa with a copy of their I94 and I20 documents.

For those individuals who are a Foreign Pharmacy Graduate and have obtained their FPGEC Certificate, in addition to the items listed in paragraph 2 above, they must submit their **Original** FPGEC Certificate to the Oregon Board of Pharmacy, as well as a copy of their country passport and U.S. Visa showing they are entitled to work in the United States (such as an H1B Visa), and a copy of their TOEFL and TSE (or TOEFL iBT) scores.

Once the above items have been received, the Oregon Board of Pharmacy will process the Intern application provide the Intern license to the individual at the address they used when filling out the application. The Oregon Board of Pharmacy will also mail the Original FPGEC Certificate to the individual.

The Intern license will expire on November 30, two years after the date of issue.

The $50.00 license fee is non-refundable and must be received by check or money order only. All returned checks will be assessed a $35.00 returned check fee pursuant to Oregon Revised Statute 30.701(5).

Pharmacists – Eligibility Report:

Candidates who have paid NAPLEX / MPJE examination fees to the NABP will have their names appear on a NAPLEX/MPJE Open Registrations Report. Your supervisor will provide you with the link to the report which is on an NABP Secure site. You will need the following items to access this confidential report:

- o User Name: Obtain from your supervisor.
- o Password: Obtain from your supervisor.

- This takes you to the NAPLEX/MPJE Open Registrations report. Print the report.

- You can find the records for those individuals who are wishing to take the NAPLEX and/or MPJE in the file cabinets to the right of Michael's computer screen. Individuals who want to take the NAPLEX/MPJE based off of the NAPLEX or Score Transfer Applications are in the cabinet marked "NAPLEX/MPJE Test Takers." Individuals who have submitted a NABP Official Application for Transfer of Pharmacist License to the State of Oregon Application are located in the cabinet marked "Reciprocity / License Transfer to Oregon."

- There may be individuals on the NABP NAPLEX/MPJE Open Registrations report that have not contacted or submitted anything to the Oregon Board of Pharmacy.

   - o For these individuals you may write "unknown" next to their name.

- To verify an individual is eligible to take an examination, all applications and paperwork / documents need to be received in the office.

- If an individual is eligible to take an examination:

- Write in the date of eligibility in the space provided.

   - o For those taking the NAPLEX or MPJE based off of the NAPLEX application, the date of eligibility will be today's date.

   - o For those taking the MPJE based off of the Score Transfer application, the date of eligibility will be the same date as when they passed the NAPLEX examination.

   - o For reciprocity / license transfer individuals, the date of eligibility needs to be the same date as the Date of Issue on their NABP Official Application to Transfer the Pharmacist License to the State of Oregon.

Pharmacists – Obtaining Score Results:

Candidates who have taken the NAPLEX / MPJE examinations receive a score report letter from the Oregon Board of Pharmacy. This letter may include an application, retake form, or other information. Scores are found on the NABP Secure site.

Obtaining Score Results:

- Your supervisor will provide you with the link to the score results report which is on an NABP Secure site. You will need the following items to access this confidential report:

    o User Name is: Obtain from your supervisor.
    o Password: Obtain from your supervisor.

- After you have entered the user name and password you will be directed to the **NAPLEX/MPJE Open Registrations Report**.

- Click on the **NAPLEX/MPJE Open Registrations Report** tab. This will direct you to the **Search Candidates Section**.

Searching for Candidates:

- The best way to conduct a search is by viewing the reports that have not been printed.

- In the **Display Filter** choice, make sure "**Show Not Printed Only**" is selected.

- In **Score Post Date Range Fields**, make sure that you start three months prior to today's date in order to capture those scores that have been Score Transferred to Oregon.

- Click on "Search." After searching, a list of names will appear under the NAPLEX, MPJE and Score Transfer Reports.

- Click on "Select for Printing." Click on Print Selected Score Report(s). A print box will appear.

- Print two copies of the Candidate Score Report

- After printing the Candidate Score Report, return to the NAPLEX/MPJE Score Reports Section.

- Click on "Clear Search."

- Log Out.

Pharmacists – Reciprocity/License Transfer:

The following procedures are to be followed when we receive an NABP Official Application for Transfer of Pharmacist License to the State of Oregon.

Reciprocity/License Transfer:

- The Receptionist will give you the "Original" NABP Official Application for Transfer of Pharmacist License to the State of Oregon after the payment has been entered into L2K.

- Verify that there is a copy of a U.S. Birth Certificate or U.S. Passport.
  - o If copy of his/her US Birth Certificate or U.S. Passport is provided write "Identification Received" near the check information field on the front of the application.

- If there is no identification provided send the individual a deficiency letter. The letter will indicate that the Board must have a copy of their identification before they take the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE).
  - o If a copy of a U.S. Birth Certificate or U.S. Passport is <u>not</u> provided write on the application "No Identification" near the check information field on the front of the application.

Verify the Following:

- Application Date of Issue: Must be received at the Board no later than <u>90 days</u> after the date of issue. If it is received <u>after</u> 90 days the individual must have requested a 90 day extension from the NABP. If there is no NABP extension, the application must be sent back to the individual. Individual must mail the application to the NABP and request an extension. NABP will process it and mail the application back to the individual with an extension page if their extension request is approved.

- <u>Verify the license</u> that is being used as the basis of transfer is active.
  Note: If the state is listed as California, then the date of issuance of their license must have been issued after January 1, 2004.

- <u>Date of License Issue</u>: Individual must have been licensed for 1 full year before submitting a License Transfer application to Oregon. However, if they have been licensed less than one full year, they can still apply for license transfer but their eligibility will be based on the number of school based internship hours earned one year immediately preceding the Date of Issue of the Official NABP Application.

- <u>Social Security Number</u>: Complete SSN must be listed. If not, individual receives a letter stating this required information was missing.

- Pharmacy Education: Must be from a pharmacy college that has received accreditation from the Accreditation Council for Pharmacy Education (ACPE). A list of accredited schools may be found on the ACPE website at: www.acpe-accredit.org

- FPGEC Certified: If they are FPGEC Certified, individual must submit their Original FPGEC Certificate to the Board. Make a copy of the Certificate and mail the original back to the individual using Certified Mail – Return Receipt Requested.

    o To verify the FPGEC Certificate go to the NAPLEX MPJE Eligibility Reporting system on the Internet. Type in the User Name and Password. Go to the FPGEC Certification tab. Type in the individual's last name and EE number (found on the FPGEC Certificate.)

    o If name appears, click on Certification Details and print a copy.

    o Log off program. On the NABP Official Application, write "verified with NABP and the date" next to the FPGEC Number.

- Photograph and Instructions for Submitting Photographs: A photo of the applicant with his/her signature on the back must be attached to the bottom right of the application. The person signing as the applicant's witness must also sign the character voucher on the official application. This individual must also be licensed in a state listed in the Applicant's License section.

- Applicant's License: Verify that the State used on the front of the application is still in active/good standing status. If not, application needs to be given to a supervisor for review.

- Practice as Pharmacist and Employment after Licensure: Verify that applicant has practiced as a pharmacist for at least one full year.

- Professional History: Questions should be marked "No." If any question is marked "Yes", supporting documentation must be submitted. Application will need to be reviewed by a supervisor if any question is answered "No."

- Affidavit: Verify that applicant has signed the affidavit and that it has been notarized by a Notary Public.

- Voucher: Verify that the person listed is the same person who signed the photograph signature card and is licensed in a state listed in the Applicant's License section.

- If anything is missing, a letter must be sent to the individual. Different letters can be found in the U drive, Board of Pharmacy, Reciprocals. If application is complete you may begin entering information into L2K.

Letters:

- Letters for reciprocity / license transfer applicants are found on the U:/drive in the Board of Pharmacy file under the Reciprocals file.

- Select the correct category and update as necessary.

- Save as using the date of the letter followed by the individuals first and last name. Example: 03-08-2012 John Smith.

- Make a copy of the letter for the individual's file.

- If the individual is being sent a fingerprint card packet, go to the Fingerprint Background Check Specialist's files in the U:/drive and type up a letter for the individual. Save the letter in the Fingerprint Background Check Specialist's files by typing in the last name, first name and middle initial and the date of the letter. Example: Smith, John Q. 03-08-12

Foreign Pharmacy Graduates:

NABP assists graduates of foreign pharmacy schools in more than 200 countries as they work toward becoming licensed pharmacists in the United States. All 50 states, District of Columbia, Guam, and Puerto Rico require graduates of pharmacy schools that are not based in the US to achieve Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification. Applicants may see if they are qualified for FPGEC Certification by contacting the NABP or visiting:
http://www.nabp.net/programs/examination/fpgec/

Once an individual obtains their FPGEC Certification from NABP, they will be eligible to become an Oregon Intern. Once an Oregon Intern license is obtained they may start earning 1,440 hours in experience toward achieving competency in the practice of pharmacy. These 1,440 hours of internship must be completed prior to applying for and taking the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in Oregon Administrative Rule 855-019-0150. However, after an individual is licensed as an Oregon Intern, they are eligible to take the North American Pharmacist Licensing Examination (NAPLEX.) Additional information regarding the NAPLEX / MPJE process may be found on the Board's Oregon Pharmacist Licensing Procedures at. http://www.oregon.gov/pharmacy/Imports/NAPLEX_MPJEInstructions.pdf

IMPORTANT INFORMATION

- To become licensed in Oregon, an individual is **not** required to be an American citizen, however, if an individual has not obtained a naturalization document from the Immigration and Naturalization Service's Department of the Office of Homeland Security he/she must have a passport with a valid U.S. Visa authorizing him/her to work in the United States (such as an H1B).

- If an individual is in the United States under a Student Visa (F-1) he/she is not entitled to have an Oregon Intern License unless they have completed one full year of academic study and their Designated School Official has signed their I-20 indicating he/she is eligible to work off campus.

- For graduates of Universities in Canada, please note that even though the Accreditation Council for Pharmacy Education (ACPE) recognizes the accreditation decisions of the Canadian Council for Accreditation of Pharmacy Programs (CCAPP), the Oregon Board of Pharmacy still requires Canadian graduates to become FPGEC Certified.

LICENSING PROCEDURES

- FPGEE/FPGEC Examination. Those that would like to obtain their FPGEC Certification must take and pass the FPGEE examination. As part of the examination process, the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT) must be passed with a minimum score of 26 in Speaking, 21 in Reading, 18 in Listening and 24 in Writing.

- After the FPGEE has been taken, the applicant will receive an examination score report. This exam score report cannot be used to obtain an Oregon Intern License. An official FPGEC certificate from the Foreign Pharmacy Graduate Examination Committee will be sent to the applicant. The certificate is required for licensure in Oregon.

- Intern License Requirements. Once the applicant has received the official FPGEC certificate, he/she is eligible to become an Oregon Pharmacy Intern. The Oregon Intern License Application may be found at: http://oregon.gov/Pharmacy/Imports/Intern_Application.pdf.

- If an applicant does not have a U.S. Passport or Naturalization Documents, he/she must have a U.S. Visa that entitles him/her to work in the United States, such as a H1B/H2B Visa or EAD document. **Please Note**: B1/B2 Visa Holders are not eligible to obtain an Oregon Intern License as this visa does not allow the holder to work in the United States.

- An applicant must submit his/her **original** FPGEE/FPGEC Certificate to the Oregon Board of Pharmacy when submitting their Intern Application, as well as a recent photograph and a copy of their passport or birth certificate (translated if necessary). The Licensing Representative will photocopy the FPGEE/FPGEC certificate, verify it with the NABP for authenticity and mail the original FPGEE/FPGEC certificate back to the applicant via Certified Return Receipt Requested or Federal Express mail. We do not accept copies of FPGEE/FPGEC certificates.

- Intern Hours. The State of Oregon requires 1440 hours of internship **after** an individual has *taken and passed the FPGEE and TOEFL (iBT) exams and AFTER the certificates has been verified with the NABP.*

    o Internship or practice as a pharmacist **outside the United States cannot** be accepted toward Oregon's internship requirement. Intern or professional practice performed before taking and passing the FPGEE and TOEFL iBT exams **will not** apply toward Oregon's required 1440 hours.

    o An applicant may complete hours as a licensed Intern in another state working under a licensed Preceptor. However, the intern will need to report the hours to the Board of Pharmacy in that state and have that state's Board of Pharmacy certify his/hers hours to us.

    o Once 1440 hours of internship have been completed. The individual will be eligible to apply for and take the Oregon Multistate Pharmacy Jurisprudence Exam (MPJE).

    o **Note**: that after becoming an Oregon Intern, an individual is eligible to request for and apply to take the North American Pharmacist Licensure Examination (NAPLEX).

NAPLEX / MPJE Process:

The Oregon NAPLEX application may be obtained from:
http://oregon.gov/Pharmacy/Imports/NAPLEXApplication.pdf.

