NON-RESIDENT, MAIL ORDER PHARMACY RENEWAL NOTICE 2019

Your facility's registration is due to expire December 31, 2018. You are required by New Hampshire Law RSA 318:5-A to renew your license before the expiration date. Please complete and submit renewal no later than December 15th. **If you ship Sterile Compounded Products into New Hampshire, you are required to have your completed renewal submitted to our office no later than November 30th to allow time to process this in-depth application and get it back to you before the December 31st deadline.**

Please go to http://nhlicenses.nh.gov to renew. Here you will create an account for a Business using your license number and your registration code **which was emailed** to complete this process. Permits/renewal notices are only emailed. Do Not Call the Office to check up on your renewal. To track your renewal go to https://nhlicenses.nh.gov/verification. You should receive your emailed permit no later than 14 days after we receive your completed renewal, unless your company is shipping **Sterile products**, this may take longer. Please keep track of your emails as we will email with any questions/issues.

2019 RENEWAL INSTRUCTIONS: Renewal fee $1,000. **Payments accepted using MasterCard or Visa only**. **S**elect the pay fee button once, or you will be charged each time. If you do not have this type of card, a local store will have a 'pre-paid credit card' (not a Gift Card) that you can purchase and pay for your renewal.

1. The person responsible for the "actions of the permit" is responsible for submitting the renewal. **A Third Party person/entity is not authorized to complete the renewal for any reason. We cannot accept Power of Attorney documents.** You cannot use an IPAD/IPHONE to renew.
2. Once you have created a user name and password, If you do not see your licensure information appear at the bottom of the page, go back and create a new user name and password. If something was transposed when creating a new account then it will not connect the user name to the license information.
3. **All documentation to be uploaded needs to be in a PDF or word document only**. **Documents need to be uploaded during the renewal process and NOT EMAILED to the office staff. If the documents are too large, split them up and just be certain to title them and include the NH facility license number.**
4. Documents required for **Non-Sterile** Compounded products:
   a. Copy of current DEA,
   b. If you have a DEA certificate number, but you are NOT shipping controlled drugs into NH, you must still register with the PDMP and apply for a waiver. This is an annual process and will exempt you from reporting. Waivers are available at https://www.oplc.nh.gov/pharmacy/drug-monitoring.htm
   c. Copy of current home state license/permit (not a verification printed from a website),
   d. Copy of most recent inspection dated within the last 18 months,
   e. Dated and signed explanation of any "yes" answers,
   f. If your company has received an FDA 483 inspection, or any state or NABP inspection with negative results between 1/1/18 - 12/31/18 please submit that report, the 483, a copy of the un-redacted response, all copies of the plans to correct the issues, and all inspections or reports showing these corrections are complete and now acceptable.
   g. If your company received an FDA 483 **before** January 1, 2018 and has already been reported to our office, please do not send it again.
   h. List of names, corporate or business addresses and titles of all principal officers, partners, owners.

<u>Items required to renew a company shipping 'Sterile Compounded' Products into NH</u>:

1. All of the above mentioned items along with the following:
2. Environmental monitoring report, 1 report (2 weeks in length, dated within the last 6 months, to include:
    a. Viable Air & Surface Sampling.
    b. HEPA Filter Performance Testing.
3. If the facility does not have a clean report, submit the following as well:
    a. CAPA report.
    b. Identify the issue and explain on paper, to the Board.
    c. What is the corrective action plan.
    d. Is this identified in your SOP'S or P & P Manual.
4. Signed attestation by the Pharmacist In Charge stating there is a Policy & Procedure manual available showing compliance with USP 795 & 797/800.
5. Submit an inventory list of the last 6 months of sterile products shipped into NH, including product name, quantity, location of shipment, date of shipment.