

Update

Third Party Administrator (TPA) Licensing and Compliance Developments

January 2020

New Laws in 2019 Regulating Pharmacy Benefit Managers

In response to calls for greater transparency in the prescription drug industry, 2019 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 or Third Party Administrator (“TPA”) licenses/registrations from state regulators were passed or became effective in at least fourteen 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 fourteen states that passed a PBM licensing/registration requirement (or had one become effective) in 2019 include:

- Alabama – SB 73 (effective 01/01/2020)
- Alaska – HB 240 (effective 07/01/2019)
- Arkansas – Rule and Regulation 118 (effective 01/01/2019)
- California – AB 315 (effective 01/01/2020)
- Delaware – HB 194 (effective 06/01/2020)
- Illinois – HB 465 (effective 07/01/2020)
- Louisiana – SB 41 (effective 07/01/2020)
- Maine – SP 466 (effective 01/01/2020)
- Minnesota – SF 278 (effective 01/01/2020)

- New Hampshire – SB 226 (effective 01/01/2020)
- South Carolina – SB 359 (effective 01/01/2021)
- Tennessee – SB 1852 (effective 01/01/2019)
- Utah – HB 370 (effective 07/01/2019)
- West Virginia – SB 489 (the statute was effective 02/26/2019, but the new license requirement is not effective until the West Virginia Office of the Insurance Commissioner issues licensing regulations).

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

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- 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.

More Information on Our PBM/TPA Team

Polsinelli's PBM/TPA team provides licensing services, monitoring of new PBM laws and regulations, regulatory and compliance services, drafting and negotiating of administrative services agreements and a number of other services for PBMs and TPAs. Our PBM/TPA team includes attorneys who were formerly in-house counsel for TPAs, as well as attorneys who were formerly insurance regulators.

By leveraging its extensive experience representing PBMs and TPAs, our PBM/TPA team helps clients avoid the learning curve and related cost implications that can be experienced by working with companies or attorneys less familiar with the regulatory and compliance needs of PBMs and TPAs.

For questions regarding this information, please contact one of the authors, a member of Polsinelli's PBM/TPA team or your Polsinelli attorney.