- A complete Oregon NAPLEX application may be submitted to the Oregon Board of Pharmacy with:

    - A $50.00 non-refundable processing fee;
    - An original passport/visa style photograph taken within the past six months;

- An applicant must register and pay NABP for their NAPLEX and MPJE exams. The NABP fee for taking the NAPLEX is currently $485.00 and the fee for the MPJE is currently $200.00. An applicant may register for their exams at: http://www.nabp.net/programs/

- Upon receiving an Authorization-To-Test (ATT) from the NABP, the applicant will need to follow the NABP instructions on how to request an exam time and date.

- The applicant will then take the NAPLEX and/or MPJE exam.

- The Oregon Board of Pharmacy will be advised if the applicant passes or fails the exam. We will inform the individual of their exam results via a letter. We do not give exam results over the phone. If the applicant successfully passes the exams, an Oregon pharmacist application will be mailed as well as a fingerprint background check packet. The pharmacist license is currently $200.00. The fingerprint background check is an additional $52.00. The applicant may submit payment for both with one or two checks.

- Upon receiving a complete Oregon Pharmacist License Application, passing the national background check and remitting payment for both items a pharmacist license is ready to be issued.

Making a Pharmacist File after Individual Becomes Licensed:

After an individual has become licensed as a pharmacist, the file folder needs to be arranged in order. This is considered cleaning out, or making a pharmacists' file.

Documents found in the individual file are to be put in the following order:

- The Pharmacist license copy is attached to the front of the Pharmacist License Application.
- The request for a Fingerprint Card Packet.
- The Fingerprint Identity Verification Form.
- If the individual was an Oregon Intern, the Intern license copy.
- The Intern License Application.
  - o The State Issued Identification or State Issued Driver's License.
  - o If the individual was not from Oregon, confirmation of their pharmacy degree enrollment from their University / College of Pharmacy.
- If the individual was an Oregon Certified Pharmacy Technician or Pharmacy Technician, copies of those applications/renewals.
- If the individual has had to retake the Oregon Multistate Pharmacy Jurisprudence Examination or North American Pharmacist Licensure Examination (Oregon as Primary) examinations, the retake applications are filed here.
- The first North American Pharmacist Licensure Examination (Oregon as Primary State) application followed by:
  - o A copy of their U.S. Passport, U.S. Birth Certificate, Certificate of Citizenship, Country Passport and copy of U.S. H1B Visa.
  - o Confirmation of their Pharmacy Degree (if not provided with their Intern License application).
  - o Confirmation of their having completed at least 1,440 school based rotational intern hours.
  - o If they have requested a copy of the Laws and Rules for Oregon, attach the form here.
  - o If they have requested any certified copies of their Intern license, attach the request form here.
- A copy of the Oregon Board of Pharmacy NAPLEX Receipt Letter.
- Any e-mails that were sent by the Oregon Board of Pharmacy to the individual, or e-mails that were received by the Oregon Board of Pharmacy.

Staple everything together and place in a reinforced manila file folder.

The test scores / score reports are placed in a manila mailing envelope (6"x9") which will be stamped with a "CONFIDENTIAL" stamp. This confidential envelope is placed behind the stapled applications packet.

Place an orange file folder label on the right corner and make three white labels. Two of the white labels should have the following format:

LAST NAME, FIRST NAME
LICENSE #: RPH-0000000
ORIG DATE: XX-XX-XXXX
RECIP OR EXAMINATION: (Select one based on how applicant applied for Oregon licensure).

One label will be attached to the left side of the file folder and the other label will be attached to the confidential envelope which will contain exam results.

The third label should have the following format:

LAST NAME, FIRST NAME   RPH-0000000

Attach the third label just below the orange file label.

File the record in the Pharmacist file cabinets

LICENSING
Establishments

General Licensing Information for all Establishments

Listed below is general information and processes that apply to all establishment license types.

- If an establishment changes from being a Limited Liability Company to becoming Incorporated or vice versa the transaction is considered to be a corporate restructure. A corporate restructure requires an Owner Change Application and fee.

- If an establishment has a name change, a Name Change Application is required 15 days prior to the change. Note that there is <u>no fee</u> for a name change only.

- If an establishment has a location change, a Location Change Application and fee is required 15 days prior to the change.

- If an establishment has a change in ownership, an Owner Change Application and fee is required 15 days prior to the change.

- If an establishment undergoes a stock transfer only written notification within 15 days of the change is required. If the transaction includes an acquisition of assets i.e. drug inventory the transaction is considered to be a change in ownership and requires an Owner Change Application and fee.

- If there is a change at the parent company level of an entity only written notification is required.

- Establishments <u>located in Oregon</u> that would like to dispense/distribute controlled substances much register with the Board of Pharmacy prior to registering with the Drug Enforcement Agency (DEA).

- Establishments <u>located outside of Oregon</u> must first have their DEA Registration prior to obtaining a controlled substance registration with the Oregon Board of Pharmacy.

- Any establishment that is located in Oregon and has a newly issued Controlled Substance Registration from the Oregon Board of Pharmacy requires Board Staff to provide notification via facsimile to the Seattle DEA Office. The same process is required when there has been a location, name or owner change.

- If an out-of-state establishment does not submit a license verification from their resident state a license verification from the resident state's website may be obtained so long as it reflects whether or not disciplinary action has been taken. The verification must be printed, initialed and dated by the Licensing Representative that verified the license. If the Licensing Representative is unable to verify the license online and a license verification is omitted from the application a deficiency letter must be sent to the applicant.

- The Oregon Board of Pharmacy does not license establishments located outside of the United States and its Territories at this time.

- If a government agency mandates a location or address change. The location change fee is not required. However, the Location Change Application must be completed.

- There is not a fee at this time for Certified Copies for establishments as they are not offered Certified Copies during their renewal periods.

- There is a $10.00 processing fee for a manual license verification. License verifications are available for free on our website.

- If an establishment has submitted an Owner or Location Change Application and decides to revert back to the old owner or location after the application has been processed next steps must be discussed with a manager.

- If an establishment would like to add a Controlled Substance Registration on to their existing registration at a later date they must complete a new application and submit payment of $100.00. If they are located out-of-state a copy of their DEA Registration is also required.

- It is not unusual for an outlet to have more than one type of registration.

- When searching for a facility always make sure the "Show licensees only" box is unchecked. Even when an establishment is a licensee sometimes it will not appear in the results if the box is checked. Leaving the box unchecked will provide the results for both licensed and unlicensed facilities.

- The asterisk symbol "*" is the wildcard symbol in L2K. If you only know part of a name you can put in the part you know as well as the asterisk. Additionally, if you do not know the name of an outlet but know the city and zip code you can enter those fields and the "*" for the name and address and it will show all outlets that are in the selected city and zip code.

Animal Euthanasia:

Any humane society or animal control agency located in **Oregon** that purchases, possesses and administers sodium pentobarbital for euthanizing injured, sick, homeless or unwanted domestic pets and other animals is required to register as an **Animal Euthanasia Outlet**. Note that the only exception is when an **Oregon licensed Veterinarian** who is also registered with the **DEA** purchases, possesses and administers sodium pentobarbital. They have the authority to do this under their **Oregon Veterinary Medical Examining Board License** and **DEA Registration**.

Registration Requirements Include:

- Submission of a complete **Animal Euthanasia Application**.

- Copies of **Certified Euthanasia Technician (CET) Registrations** through the **Oregon Veterinary Medical Examining Board**. Note that only persons certified by the Oregon Veterinary Medical Examining Board may withdraw and administer sodium pentobarbital. A copy of their certification must be included with new animal euthanasia applications as well as renewal applications.

    o **CET Registrations** may be verified on the **Oregon Veterinary Medical Examining Board's website**: www.oregon.gov/ovmeb.

- Payment in the amount of **$50.00** to satisfy **Animal Euthanasia Application Fee**.

Renewal Information:

- Animal Euthanasia Registrations **expire December 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$50.00** and there is **no** delinquent renewal fee at this time.

Other Information:

- A humane society or animal control agency that handles **sodium pentobarbital** must have a **DEA Registration**. Their State registration issued by the Oregon Board of Pharmacy must be issued prior to the DEA Registration.

Applicable Rules:

- **Oregon Administrative Rules 855-080-0100**

Charitable Pharmacies:

A **pharmacy** that **accepts donated drugs for distribution** when the **pharmacist** can reasonably be assured of the purity and integrity of the drug may register as a **Charitable Pharmacy**.

Registration Requirements Include:

- Submission of a complete **Charitable Pharmacy Application**.

- Application must **include proposed policies and procedures as well as a description of the organization.**

- An applicant must designate a **Point-of-Contact**.

- A Charitable Pharmacy must have a **licensed pharmacist**. The **pharmacist** may also be the **Point-of-Contact**.

- A list of **corporate officers** or **members**.

- Payment in the amount of **$75.00** to satisfy **Charitable Pharmacy Application Fee**.

- There are few establishments that qualify for this registration. The Compliance Director should review new applications and approve the proposed policies and procedures.

Renewal Information:

- Charitable Pharmacy Registrations expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$75.00**.

- If a **renewal application** is received **after** the **postmark deadline** of **February 28th** a **$25.00 delinquent fee** is **required**.

Other Information:

- This registration is **not** applicable to **out-of-state establishments**.

Applicable Rules:

- **Oregon Administrative Rules 855-044-0001**

Consulting Pharmacies with No Drugs:

Establishments that provide **consulting services** and do **not** directly provide **prescriptions** to **Oregon patients** must register with the Oregon Board of Pharmacy as a **Retail or Institutional Drug Outlet**. **Registration Requirements Include**:

- Submission of a complete **Retail or Institutional Drug Application.** Note that establishment will be registered as either a **Retail or Institutional Drug Outlet**.

- Application must include a **waiver request** addressed to the Board to waive the minimum equipment requirements (OAR 855-041-0040) to operate as a **drugless pharmacy**.

- Also required for submission is a **description of pharmacist duties** as well as **policies and procedures** for:

    o Order Entry;

    o Counseling;

    o Training of Technicians;

    o Utilization of Computer Systems; and

    o Method of Record Keeping.

- Payment in the amount of **$300.00** to satisfy **Retail or Institutional Drug Outlet Application Fee**.

- Original **license verification from resident state.** Applicable to **out-of-state** establishments.

Renewal Information:

- **Retail and Institutional Drug Outlet Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$300.00**.

- If a **renewal application** is received **after** the **postmark deadline** of **February 28th** a **$75.00 delinquent fee** is **required**.

Other Information:

- Note that all **pharmacists** and technicians who provide services to Oregon residents much also be registered with the Oregon Board of Pharmacy.

Correctional Facility Drug Rooms:

Any **correctional facility** that is located in **Oregon** that **dispenses** medications to **inmates** must register as a **Correctional Facility**.

Registration Requirements Include:

- Submission of a complete **Correctional Facility Application**.

- If establishment will **dispense controlled substances** a **Controlled Substance Application** must be completed. If not, the Controlled Substance Application needs to be marked "Not Applicable".

- A **Correctional Facility** must have a **registered nurse** or **nurse practitioner**.

- A **Correctional Facility** must have an Oregon licensed **consultant pharmacist**.

- Payment in the amount of **$100.00** to satisfy the **Correctional Facility Application Fee**.

Renewal Information:

- **Correctional Facility Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the postmark deadline of **February 28th** a **$75.00 delinquent fee** is **required**.

Other Information:

- This registration is **not** applicable to out-of-state establishments.

- All registered Correctional Facilities must obtain their medications from pharmacies that are registered with the Oregon Board of Pharmacy. This applies to both in and out-of-state pharmacies. The Board requests the names of pharmacies utilized during the renewal period.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0170**

County Health Clinics:

A local **health department** established under the authority of a **county or district board of health** that **dispenses a drug or device** to a **client** of the health department for purposes of **caries prevention, birth control, or prevention or treatment of a communicable disease** must register as a **County Health Clinic**.

Registration Requirements Include:

- Submission of a complete **County Health Clinic Application**.

- A **County Health Clinic** must have a **health officer**. The **health officer** is required to be a **physician**.

- A **County Health Clinic** must have a **registered nurse**.

- Payment of **$100.00** to satisfy the **County Health Clinic Application Fee**.

Renewal Information:

- **County Health Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00**.

- If a renewal application is received after the postmark deadline of **February 28th** a **$75.00 delinquent fee** is **required**.

Other Information:

- This registration is **not** applicable to out-of-state establishments.

Applicable Rules:

- **Oregon Administrative Rules 855-043-0110**

Drug Distribution Agents:

Any person whose **sole purpose** is the **marketing, brokering or arranging the initial distribution of drugs manufactured** by a registered manufacturer must register as a **Drug Distribution Agent**. **Brokers, import brokers, drug order contractors and any agent for a foreign manufacturer who is registered with the FDA** must also register as a **Drug Distribution Agent**.

Registration Requirements Include:

- Submission of a complete **Drug Distribution Agent Application**.

