

ALABAMA BOARD OF PHARMACY

SUSAN ALVERSON R.Ph.
Executive Secretary

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August 30, 2016

Dear Pharmacy,

Renewal of Alabama licenses for pharmacies and facilities will begin this year on September 1, 2016. The two year renewal application will only be available online. This will allow your information to be entered directly into your file without it being retyped by our office. The license renewal fee will be \$100 for your license and \$300 for your Controlled Substance permit for pharmacies, \$100 for Pharmacy Services and \$250 for Retail Medical Oxygen, which can be paid by credit card at the end of the renewal form. If you do not need a controlled substance permit, you will be able to complete a Controlled Substance Waiver during the renewal process (Not necessary for Retail Medical Oxygen and Pharmacy Services permit). The law reads that renewals are due by October 31st; however, we will allow renewal until December 31, 2016. Please do not wait until the last day. We cannot promise that we will be able to process all last minute renewals if there is a backlog. We are facing new federal requirements for licensing wholesalers, manufacturers, etc. and we do not want pharmacies to be caught in a last minute push. Please allow additional time to complete the application process. The application this year is detailed and will require additional information that has not been asked for previously. If you have incurred discipline since your last renewal, you will be asked to upload that information.

At the Board meeting that was held on July 20, 2016 the Board discussed the need for a separate mail order permit. The following law was reviewed:

§ 34-23-3. Permits for mail-order houses

Every mail-order house which dispenses drugs or medicines through the United States mail or otherwise from any point in the state of Alabama to any point outside of the state of Alabama, and every such business which dispenses drugs or medicines through the United States mail or otherwise from any point outside the state of Alabama to any point within the state of Alabama shall obtain a permit from the state board of pharmacy as a condition precedent to being qualified and authorized to transact such business in the state of Alabama. (Acts 1966, Ex. Sess., No. 205, p. 231, §29.)

After discussion between our attorney and the board members the decision was made that the pharmacy permit itself covered the need for mailing drugs or medicines inside or outside of Alabama. For that reason we will no longer issue a mail order permit for in-state or out-of-state pharmacies.

503B- Outsourcing Facility

The Drug Quality and Security Act, signed into law on November 27, 2013, created a new compounding pharmacy type: the 503B business or “outsourcing facility”. The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs, and which will compound in compliance with FDA cGMP.

To be given a permit in the State of Alabama as an outsourcing facility you will need to:

- 1) Register your facility with the FDA as an Outsourcing Facility.
- 2) Complete a Non-Resident Pharmacy application or if you are in state a Pharmacy application.
- 3) Complete a Manufacturers application.

We are working to legislatively create a single 503B license.

The Board has approved a new rule effective August 21, 2016. This updated rule will allow you to pay a non-disciplinary penalty of \$1000 for your license and \$500 for your controlled substance license, if you have engaged in pharmacy practice after your license expires 12/11/16. You can choose this option in January, 2017 only when completing your online renewal, and if there will be no discipline reported.

680-X-2-.40 NON-DISCIPLINARY PENALTY FOR LATE RENEWAL OF LICENSE, PERMIT, REGISTRATION, CERTIFICATION, OR ANY SIMILAR DOCUMENT ISSUED.

(1) In the event an application for renewal of any type of license, permit, registration, certification or any other similar document issued and required by the Alabama Pharmacy Practice Act, the Alabama Uniform Controlled Substances Act or any applicable Rule and the appropriate renewal fee is not received in the Board's office by December 31 of the applicable year, but is received in the Board's office no later than January 31 of the following year and activities requiring renewal were ongoing, a non-disciplinary administrative penalty as indicated below shall be received in the Board Office within fourteen (14) days of the Board's receipt of the renewal and if not, the opportunity to avoid discipline shall no longer be available, rather the Board shall initiate appropriate disciplinary actions. This penalty shall be in addition to the prevailing renewal fee.

- a) Pharmacy permits to include retail, institutional, non-resident pharmacies, and pharmacy services permits - \$1,000.00.
- b) Pharmacist license - \$1,000.00
- c) Technician Registration - \$250
- d) Pharmacist controlled substance permits - \$500.00
- e) Pharmacy controlled substance permits to include retail, institutional, non-resident, manufacturer/wholesaler/distributor - \$500.00
- f) Manufacturer/wholesaler/distributor to include manufacturer/wholesaler/distributors of oxygen and veterinarian medication - \$1,000.00.
- g) This Rule is adopted pursuant to the Board's authority set forth in Code of Alabama (1975), § 34-23-33(b) and is in lieu of formal disciplinary proceedings.

Thank you for your cooperation.

Sincerely,



Susan P. Alverson, D.P.A., M.H.P., R.Ph.
Executive Secretary