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FLORIDA ENACTS SWEEPING NEW LEGISLATION REGULATING PHARMACY BENEFIT MANAGERS

New laws have recently been enacted in Florida that will change the regulatory framework for prescription drug manufacturers and pharmacy benefit managers (PBMs). Chapter 2023-29, Laws of Florida, goes into effect on July 1. The first part of the bill requires prescription drug manufacturers to report certain price increases to the Florida Department of Business and Professional Regulation. This paper will focus on the other part of the new legislation that imposes new regulatory requirements on PBMs. The regulatory authority will be housed in the Florida Department of Financial Services. There is a new definition of a “pharmacy benefit manager” as well as definitions for a variety of other terms used in the industry. PBMs will have to obtain a certificate of authority from the Office of Insurance Regulation (OIR) by January 1, 2024. If a PBM fails to obtain a certificate of authority by that deadline but continues to operate, it will be subject to a \$10,000 fine per day. To obtain the certificate, PBMs must submit background information, contract templates, information about direct and indirect ownership interests and much more.

Contracts between PBMs and pharmacy benefit plans will also be subject to regulation. These contracts will now need to use a pass-through pricing model. In addition, the law will no longer allow PBMs to engage in the practice of “spread pricing” unless the difference is passed along to the pharmacy benefits plan. PBMs must pass the entirety of all manufacturer rebates received to the pharmacy benefits plan. PBMs will also be required to set up pharmacy networks that meet or exceed Medicare Part D standards for convenient access to network pharmacies. PBMs will not be allowed to make participation in one pharmacy network conditional on participating on any other network. PBMs will not be allowed to require participating pharmacies to meet accreditation standards that are more stringent than state pharmacy licensing requirements.

The new law also deals with contracts between PBMs and participating pharmacies. Among other things, PBMs will have to provide pharmacies with detailed information as needed to validate payments following adjudication or reimbursement of claims. Financial clawbacks, reconciliation offsets, and certain recoupments will no longer be allowed. PBMs may no longer unilaterally

change the terms of participation contracts with pharmacies. In addition, PBMs cannot restrict pharmacists from disclosing:

- Information about the nature of the treatment and possible side effects
- Alternative forms of treatment
- Information about any financial incentives used by the benefits program
- Information that may reduce the cost of pharmacist services

There are also extensive provisions for investigations of PBMs, sanctions and other regulatory controls. The Department of Financial Services will be developing new administrative rules to further refine and implement the new statutes. Interested parties should be paying attention as Florida administrative law provides for input by those affected by these rules. PBMs and others in the industry can have a say in how this unfolds but engagement is required to have that input.

Ausley McMullen is available to answer questions and help navigate this new world for PBMs in Florida. For assistance, contact:

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