- Original **license verification from resident state.** Applicable to **out-of-state** establishments.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- If an outlet will **market or facilitate the distribution** of a **controlled substance into or out of Oregon** the **Controlled Substance Application** must be completed. If not, the Controlled Substance Application needs to be marked **"Not Applicable".**

- Payment of **$400.00** to satisfy the **Drug Distribution Application Fee**.

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Drug Distribution Agent** Registrations expire **September 30th annually**.

- **Renewals notices** are mailed in **early July**.

- The **renewal fee is $400.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the **postmark deadline** of **August 31st** a $**100.00 delinquent fee** is **required**.

Other Information:

- A Drug Distribution Agent may not distribute drugs or devices. They must have a Wholesaler Registration to distribute drugs or devices.

- All applications require management approval prior to issuance.

Applicable Rules:
- **Oregon Administrative Rules 855-062-0003**

Family Planning Clinics:

A clinic supported by the **Oregon Department of Human Services** for purposes of providing **public health family planning services** may **dispense a drug or device** to clients for the purpose of **birth control, the treatment of amenorrhea, hormone deficiencies, urinary tract infections or sexually transmitted diseases** with a **Family Planning Clinic Registration**.

Registration Requirements Include:

- Submission of a complete **Family Planning Clinic Application**.

- A **Family Planning Clinic** must have a **consultant pharmacist**.

- A **Family Planning Clinic** must have a **registered nurse or practitioner** who has been given **dispensing privileges** by their licensing board **i.e. Physician Assistant**.

- Payment of **$100.00** to satisfy **Family Planning Clinic Application Fee**.

Renewal Information:

- **Family Planning Clinic Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00**.

- If a renewal application is received after the **postmark deadline** of **February 28th** a **$75.00 delinquent fee** is **required**.

Other Information:

- This registration is not applicable to out-of-state outlets.

Applicable Rules:

- **Oregon Administrative Rules 855-043-0300**

Home Dialysis Outlets:

An establishment that provides dialysis solutions under the general supervision and direction of a pharmacist with special training in renal disease and dialysis to end stage renal disease (ESRD) patients must register the establishment as a **Home Dialysis Outlet**.

Registration Requirements Include:

- Submission of a complete **Home Dialysis Outlet Application**.

- A **Home Dialysis Outlet** must have an **Oregon licensed pharmacist** on site designated as the **Pharmacist-in-Charge**.

- A **floorplan** of the **pharmacy** with the **sink(s)** and **refrigerator(s) labeled**. It must also be noted whether the **windows** and **doors are secured or unsecured**.

- The **Controlled Substance Registration** does not apply to the **Home Dialysis Outlet Registration**.

- Original **license verification from resident state** for **out-of-state** establishments only.

- Payment of **$300.00** to satisfy the **Home Dialysis Application Fee.**

Renewal Information:

- **Home Dialysis Outlet Registrations** expire **March 31ˢᵗ annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$300.00**.

- If a renewal application is received after the **postmark deadline** of **February 28ᵗʰ** a **$75.00 delinquent fee** is **required**.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0350**

Hospital Drug Rooms

Hospitals that have a drug room for the adequate storage of drugs and do not have a pharmacy may register as a **Hospital Drug Room**.

Registration Requirements Include:

- Submission of a complete **Hospital Drug Room Application**.

- If the Hospital Drug Room will **dispense Controlled Substances** a **Controlled Substance Application** must be submitted. If **not,** the **Controlled Substance Application** needs to be marked **"Not Applicable"**.

- A **Hospital Drug Room** must have an **Oregon licensed pharmacist** designated as the **Consultant Pharmacist** and part-time **Director of Pharmaceutical Services**.

- A **Hospital Drug Room** must have one **Registered Nurse Supervisor**.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Payment of **$100.00** to satisfy the **Hospital Drug Room Application Fee.**

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Hospital Drug Room Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the **postmark deadline** of **February 28th** a **$75.00 delinquent fee** is **required**.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0135**

Institutional Drug Outlets

Pharmacies that dispense medications to **Skilled Nursing Facilities (SNF) i.e. Nursing Homes** or **Intermediate Care Facilities (ICF)** are required to register as an **Institutional Drug Outlet**.

Registration Requirements Include:

- Submission of a complete **Institutional Drug Outlet Application**.

- If the pharmacy will **dispense Controlled Substances** a **Controlled Substance Application** must be submitted. If **not,** the **Controlled Substance Application** needs to be marked **"Not Applicable"**.

- An **Institutional Drug Outlet** must have an **Oregon licensed pharmacist** on site designated as the **Pharmacist-in-Charge**.

- A floorplan of the pharmacy with the sink(s) and refrigerator(s) labeled. It must also be noted whether the windows and doors are secured or unsecured.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Original **license verification from resident state.** Applicable to **out-of-state** establishments.

- Payment of **$300.00** to satisfy the **Institutional Drug Outlet Application Fee**

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Institutional Drug Outlet Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$300.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the **postmark deadline** of **February 28th** a **$100.00 delinquent fee** is **required**.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0005**

Manufacturers

The following activities require a **Manufacturer Registration**:

- Any outlet that makes a drug (prescription or over-the-counter) or prescription device that comes to Oregon.

- Contract Manufacturers. A contract manufacturer is an outlet that manufacturers a drug or device on behalf of another entity.

- An outlet that is the first point of entry from a foreign manufacturer. If a drug or device is made in a country outside of the United States and its Territories, the first location that receives the product is required to be registered if it will come into Oregon. This will initiate the pedigree of a drug. The registration requirement does not include airports or ship ports it is intended for warehouses etc.

- Repackaging. Repackaging is when an establishment repackages drugs and/or devices. Any establishment that repackages a drug or prescription device that will come into Oregon is required to be registered.

- Transfilling. Transfilling occurs when an establishment fills oxygen tanks or cylinders. Transfilling also occurs when a cylinder is being filled from a tank for distribution into or from Oregon.

Registration Requirements:

- Submission of a complete **Manufacturer Application**.

- An **FDA Registration Number** is required for a Manufacturer Registration.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Original **license verification from resident state**. Applicable to **out-of-state** establishments.

- If an outlet **manufacturers, holds title to** or their **name is on the label** of a **controlled substance** that comes into **Oregon** the **Controlled Substance Application** must be completed. If **not**, the **Controlled Substance Application** needs to be marked **"Not Applicable"**.

- Payment of **$400.00** to satisfy the **Manufacturer Application Fee**.

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Manufacturer Application Checklist:

- **Question two** needs to be answered **"yes"**. If **"no"** a **letter needs to be sent along with** Registration which indicates that they are required to verify that the recipient of a drug is legally authorized to receive it.

- At least **one "yes"** answer for questions **four-six**. Otherwise they may not have the appropriate registration and more information is required.

- If question **five** is answered **"yes" question three** should be answered **"yes"** as well.

- **Question seven** should be answered **"no"**. If they answer **"yes"** they also need to obtain a **wholesaler registration**.

Renewal Information:

- **Manufacturer Registrations** expire **September 30th annually**.

- **Renewal notices** are mailed in **early July**.

- The **renewal fee** is **$400.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If **renewal application** is received after the **postmark deadline** of **August 31st** a **$100.00 delinquent fee** is required.

Other Information:

- If a manufacturer **manufacturers a drug/device at one location** and **ships a drug/device from another location both sites need to be registered**. The location that manufacturers a drug or device needs to be registered as a manufacturer. **The location that ships directly into Oregon needs to be registered as a wholesaler**. This is true even if both outlets are the same company.

- A manufacturer may **need a wholesaler registration** in **addition to its manufacturer registration** if it is manufacturing and shipping its drugs/devices and **shipping drugs/devices for another company**.

- All applications require management approval prior to issuance.

Applicable Rules

- **Oregon Administrative Rules 855-060-0001**

Medical Device, Equipment & Gas (Class C) Outlets

Any outlet that is located in Oregon or sells any of the following to a person located in Oregon must register as a Medical Device, Equipment & Gas (Class C) Outlet:

- Nonprescription/over-the-counter medications;

- Specific drugs and materials that require the order or prescription of a practitioner:

- USP Oxygen,

- USP Sodium Chloride Irrigation,

- USP Sodium Chloride Injection,

- Sterile water for irrigation,

- Urological catheters, and

- Respiratory devices

- Nitrous Oxide may be distributed with this registration only to practitioners or institutional drug outlets.

Registration Requirements

- Submission of a complete **Medical Device, Equipment & Gas Outlet Application**.

- **Types of items to be sold** must be **listed** on the application.

- List of **corporate officers** or **members**.

- Note that a **license verification** is **not** required for **out-of-state** establishments.

- Payment of **$50.00** to satisfy the **Medical Device, Equipment & Gas Outlet Application Fee.**

Renewal Information:

- **Medical Device, Equipment & Gas Outlet Application Registrations** expire **January 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$50.00**.

- If a **renewal application** is received after the **postmark deadline** of **December 31st** a **$25.00 delinquent fee** is required.

Applicable Rules

- **Oregon Administrative Rules 855-035-0005**

Non Prescription Drug (Class A & B) Outlets

The following activities require a **Non Prescription Drug Class A or B Registration**:

- Any outlet that is located in Oregon and **sells over-the-counter medications to the public**.

- Any **pharmacy** that **sells over-the-counter medications to the public after the pharmacy closes.**

- Any establishment that **ships over-the-counter medications to a resident located in Oregon**. Note that some items that are over-the-counter medications in other states **require a prescription in Oregon**. This includes **pseudoephedrine**. If an outlet would like to ship a pseudoephedrine product to an Oregon patient a **Retail or Institutional Drug Outlet with Controlled Substance Registration** is required.

Registration Requirements:

- Submission of a complete **Non Prescription Drug Outlet Application**.

- List of **corporate officers or members**.

- Note that a **license verification** is **not** required for **out-of-state** establishments.

- Payment of **$50.00** to satisfy the **Non Prescription Drug Outlet Application Fee**.

Renewal Information:

- **Non Prescription (Class A & B) Drug Outlet Registrations expire January 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$50.00**.

- If a **renewal application** is received after the **postmark deadline** of **December 31st** a **$25.00 delinquent fee is required.**

Applicable Rules

- **Oregon Administrative Rules 855-035-0005**

Non Prescription Drug (Class D) Outlets

Companies that have more than one vending machine that contains over-the-counter medications require a **Non Prescription Drug Class D Registration**:

Registration Requirements:

- Submission of a complete **Non Prescription Drug Outlet Class D Application**.

- List of **corporate officers or members**.

- Payment of **$100.00** to satisfy the **Non Prescription Drug Outlet Class D Application Fee**.

- A list of all **vending machines** in **Oregon** that contain over-the-counter medications.

Renewal Information:

- **Non Prescription Drug Class D Registrations** expire **January 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$100.00**.

- If a **renewal application** is received after the **postmark deadline** of **December 31st** a **$25.00 delinquent fee is required.**

Applicable Rules

- **Oregon Administrative Rules 855-035-0005**

Prophylactic/Contraceptive

Every wholesaler or manufacturer of prophylactics or contraceptives which distributes in Oregon the items specified in **Oregon Revised Statute 435.010** must obtain a Prophylactic and Contraceptive Registration.

Registration Requirements

- Submission of a complete **Prophylactic/Contraceptive Application**.

- List of **corporate officers or members**.

- Payment of **$100.00** to satisfy the **Prophylactic/Contraceptive Application Fee**.

Renewal Information:

- **Prophylactic/Contraceptive Registrations** expire **December 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$100.00** and there is **no delinquent fee**.

Applicable Rules

- **Oregon Administrative Rules 855-070-0001**

Remote Dispensing Facility

A facility where drugs are prepared for administration and where pharmacist supervision is provided remotely as approved by the Board shall register as a Remote Dispensing Facility.

Registration Requirements

- Submission of a complete **Remote Dispensing Facility Application**.

- Completed **Application Checklist of Minimum Requirements for Licensure.**

- **Proposed Policies and Procedures** for Board consideration.

- **Description** of the **Organization.**

- **Distribution and Dispensing Procedures** for Board consideration.

- If outlet will be handling controlled substances a Controlled Substance Registration is required. If not, the Controlled Substance Application needs to be marked "Not Applicable".

- List of **corporate officers or members**.

- List of all **pharmacists** that will work at or monitor the facility. *Note all pharmacists need to be entered in the "Employees" tab of the RDF's record in L2K.*

- List of all **technicians** and other staff that will work at the facility. *Note all technicians need to be entered in the "Employees" tab of the RDF's record in L2K.*

- Payment of **$100.00** to satisfy the **Remote Dispensing Facility Application Fee**.

- If applicable, payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Remote Dispensing Facility Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**. There is no delinquent fee.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0600**

Remote Dispensing Machine

A component of an Automated Pharmacy System that contains prepackaged drugs for dispensing shall register as a Remote Dispensing Machine.

