

Pharmacy Benefit Managers Licensing and Compliance Developments

Article By:

Steven L. Imber

Jennifer L. Osborn

Justin T. Liby

In response to calls for greater transparency in the prescription drug industry, 2021 continued a nationwide trend of increased state licensing and regulation of Pharmacy Benefit Managers (“PBMs”). In the last year, laws requiring PBMs to obtain PBM, Third Party Administrator (“TPA”) or Health Care Benefit Manager (“HCBM”) licenses/registrations from state regulators were passed or became effective in at least eighteen states. In addition to the new licensing requirements, numerous states also adopted requirements regulating other aspects of PBM operations.

New PBM Licensing and Registration Requirements

The eighteen states that passed a PBM licensing/registration requirement (or had one become effective) in 2021 include:

- Alabama – SB 227 (effective 07/01/2021)
- Alabama – Rule and Regulation 482-1-164-.01 (effective 01/01/2022)
- Delaware – HB 219 (effective 10/26/2021)
- Georgia – Rule and Regulation 120-2-97-.01 (effective 01/01/2021)
- Hawaii – SB 1096 (effective 06/28/2021)
- Indiana – HB 1405 (effective 04/29/2021)
- Kentucky – Rules and Regulation 806 KAR 9:360 (amendment effective 07/06/2021)
- Maine – Rule and Regulation Chapter 210 (effective 02/14/2021)

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- Maryland – HB 601 (effective 01/01/2022)
 - Maryland – Bulletin 21-07 (effective 03/04/2021)
 - Minnesota – Insurance Code 62W.11 (amendment effective 07/01/2021)
 - Mississippi – Rules and Regulations R30-3001-4501 (amendment effective 12/30/2021)
 - Missouri – Rule and Regulation 20 CSR 200-22.010 (effective 10/30/2021)
 - Montana – SB 395 (effective 01/01/2022)
 - Montana – Rule and Regulation dated October 12, 2021 (effective 10/12/2021)
 - New Hampshire – Bulletin 21-001-AB (effective 01/04/2021)
 - New Hampshire – Bulletin 21-104-AB (effective 12/17/2021)
 - New Mexico – Rules and Regulation 13.10.30.9 (effective 03/01/2021)
 - North Carolina – SB 257 (effective 10/01/2021)
 - Oklahoma – HB 2677 (effective 05/04/2021)
 - South Carolina – Bulletin 2021-08 (effective 12/01/2021)
 - Washington – Insurance Code 48.200.010 (effective 01/01/2022)
 - Washington – Rules and Regulations 284-180-110 (effective 01/01/2022)

The above states all prohibit an entity from acting as a PBM without first becoming licensed or registered with the appropriate state authority (e.g., the state's insurance department, state pharmacy board, etc.). The specific application requirements for licensure or registration vary by state. However, applications often require submission of the following documents and information:

- Organizational information about the applicant entity, including documents such as the applicant's Articles of Incorporation and Bylaws
- A Certificate of Good Standing (or its equivalent) from the applicant's state of domicile and the state in which the applicant is applying for a license
- The professional qualifications of the applicant's principals
- Background information of the applicant entity and certain of its principals regarding criminal history, regulatory actions, financial issues and civil litigation
- Financial statements showing that the applicant is financially sound
- A surety bond and/or proof of certain insurance coverages

- A detailed business plan
- Form contracts with payers and/or pharmacies

New Operational Requirements

In addition to the new licensing and registration requirements referenced above, numerous states also recently adopted requirements regulating certain aspects of PBM operations. Common operational issues addressed by those new requirements include:

- Prohibited terms and mandatory provisions in agreements between PBMs and their contracted payers and/or pharmacies
- Minimum standards for, and restrictions on, the use of maximum allowable cost (“MAC”) pricing
- A pharmacy’s right to appeal a claim determination and a PBM’s right to amend a past claim determination
- Pharmacy network adequacy standards and eligibility for network participation
- Pharmacy auditing rights and protections

As a result of the significant recent increase in the number of states that are currently licensing and regulating PBMs, it is important for PBMs to confirm that they are in compliance with the licensing/registration and operational requirements of the states in which they are active.

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