Registration Requirements

- Submission of a complete **Remote Dispensing Machine Application**.

- **Proposed Policies and Procedures** for Board consideration as specified in
  OAR 855-041-0610 through **855-041-0620.**

- **Remote Dispensing Machine** must have a **Pharmacist-in-Charge** as well as a **responsible pharmacy**.

- Payment of **$100.00** to satisfy the **Remote Dispensing Facility Application Fee**.

Renewal Information:

- **Remote Dispensing Machine Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$100.00** and there is no delinquent fee.

Applicable Rules:

- **Oregon Administrative Rules 855-041-0600, 855-041-0620**

.

Retail Drug Outlet

Pharmacies that dispense/deliver/mail medications directly to a patient are required to register as a **Retail Drug Outlet**

Registration Requirements Include:

- Submission of a complete **Retail Drug Outlet Application**.

- If outlet will be handling **controlled substances** a **Controlled Substance Registration** is required. If not, the Controlled Substance Application needs to be marked "Not Applicable".

- A **Retail Drug Outlet** must have an **Oregon licensed pharmacist** on site designated as the **Pharmacist-in-Charge**.

- A **floorplan** of the **pharmacy** with the **sink(s)** and **refrigerator(s)** labeled. It must also be noted whether the **windows** and **doors** are **secured** or **unsecured**.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Original **license verification from resident state.** Applicable to **out-of-state** establishments.

- Payment of **$300.00** to satisfy the **Retail Drug Outlet Application Fee.**

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Retail Drug Outlet Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$300.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the **postmark deadline** of **February 28th** a **$100.00 delinquent fee** is **required**.

Applicable Rules:

- **Oregon Administrative Rules 855-041-1010**

Schedule II Precursor

Any outlet that receives or distributes a Schedule II Precursor must obtain a **Schedule II Precursor Registration**.

Registration Requirements Include:

- Submission of a complete **Schedule II Precursor Application**.

- Payment of **$100.00** to satisfy the **Schedule II Precursor Application Fee**.

Renewal Information:

- **Schedule II Precursor Registrations** expire **December 31st annually**.

- **Renewal notices** are mailed in **early November**.

- The **renewal fee** is **$100.00** and there is **no delinquent fee**.

Other Information:

- Establishment needs to obtain a **DEA Registration**.

Applicable Statutes:

- **Oregon Revised Statute 475.940**

- **DEA Section 1308 Schedule II** for most current list of Schedule II Controlled Substances.

Supervising Physician Dispensing Outlets

Any clinic, office, health care center, treatment center or other establishment from which a physician assistant with dispensing authority dispenses drugs needs to register the dispensing site as a Supervising Physician Dispensing Outlet.

Registration Requirements Include:

- Submission of a complete **Supervising Physician Dispensing Outlet Application**.

- **Description of organization** and **dispensing process.**

- If the establishment will **dispense controlled substances** a **Controlled Substance Application** must be submitted. Note that the Controlled Substances they are allowed to dispense are <u>limited to Schedule Five</u> drugs at this time. If the establishment will **not** dispense controlled substances the **Controlled Substance Application** needs to be marked **"Not Applicable"**.

- A **Supervising Physician Dispensing Outlet** must have an **Oregon licensed pharmacist** designated as the **Consultant Pharmacist**.

- A **Supervising Physician Dispensing Outlet** must have a **Supervising Physician**.

- A **floorplan** of the **dispensing site** with the **sink(s)** and **refrigerator(s)** labeled. It must also be noted whether the **windows** and **doors** are **secured** or **unsecured**.

- List of **corporate officers or members**. Note that an officers or members social security number is **not** required. Alternatively the **establishment's Federal Tax ID number** may be listed

- Payment of **$300.00** to satisfy the **Supervising Physician Dispensing Outlet Application Fee.**

- If applicable payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- **Supervising Physician Dispensing Outlet Registrations** expire **March 31st annually**.

- **Renewal notices** are mailed in **early January**.

- The **renewal fee** is **$300.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a renewal application is received after the **postmark deadline** of **February 28th** a **$25.00 delinquent fee** is **required**.

Applicable Rules:

- **Oregon Administrative Rule 855-043-0405**

Wholesaler Class I Outlets

The following activities require a **Wholesaler Class I Registration**:

- Any distributor that ships a prescription drug directly into or out of Oregon. This includes to places such as institutions, retail outlets or practitioners.

- Any establishment that is the **second recipient** of a **drug** that is **legally imported** in the **United States** (normally a warehouse) that in turn **distributes** the drug directly into **Oregon**.

Registration Requirements:

- Submission of a complete **Wholesaler Class I Application**.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Original license verification from resident state. Applicable to out-of-state establishments.

- If outlet will distribute controlled substances into Oregon a Controlled Substance Application must be completed. If not, the Controlled Substance Application needs to be marked "Not Applicable".

- Designated Representative. See Oregon Administrative Rule **855-065-0009** for DR requirements. Note than a person can serve as a DR for one registration. If they would like to be the DR for more than one registration an exception request needs to be submitted for consideration. These requests are reviewed by the Compliance Director.

- **Verified Accredited Wholesale Distributer (VAWD)** through the **National Association of Boards of Pharmacy (NABP)**. A copy of the VAWD **certificate** or written notification that **VAWD** has been **applied for is** required. The certificate may be **verified** on NABP's website at: http://www.nabp.net/programs/accreditation/vawd/vawd-accredited-facilities/Application status can be verified via email at vawd@nabp.net.

    - NABP will provide VAWD Accreditation to wholesalers that only distribute prescription drugs or API (Active Pharmaceutical Ingredients). They will also accredit wholesalers that distribute pseudoephedrine products because it is a prescription drug in Oregon.

                              -OR-

- **$100,000 surety bond** or **irrevocable letter of credit** naming the Oregon Board of Pharmacy as the **sole beneficiary**. (Original or copy)

                              -AND-

- An **approved inspection report** or **FDA Final Agency Determination Report**. Inspection must have been completed within the **last three years**.

- Payment of **$400.00** to satisfy **Wholesaler Class I Application Fee**.

- If applicable, payment of **$100.00** to satisfy the **Controlled Substance Application Fee**.

Renewal Information:

- Registration expires **September 30th annually**.

- **Renewal notices** are mailed in early **July**.

- The **renewal fee** is **$400.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a **renewal application** is received after the **postmark deadline** of **August 31st** a **$100.00 delinquent fee** is required.

Other Information:

- A wholesaler may also need a manufacturer registration if their name appears on the label of a drug/device.

- All applications require management approval prior to issuance.

Applicable Rules

- **Oregon Administrative Rules 855-065-0001**

Wholesaler Class II Outlets

The following activities require a **Wholesaler Class II Registration**:

- Any distributor that ships an over-the-counter medication, prescription device, prescription drug for veterinary use only, medical gas or oxygen USP directly into or out of Oregon. This includes to places such as institutions, retail outlets or practitioners.

Registration Requirements:

- Submission of a complete **Wholesaler Class II Application**.

- List of **corporate officers or members**. Note that an officer's or member's Social Security Number is **not** required. The **establishment's Federal Tax ID number** may be listed.

- Original license verification from resident state. Applicable to out-of-state establishments.

- If outlet will distribute controlled substances a **Controlled Substance Application** must be completed. The Controlled Substance Application for this registration type is only applicable to **government agencies**, **non-profit relief organizations** approved by the Board and **distributors of drugs for veterinary use** only. It is not available online and must be requested in writing at this time. Please provide your supervisor with an overview of applicant's distribution activities before providing a Controlled Substance Application to a Wholesaler Class II applicant or registrant.

Renewal Information:

- Registration expires **September 30th annually**.

- **Renewal notices** are mailed in early **July**.

- The **renewal fee is $400.00.** An additional **$100.00** is required if outlet also has a **Controlled Substance Registration**.

- If a **renewal application** is received after the **postmark deadline** of **August 31st** a **$100.00 delinquent fee** is required.

Other Information:

- A wholesaler may also need a manufacturer registration if their name appears on the label of a drug, device or gas.

- A local government agency or non-profit relief organization approved by the Board may register as a Wholesaler Class II Outlet and may distribute both prescription and non prescription drugs.

- A distributor of drugs for veterinary use may register as a Wholesaler Class II Outlet and may distribute both prescription and non-prescription drugs.

Applicable Rules

- **Oregon Administrative Rules 855-065-0001**

Application Processing for Establishments:

- Review Application and Verify Information has been correctly entered in the database and all required information has been captured.

- Next, Open Cool Dude in L2K.
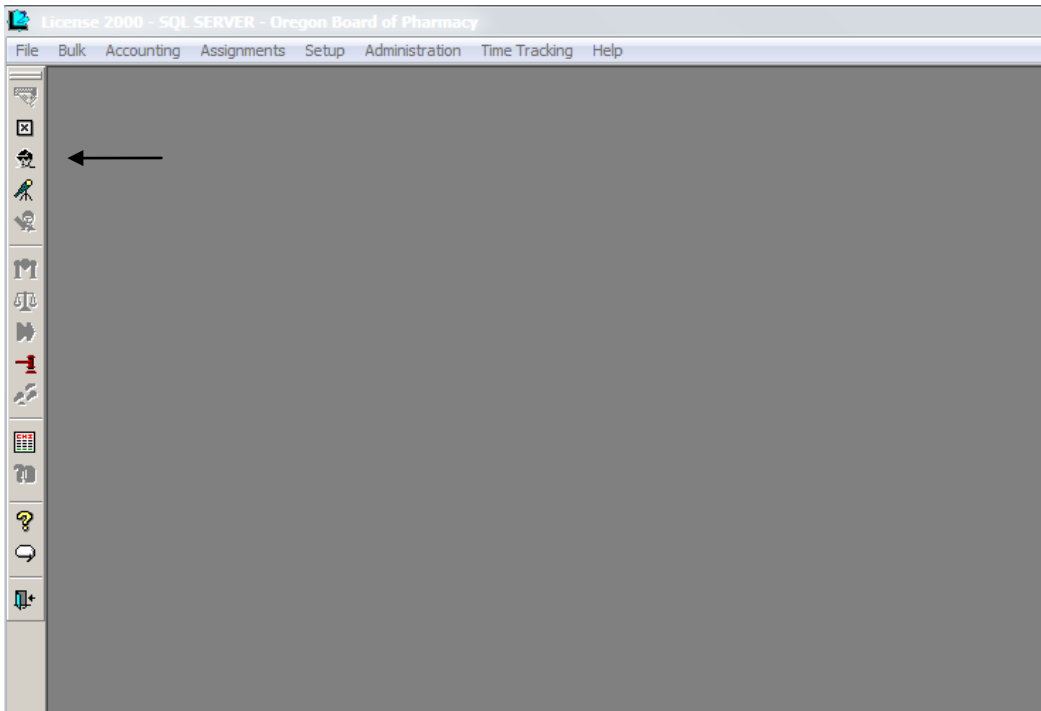
- For an Establishment Search by Name or Location.

- Select Appropriate Applicant.

- Verify information in General and License tab match information listed on Application. For Establishments that have a Location or Owner Change changes cannot be made to the database until Application is complete. Applications for Drug Distribution Agents, Manufacturers and Wholesalers require Supervisor approval before the application may be processed.

- Add additional required information into the General, License, and Supplemental tabs.

  o For Wholesaler Class I Outlets, check "VAWD Certification" if establishment is VAWD Accredited or VAWD is pending.

  o For Manufacturers, enter FDA Registration Number.

o List Corporate Officers or LLC Members in the "Corporation" tab.

o Perform a Search to verify if Officer or Member is already in the Database. Make sure the box "Show licensees only" is not checked. Next enter First and Last Name then select "Search."

o If Officer or Member is not in the Database select New and input the Contact Information for the Individual.


o Perform the same functions to input the Following Information for the appropriate License Category.

- Animal Euthanasia – Shelter Manager

- Charitable Pharmacy – Point of Contact and Officers/Members

- Consulting Pharmacy – Officers/Members

- Correctional Facility – Registered Nurse or Nurse Practitioner

- County Health Clinic – Registered Nurse and Health Officer/Physician

- Drug Distribution Agent – Officers/Members

- Family Planning Clinic – Registered Nurse or Nurse Practitioner

- Home Dialysis Outlet – Officers/Members

- Hospital Drug Room – Registered Nurse and Officers/Members

- Institutional Drug Outlet – Officers/Members

- Manufacturer – Officers/Members

- Medical, Device, Equipment & Gas Outlet – Officers/Members

- Non Prescription Drug Outlets – Officers/Members/Owner

- Prophylactic Contraceptive – Officers/Members

- Remote Dispensing Facility – Officers/Members

- Remote Dispensing Machine – Officers/Members

- Retail Drug Outlet – Officers/Members

- Schedule II Precursor – Officers/Members

- Supervising Physician Dispensing Outlets – Supervising Physician and Officers/Members

- Wholesaler Class I Outlet – Designated Representative and Officers/Members

- Wholesaler Class II Outlet – Contact Representative and Officers/Members

Additional information that needs to be in the Database includes the Consultant Pharmacist and Pharmacist-in-Charge.

- o From the "Licenses" tab select the "Prerequisite" icon.
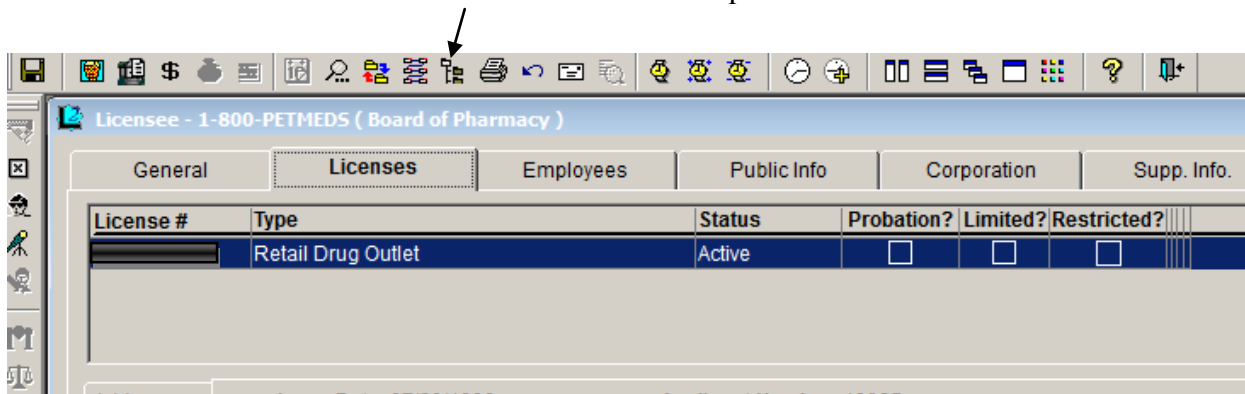
- o Select "New"
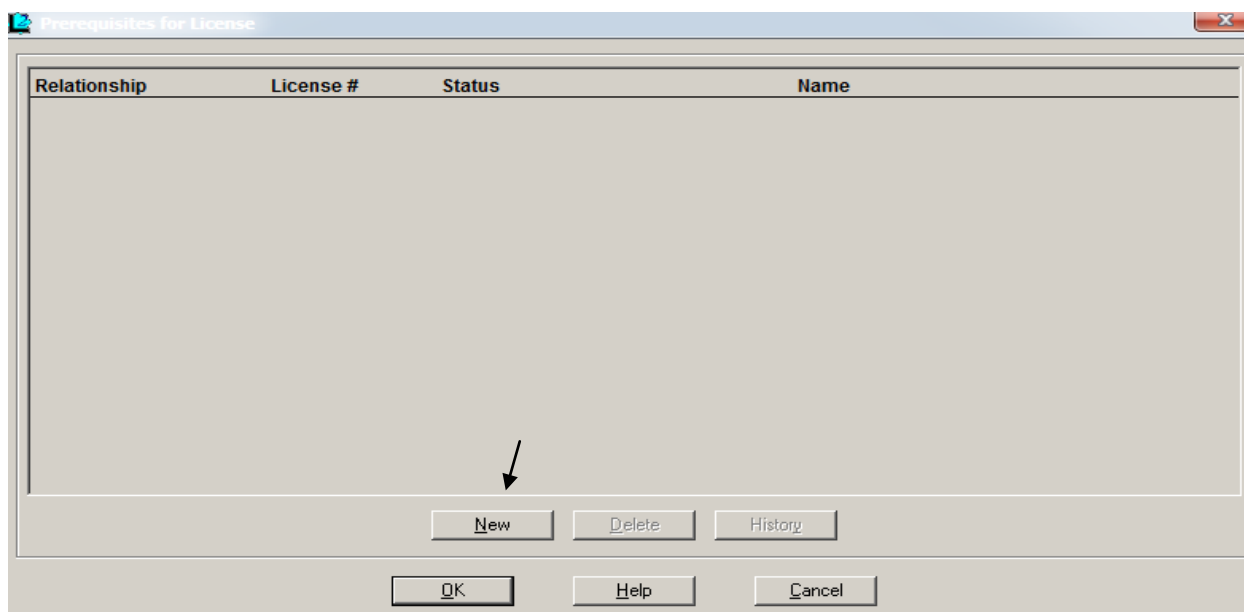
o Select "Pharmacist in Charge" or "Consultant Pharmacist" from the Drop Down Menu.

o Enter Information then Select "Search".

o Select the Appropriate Person then Select "OK".

o Enter the "Association Date" and check the "Selected Prereq" box.

o The following License Categories require a Pharmacist-in-Charge.

- Consulting Pharmacy

- Home Dialysis Outlet

- Institutional Drug Outlet

- Remote Dispensing Machine

- Retail Drug Outlet

o The following License Categories require a Consultant Pharmacist.

- Charitable Pharmacy

- Correctional Facility

- Family Planning Clinic

- Hospital Drug Room

Renewal Notices

Most renewal notices are manually created templates. You may access the templates by doing the following:

- Make sure you are already in Microsoft Word before opening the following Directories otherwise the template will not save.

- Open the "G" Drive

- Open "OR BOP Templates"

- Open "inis" Folder

- Open "RENEWAL NOTICES" Folder

The following registration types use templates for renewal:

- Animal Euthanasia

- Charitable Pharmacies

- County Health/Family Planning (share the same template)

- Drug Distribution Agent

- Hospital Drug Room and Correctional Facilities (share the same template)

- Home Dialysis

- Manufacturer

- Non Prescription Drug Outlet Class A

- Non Prescription Drug Outlet Class B

- Medical Device & Equipment Class C

- Non Prescription Drug Outlet Class D

- Precursor

- Prophylactic Contraceptive

- Remote Dispensing Facility

- Remote Dispensing Machine

- Retail/Institutional Drug Outlet (share the same template)

- Wholesaler Class I and Wholesaler Class II

Before each renewal cycle update the appropriate file for each license category by doing the following:

- Update the Date.

- Update the Expiration Date in the First Paragraph.

- Verify that Fees are Correct.

- Verify that the Referenced Rules are still Valid and have not Changed.

- Verify the Fee Reference Codes on the Bottom are Accurate as well as the Amounts.

- Update the Expiration Date on the Bottom of the Renewal Form.

- Update the Color of the Supplemental Information Form if Applicable. Go through a file for each license category and view the most recent colors selected. You do not want to use a color that has been recently selected for the license category.

Save each file under its current name. By selecting "File" then "Save". If you change the name of the Document the Template will not pull from the Database.

Once you have updated the renewal form you will want to generate the renewal records for each applicable license category. This is done by going in to L2K and doing the following:

- Select the "Bulk" File

- Select "Renewal"

- Select "Generate"

- Select the Appropriate License Category

- For Status select "Active"

- Select "Search"

- Multiple records should appear.

- Select Generate

- Generating the renewal record can take a few minutes or hours depending on how many licenses are in each category
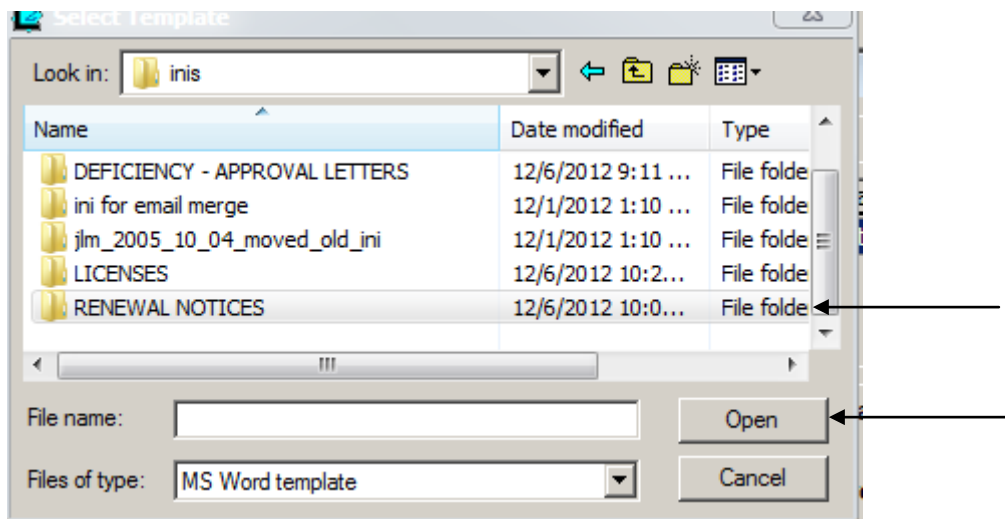
Before you print any renewal notice you will want to test each template to make sure that it works and that it is pulling the right information. You can do this by opening a facility record in L2K and selecting the "Licenses" tab.
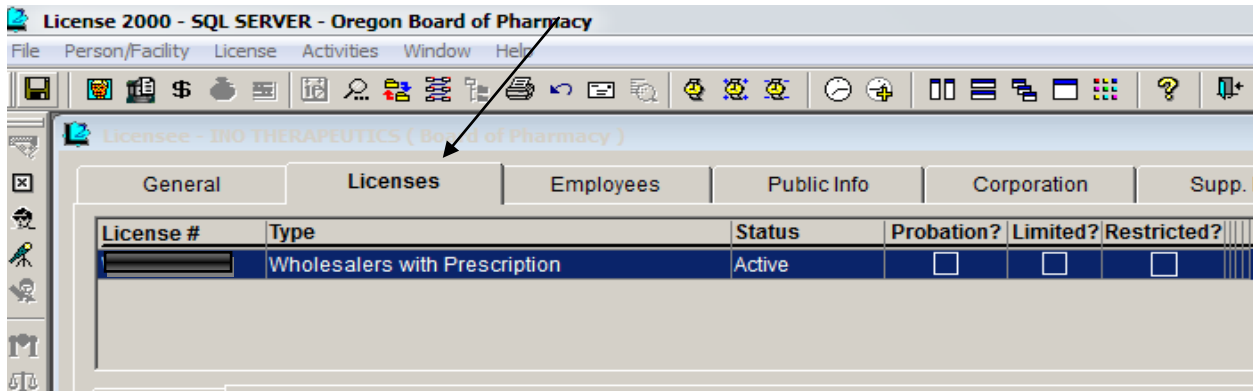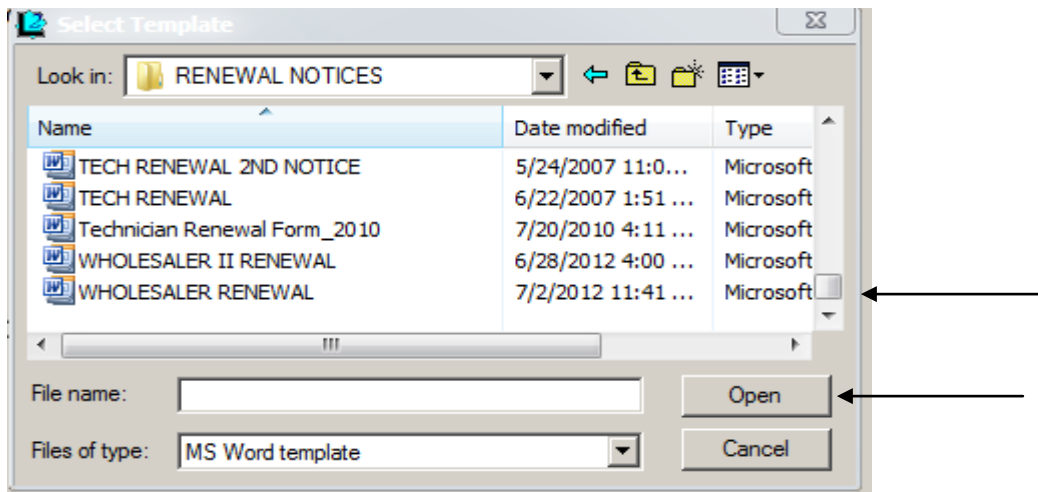
Next select the Mail Merge Icon
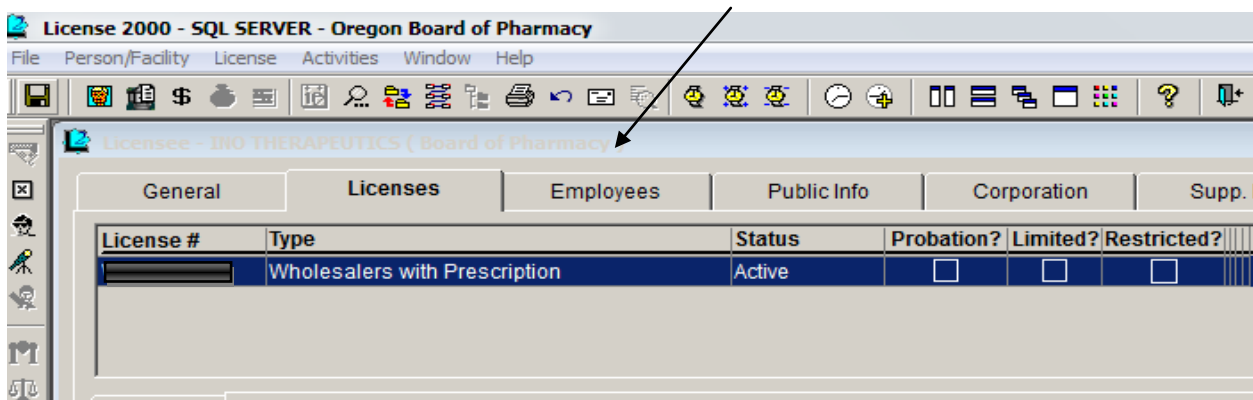
Select the Correct Directory "RENEWAL NOTICES" in the "inis" Folder and select "Open."

Next Select the correct Renewal Notice. For a Wholesaler License it is the "WHOLESALER RENEWAL" template.

Once the template opens verify that the information is correct and do a test print. Note that these renewal notices are printed on perforated paper. The notice on the bottom should detach.

Once the renewal form has printed make sure everything prints on one page, that the notice will detach on the bottom and that the address lines up in a window envelope. If the registration has CS make sure the renewal notice reflects that and that the fee is correct. If everything is okay then you can go to the Print Batch in L2K and begin printing.

Note that for licenses with "CS" two sets of renewal notices will print. One with "CS" and one without. These forms should be exactly the same. To avoid confusion delete one of the files. For large cycles print a selected amount at a time i.e. 150 or 200.

When printing look for chains with the same mailing address. It is easiest to select these first and print them together. Each chain should go in one or two large 8 x 11 envelopes.

For individual renewal notices it is easiest to put them through the folding machine in the kitchen. Do a test run before putting a large stack of renewals in to the machine to make sure the folds line up appropriately.

Most outlet renewal forms are accompanied with a Supplemental Information Form. These forms are currently in Courtney's Directory.

Check with supervisor before each renewal cycle to see if there is a Memo that will be included with the renewal notice.

Sometimes a Memo is included with the renewed registrations and the renewed registrations are held until the Memo is finalized. Check with supervisor to see if that is applicable to your current renewal cycle.

Note: If the postmark deadline falls on a Sunday the date is extended until the next business day. This should be reflected in the template.

A supervisor must review all renewal material before it is mailed.

Renewal Schedule for Establishments

Registrations Expiring **December 31st**

- Animal Euthanasia

- Prophylactic and Contraceptive

- Precursor

Registrations Expiring **January 31st**

- Non Prescription Drug Outlet Class A

- Non Prescription Drug Outlet Class B

- Medical Device and Equipment Class C

- Non Prescription Drug Outlet Class D

Registrations Expiring **March 31st**

- Charitable Pharmacies

- Correctional Facilities

- County Health

- Family Planning

- Home Dialysis

- Hospital Drug Room

- Institutional Drug Outlet

- Remote Dispensing Facility

- Remote Dispensing Machine

- Retail Drug Outlet

- Supervising Physician Dispensing Outlet

Registrations Expiring **December 31st**

- Drug Distribution Agents

- Manufactures

- Wholesalers Class I and Class II

LICENSING
Other Activities

Processing List Orders:

A List Order Form can be found on the Oregon Board of Pharmacy's website under the "Licensing Info, Forms, Fees & Procedures" tab.

The cost of a list is $80.00 per license category and is paid to the Oregon Board of Pharmacy by check or money order. The list is completed in an Excel format and can be e-mailed back to the requestor. The list can be sorted by City, Last or Business Name, License Number or Zip Code. If the requestor does not select a format for sorting, the list will be sorted by last or business name by default.

How to Create a List:

In L2K, click on the reports icon on the left hand column:
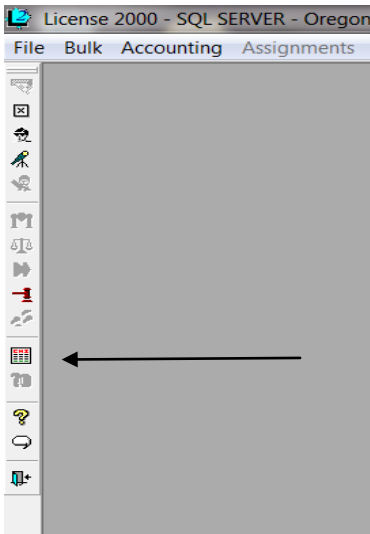
The highlight the LI-License Report from the list available and double click:
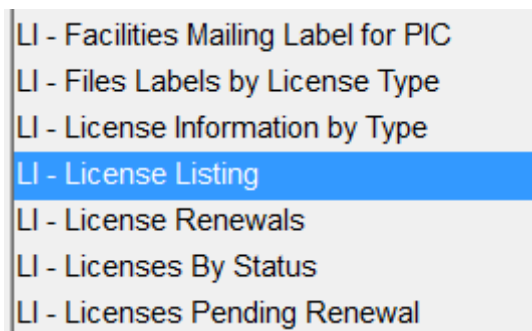

A Report Criteria dialogue box appears. For the License Type of Pharmacists, make sure the following information has been selected in the criteria box:

License Type:	Pharmacist
Obtained By:	Leave Blank
Licensee:	Select Person
License Primary Status:	Select Active

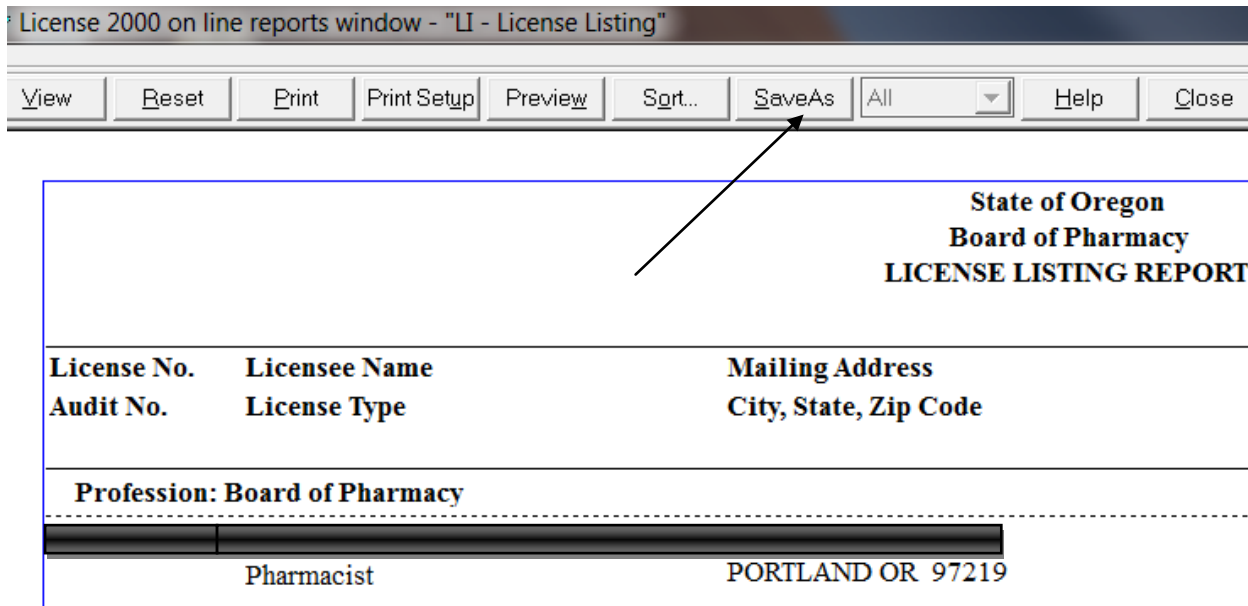| License Status: | If License Primary Status has been selected Active, |
	Leave this section Blank
Status Change Reason:	Leave Academic high-lited
License Number:	Defaults to All
Zip Code:	Defaults to All
Date:	Defaults to All
Print Options:	Leave Blank

Click on "View"
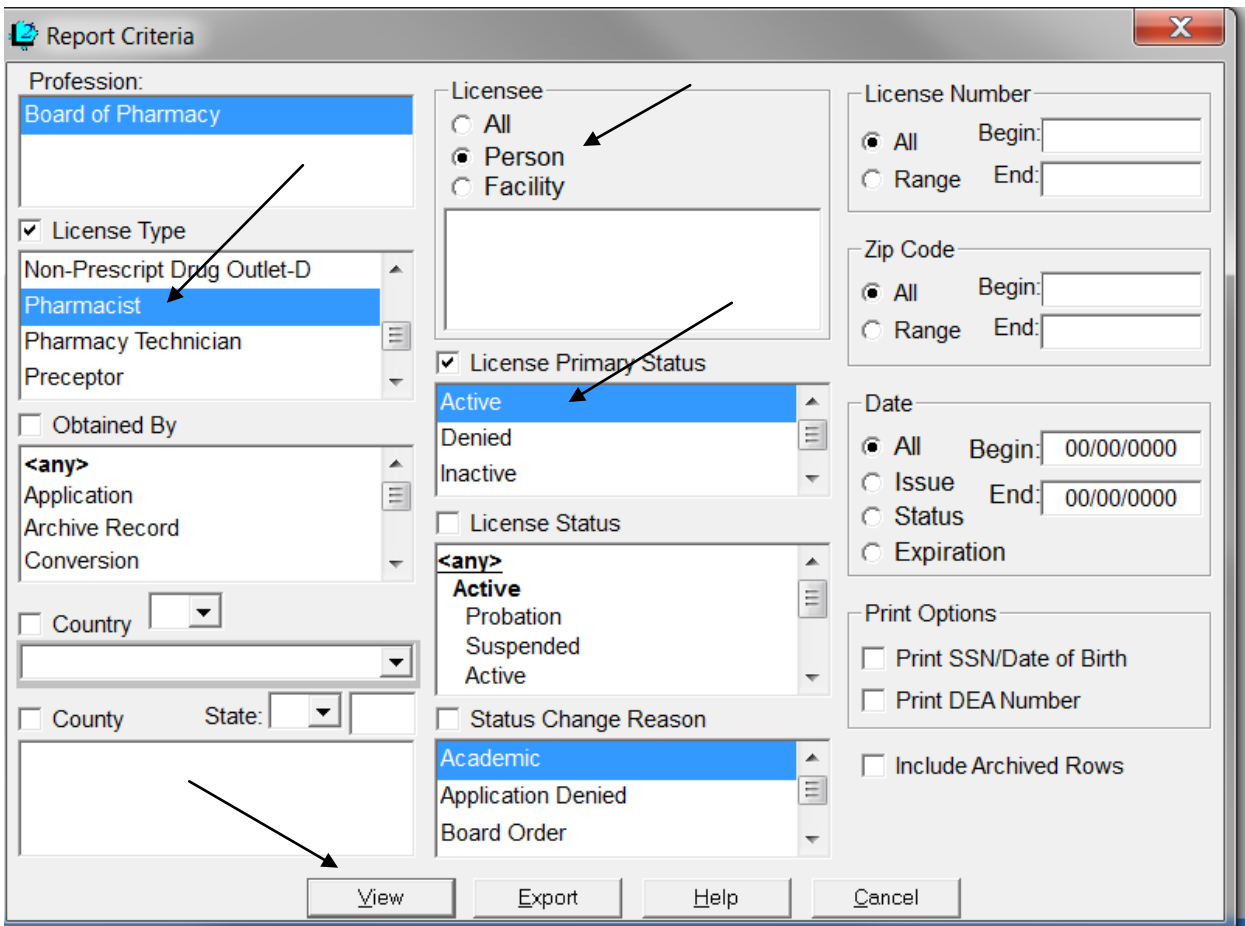
After Clicking on "View" a License Listing Report will have a listing of those licensees that have met your selected criteria.

There will be a long delay before the report appears because L2K is searching through the entire Oregon Board of Pharmacy database for the records you are pulling up into the report.

After the report appears, click on "Save As."

| View | Reset | Print | Print Setup | Preview | Sort... | SaveAs | All ▼ | Help | Close |

State of Oregon
Board of Pharmacy
LICENSE LISTING REPORT

| License No. | Licensee Name | Mailing Address |
| Audit No. | License Type | City, State, Zip Code |

Profession: Board of Pharmacy

Pharmacist   PORTLAND OR 97219

A "Warning" Box will appear indicating that due to the complex structure of this report, some information may not be saved. Do you wish to continue? Select "Yes."
If more information is being asked of by the requestor, the Office Manager may be able to provide the information via the Crystal Reports system, otherwise, the above information can be downloaded from the database into an Excel format as follows:

A "Save As" Box appears. Select where you want it saved, type in the File Name. The Save As Type should be selected as Excel with Headers. After it saves to the new location, close out of the License Listing Report by clicking on "Close." You can now click out of the L2L Selected Reports section.

Go into the new Excel File you saved the file to. You need to clean up the file so the correct information is provided in the correct order. The below instructions will be used for "people" records. Expand all of the columns so you can see all of the information in each column.

Delete Column "B" which is Sort_Name by moving your cursor above "Column B" and Right Click. Delete the new Column "B" and Column "C" and "D". Column B should now be the Issue Date and Column C should be the Expiration Date.

Delete Columns D thorugh K. The new Column D should be First Name, column E should be Middle Name and Column F should be Last Name.

Delete Columns G through W. The New Columns should be:

G = Person Address Addr Line 1
H = Person Address Addr Line 2

Delete Column I and J. The New Columns should be:

I = Person Address Addr City
J = Person Address Addr State

K = Person Address Addr Zipcode

Delete Columns L through N.

Move Columns B and C to the Columns L and M by Click on Column B and with the left mouse button pushed, draft your cursor over to column C. Both columns should be highlighted. Right click the mouse and select "Cut." Columns B and C should be outlined. Move your curser to column L and left click the mouse. Drag your cursor over to column M. Both columns L and M should be highlighted. Click "Paste." Go back to Columns B and C and delete the two blank columns.

Move the cursor to row 1 and left click on the number 1. Row 1 should be selected. Select Bold and Underline from the menu bar. Row 1 should now be bolded and underlined.

Change the column headings to Upper Case and with following titles:

Column A = License #
Column B = First Name
Column C = Middle Name
Column D = Last Name
Column E = Address Line 1
Column F = Address Line 2
Column G = City
Column H = State
Column I = Zip Code
Column J = Issue Date
Column K = Expiration Date

At the menu bar, you can now chose on Data, and sort the information by the different columns, accordingly.

For "People" Records, some individuals have provided the Oregon Board of Pharmacy requests to have their information kept Confidential. These records will have "Confidential" in Address Line 1. To find these records, in the menu bar, find "Find & Select."

Click on "Find" and type in "Confidential."
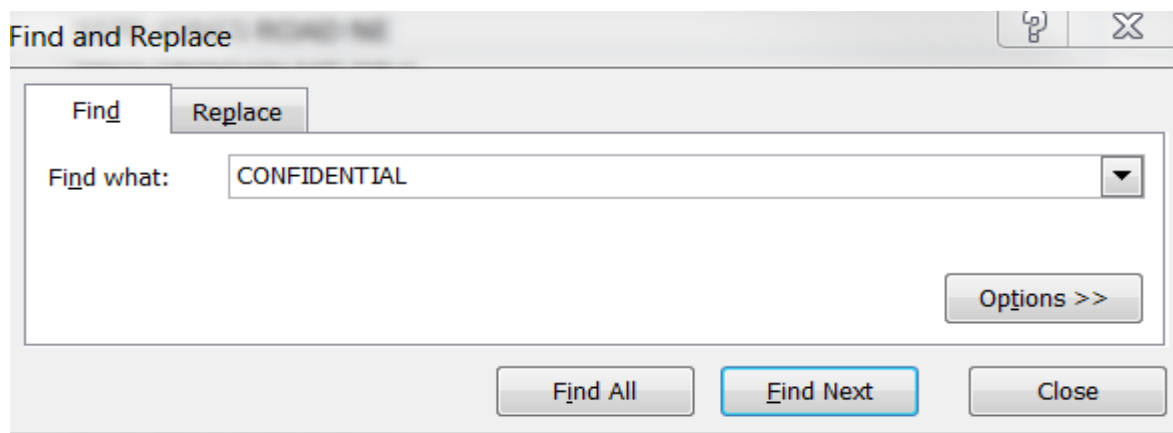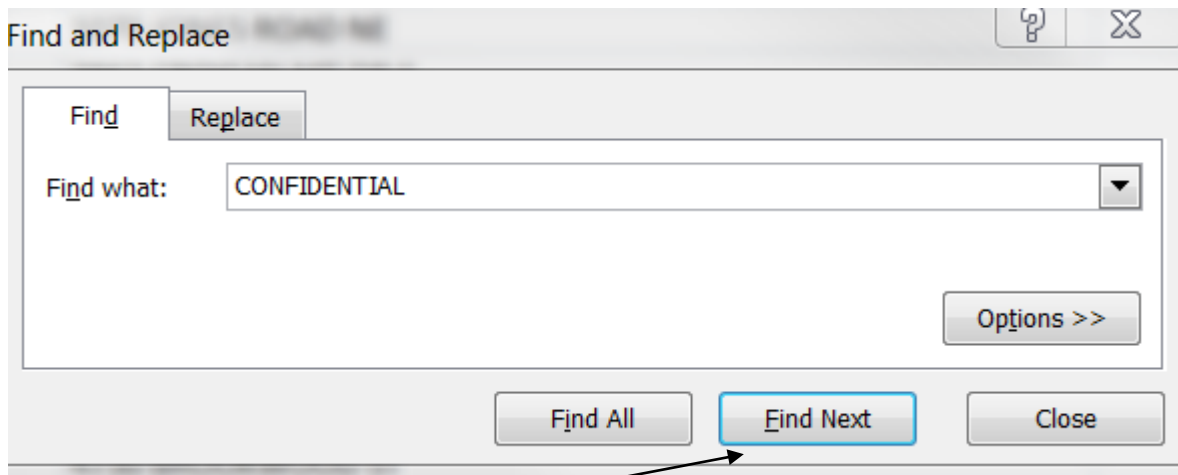
Click on "Find Next." The first record showing they have a Confidential Mailing Address will appear. Highlight the entire row and delete the record. Click on "Find Next" again to find the next Confidential record in your Spreadsheet. Continue until all confidential rows have been deleted.

Scroll to the top of your report. Click on "Data"
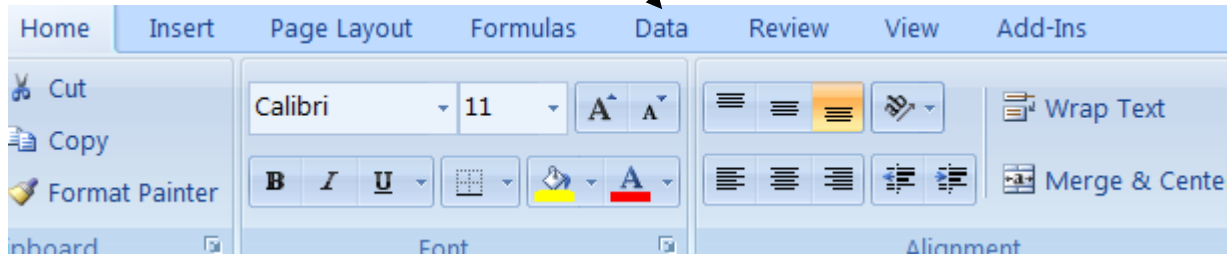
Click on "Sort."
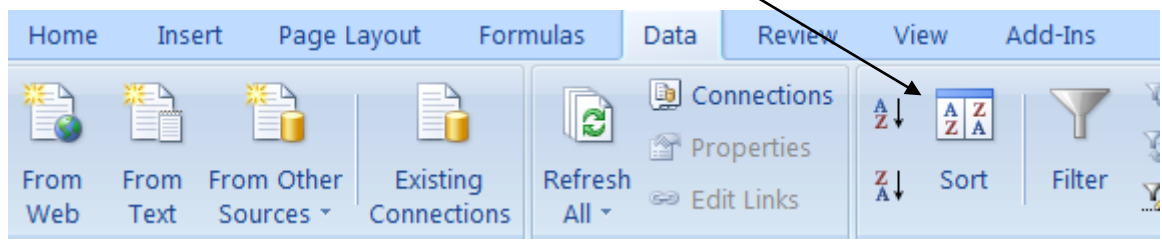
A Sort dialogue box appears. Choose the Sort by: Zip Code in order to find those records that have an international mailing address. Click "Ok."

Find those records that have the zip code listed as all zero's or the zip code is blank, and delete the incorrect information, or type in the correct information. We have pharmacists that reside in Canada, Korea, Germany, Egypt, Indonesia, The Netherlands and Australia. In the "State" column, type in the country the individual resides in.

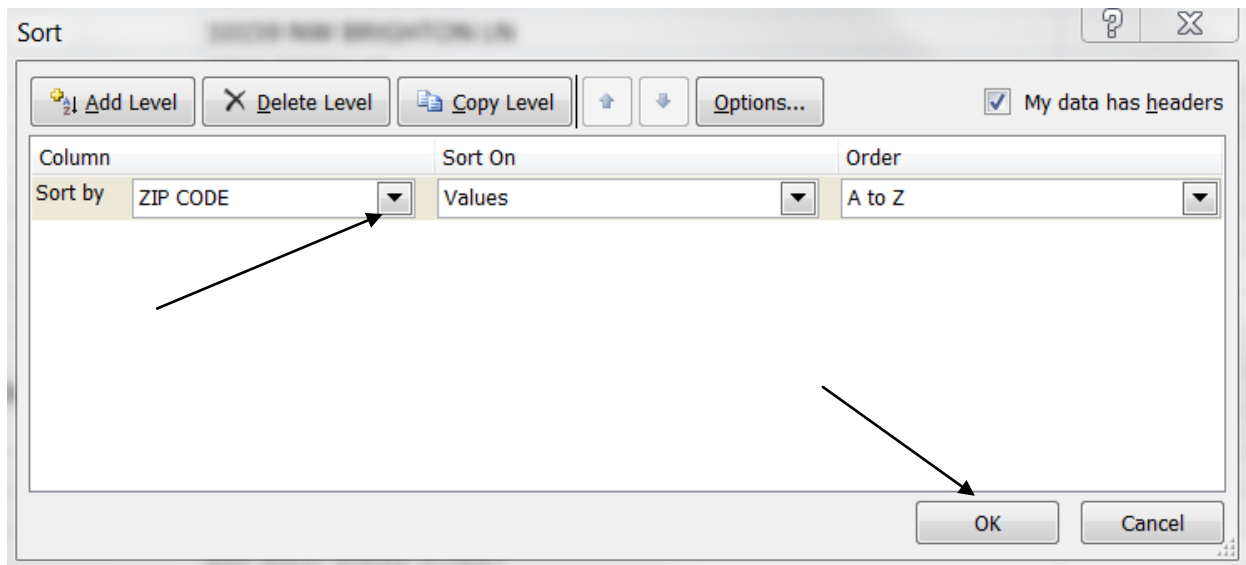Go back to the "Sort" menu and sort on the correct category the requestor has chosen.

Once you have finalized your report, click "Save" or "Save As." You are now ready to e-mail the file to the requestor.

After e-mailing your spreadsheet, print a copy of your outgoing e-mail and attach it to the List Order Form. Three hole punch your form and e-mail, file it in the binder called "Orders for Lists and Labels."

Most reports may be downloaded from the database into an Excel format. However, the Office Manager may need to utilize the Crystal Report database for more complex reports.

LICENSING
Appendices

Sample Memos:

The following documents are Memos that have been mailed to licensees during a renewal cycle. These Memos have been with the renewal form or with the renewed license. It is always important to ask in advance if there is any communication that needs to be given to a specific renewal group. This will give the Licensing Representative plenty of time to draft, edit and review the Memo with his/her Supervisor.

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

To: All Registered Oregon Wholesalers

From: Oregon Board of Pharmacy

Date: July 9, 2007

Re: Reminder of New Wholesaler Rules

On December 6, 2006 the Oregon Board of Pharmacy adopted changes to its Wholesaler Rules. The new rules are based on the NABP model rules and change registration requirements. The Oregon Wholesaler Rules require greater accountability and record keeping in the supply chain, and create a list of prohibited practices. These rules (OAR 855-065-0001 to 855-065-0013) apply to any person, including any business entity, located in or outside Oregon that engages in the wholesale distribution of prescription or non-prescription drugs in Oregon.

Although the rule changes went into effect January 2, 2007 some wholesaler specific rules defined as OAR 855-065-0022 to 855-065-0024 do not take effect until 2008.

Major changes effective <u>January 2, 2007</u> include the following:

- Prohibited Practices; OAR 855-065-0013. Both Class I and Class II Wholesalers should note in particular:

  o Before furnishing a drug to any person not known to the wholesaler distributor who is required to be registered with the Oregon Board of Pharmacy the wholesaler distributor must verify that the person is registered with the Board and legally authorized to receive the drug.

  o Before purchasing a drug from any person not known to the wholesaler distributor who is required to be registered with the Oregon Board of Pharmacy the wholesaler distributor must verify that the person is registered with the Board and legally authorized to sell the drug.

- All Class I Wholesalers, including; a Cooperative Pharmacy Warehouse; a Manufacturer's Exclusive Distributor; a Specialty Wholesale Distributor and a Third Party Logistics Provider, who wish to be considered as part of the Normal Chain of Distribution, must obtain a letter from the drug manufacturer listing them as an "Authorized Distributor of Record" for that manufacturer's drugs.

- A Wholesale Distributor's Policies and Procedures must meet new standards- Please see OAR 855-065-0010(5).

- Record keeping must meet new standards – Please see OAR-855-065-0010.

Appendix A

- Each Class I Wholesaler must appoint a Designated Representative – Please see OAR-865-065-0009.

- The Designated Representative for each Class I Wholesaler is required to complete the Oregon Wholesaler Self-Inspection Form by September 1 each year and to keep it on file and available for inspection. This form is available on our website.

Major changes effective on or after January 1, 2008 include the following:

- Any wholesale distributor located **outside** the boundaries of Oregon applying for registration or renewal, as a Class I Wholesaler, after **January 1, 2008** must provide evidence of one of the following:

  o A current license or registration as a wholesale distributor in a state that has a license or registration procedure approved by the Board that includes a physical inspection within the past three years; or

  o A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service.

- Any wholesale distributor located **inside** the boundaries of Oregon applying for registration or renewal, as a Class I Wholesaler, after **January 1, 2008** must provide evidence of one of the following:

  A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service; or

  o That it is a small business as defined in ORS 183.310(10); and the applicant has no affiliation with any out-of state pharmaceutical company and all owners and principals of the applicants are Oregon residents; and no owner or principal, or close family member of an owner or principal, has a controlling or business interest in any other pharmaceutical company; and neither the applicant, nor any of its owners or principals has ever been found to be in violation of any drug law or regulation in this or any other state.

- An applicant for registration as a Class I Wholesaler under this rule must provide evidence that it has obtained a bond or equivalent means of security of at least $100,000 that provides direct access to the Oregon Board of Pharmacy as a beneficiary to secure payment of any administrative penalties that may be imposed by the Board and any fees and costs that may be incurred by the Board and that are related to a registration held by the wholesale distributor and are authorized under Oregon law and the wholesale distributor fails to pay less than thirty days after the penalties, fees, or costs become final.

Appendix A

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

Reminder

To: All Oregon Licensed Non-Prescription Drug Outlets

From: Oregon Board of Pharmacy

Date: November 8, 2007

Oregon Administrative Rule 855-035-0020 states that *registered non-prescription drug outlets may sell non-prescription drugs in the original and unbroken packages only, properly labeled according to state and federal law, in conformity with rules of the Board.* In addition *no non- prescription drug outlet shall* <u>purchase or receive</u> *non-prescription drugs from a source* <u>not registered</u> *with the Board.* You may confirm that your distributor is registered with the Board by using our online license verification available at www.pharmacy.state.or.us. Furthermore, it is your responsibility to regularly verify your non-prescription drug inventory to ensure that you are not selling <u>any</u> expired drugs. If you currently have any expired drugs return them to your wholesaler immediately.

The regulations for the operation of non-prescription drug outlets may be found on our website at www.pharmacy.state.or.us under laws and rules, Division 35.

Appendix B

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

To: All Registered Oregon Wholesalers

From: Oregon Board of Pharmacy

Date: August 20, 2007

Re: Clarification of New Wholesaler Rules (Chapter 855, Division 065)

Please note that designated representative requirements went into effect January 1, 2007. Surety bond or other financial equivalent and inspection requirements do not take effect until January 1, 2008 for *new outlets.* For outlets that already hold a registration these are not required until the 2008 renewal cycle (September 30, 2008). Renewal information will be mailed in July 2008 with more instruction.

Designated Representative Requirements

• The Board requires one Designated Representative per facility. To be the Designated Representative of more than one facility you must first obtain Board approval. For exception information please see the Wholesaler FAQ's available on our website.

Inspection Requirements

• Board Staff is currently reviewing the registration and inspection procedures of other states and will be posting a list of accepted state inspections on our website. If you have been inspected within the last three years and we accept your resident state's inspection practices, VAWD or an additional accreditation program is not required. Please note that this only applies to out-of-state facilities.

• VAWD is currently the only approved accreditation program that the Board is accepting. The Board may recognize other accredited programs and inspection services, however, documentation must be submitted for Board approval and consideration.

Surety Bond or other Financial Equivalent Requirements

• For information on what is required to obtain a surety bond or other equivalent, please contact your insurance carrier or financial institution. If your insurance carrier or financial institution requires a letter from the Board that states a surety bond is a registration requirement, one will be provided upon receipt of your written request.

For additional information regarding Oregon wholesaler licensure requirements please refer to the frequently asked questions available on our website at www.pharmacy.state.or.us

Appendix C

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

Reminder

To: All Oregon Renewing Registered Non-Prescription Drug Outlets

From: Oregon Board of Pharmacy

Date: November 10, 2008

Oregon Administrative Rule 855-035-0020 states that *registered non- prescription drug outlets may sell non-prescription drugs in the original and unbroken packages only, properly labeled according to state and federal law, in conformity with rules of the Board.* In addition *no non-prescription drug outlet shall <u>purchase or receive</u> non-prescription drugs from a source not <u>registered</u> with the Board.* You may confirm that your distributor is registered with the Board by using our online license verification available at www.pharmacy.state.or.us. Furthermore, it is your responsibility to regularly verify your non-prescription drug inventory to ensure that you are not selling any expired drugs. If you currently have any expired drugs, return them to your wholesaler immediately.

Finally, please be reminded that effective July 1, 2006 ephedrine, pseudoephedrine, and phenlypropanolamine became Schedule III Controlled Substances. Drugs that contain these ingredients require a prescription. Please note that Non-Prescription Drug Outlets are prohibited from purchasing or selling **any** products containing **any** amount of ephedrine, pseudoephedrine
or phenlypropanolamine. This includes all forms of the drugs (tablets, capsules, liquid, etc). If you are purchasing or selling any of these products Oregon law provides that you may be subject to a fine of up to $10,000.00 **per** violation in addition to revocation of your license. If you currently have any of these products please return them to your wholesaler immediately.

The regulations for the operation of non-prescription drug outlets may be found on our website at pharmacy.state.or.us under laws and rules, Division 35.

Appendix D

March 11, 2008

REMINDER TO ALL OREGON REGISTERED CLASS I WHOLESALER WITH PRESCRIPTION DRUG OUTLETS

Your Wholesaler Class **1** Registration will expire <u>September 30, 2008</u>. In order to renew your Class **1** Wholesaler Registration you will need to submit the following information with your renewal notice by the postmark deadline of August 31,2008. Renewal notices will be mailed in early July 2008.

Surety Bond Requirement:

- Evidence of a surety bond or other equivalent means of security for at least $100,000. Such means of security must provide the Oregon Board of Pharmacy with direct access to secure payment of any administrative penalties that are not paid within 30 days of becoming final. Typically the Board would expect to see an original letter from an insurance company or other financial institution. *See Oregon Administrative Rule OAR 855-065-0006(8).*

Accreditation Program or Inspection Requirement:

- Confirmation that The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) or other nationally recognized accreditation program or contract inspection service has been obtained. At this time VAWD is currently the only approved accreditation program that the Board is accepting. You may contact the National Association of Boards of Pharmacy regarding their VAWD accreditation process at www.nabp.net or (847) 391- 4406. Please note the Board may recognize other accredited programs and inspection services, however, documentation must be submitted for Board approval and consideration.

A. Wholesalers out of Oregon:

- o VAWD or other accreditation program; or

- o Wholesalers located outside of Oregon may submit a copy of their most recent Out-of-State Wholesaler Inspection Report that has been conducted within the last year to meet the requirements of *Oregon Administrative Rule 855-065-0006(5)* so long as their resident state is listed below. Each inspection report will be reviewed on a case-by-case basis. If your Out-of-State Wholesaler Inspection Report has been approved and accepted, VAWD or other nationally recognized accreditation program or contract inspection service will not be required.

  Alabama, Colorado, Florida, Kentucky, Louisiana, Missouri, New Hampshire, North Dakota, Oklahoma, South Dakota, Tennessee or Vermont.

- o If your state is not listed above and you have had an inspection within the last three years that you believe meets the requirements of *OAR 855-065-0006(5)* please submit the inspection report for Board consideration.

Appendix E

<u>B. Wholesalers in Oregon:</u>
o   VAWD or other accreditation program; or

o   Wholesalers located within Oregon may be inspected by the Oregon Board of Pharmacy in lieu of VAWD or other nationally recognized accreditation program or contract inspection service. However, outlets must be inspected by the Board before August 31, 2008. Please contact our Compliance Department at (971) 673-0001 to schedule an inspection; or

o   Wholesalers located in Oregon which are small businesses and meet the criteria listed below may not have to be VAWD accredited or inspected by the Board so long as they are a small business and meet the criteria listed below. Per *Oregon Revised Statute 183-310(10)* a "small business" is defined as a corporation, partnership, sole proprietorship or other legal entity formed for the purpose of making a profit, which is independently owned and operated from all other businesses and which has 50 or fewer employees. In addition these small outlets must meet the following:

o   Have no affiliation with any out-of-state pharmaceutical company.
   •   All owners and principals of the applicant must be Oregon residents.
   •   No owner or principal, or close family member of an owner or principal, may have a controlling or business interested in any other pharmaceutical company; and
   •   Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.

   Note: That a "small business" may be subject to inspection anytime during normal business hours by the Oregon Board of Pharmacy.

<u>Designated Representative Reminder:</u>
•   Every Oregon Class 1 Wholesaler must have a Designated Representative physically present at the wholesale distributor during normal business hours. Please be reminded that one individual may not be the Designated Representative for more than one registration without an exception request approved by the Board. Failure to submit an exception request caused a delay in the renewal process of many outlets last year. Exception request information may be found on our website under the "FAQ" tab. In addition ensure that your Designated Representative is fully aware of their responsibilities see *Oregon Administration Rule 855-065-0009.*

For additional information regarding Oregon wholesaler licensure requirements please refer to the "What's New" and "FAQ" tabs on our website at www.pharmacy.state.or.us. A complete copy of the wholesaler rules may also be viewed on our website by clicking on the "Laws and Rules" tab under the "Division 65" subsection.

Appendix E

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

To: All Registered Oregon Wholesalers

From: Oregon Board of Pharmacy

Date: June 23, 2009

Re: 2008 Renewal Requirements

Please note that the designated representative requirement went into effect January 1, 2007. In addition, the surety bond or other financial equivalent and inspection requirements took effect <u>January 1, 2008</u>. It is now required that all Wholesalers Class 1 Outlets submit evidence of their VAWD Accreditation or state inspection as well as evidence of their $100,000 surety bond or financial equivalent. Renewals will not be processed without these items. *Please submit your renewal as soon as possible, as it is anticipated that this will be a very busy renewal period.*

Designated Representative Requirements

- The Board requires one Designated Representative per facility. To be the Designated Representative of more than one facility you must first obtain Board approval. For additional exception information, please see the Wholesaler FAQ's available on our website.

Inspection Requirements

- Board Staff has reviewed the registration and inspection procedures of other states. At this time the following states have been conditionally approved: *Alabama, Colorado, Florida, Kentucky, Louisiana, Missouri, New Hampshire, North Dakota, Oklahoma, South Dakota, Tennessee end Vermont.* If you have been inspected within the last three years and your state is not listed, we may accept your resident state's inspection practices. Please submit inspection documentation for review.

- VAWD is currently the only approved accreditation program that the Board is accepting. The Board may recognize other accredited programs and inspection services; however, documentation must be submitted for Board approval and consideration.

Appendix F

- Oregon resident wholesalers, contact the Board to schedule an inspection.

Surety Bond or other Financial Equivalent Requirements

- To obtain a surety bond or other equivalent, please contact your insurance carrier or financial institution. If your insurance carrier or financial institution requires a letter from the Board that states a surety bond is a registration requirement, one will be provided upon receipt of your written request. NOTE: At the Board's June 11, 2008 meeting, it was decided that no exceptions to this rule will be approved for the 2008 renewal period.

Wholesaler Class 1 - 2008 Renewal Check List *(for licensee use, do not submit to Oregon Board of Pharmacy).*

Renewal payment paid by check or money order	Yes_____No
Designated Representative Information	Yes_____No
Completed Supplemental Information Form (yellow document)	Yes_____No
Disciplinary Action Documentation (if applicable)	Yes_____No
Evidence of VAWD Accreditation or Inspection by Resident State	Yes_____No
Surety Bond, Irrevocable Letter of Other Financial Means	Yes_____No

RENEWALS WILL NOT BE PROCESSED WITHOUT ALL ITEMS LISTED ABOVE.

For additional information regarding Oregon wholesaler licensure requirements please refer to the frequently asked questions (FAQ's) available on our website at
www.pharmacy.state.or.us

Appendix F