The State of PBM Legislation and Important Federal Transparency Reminders

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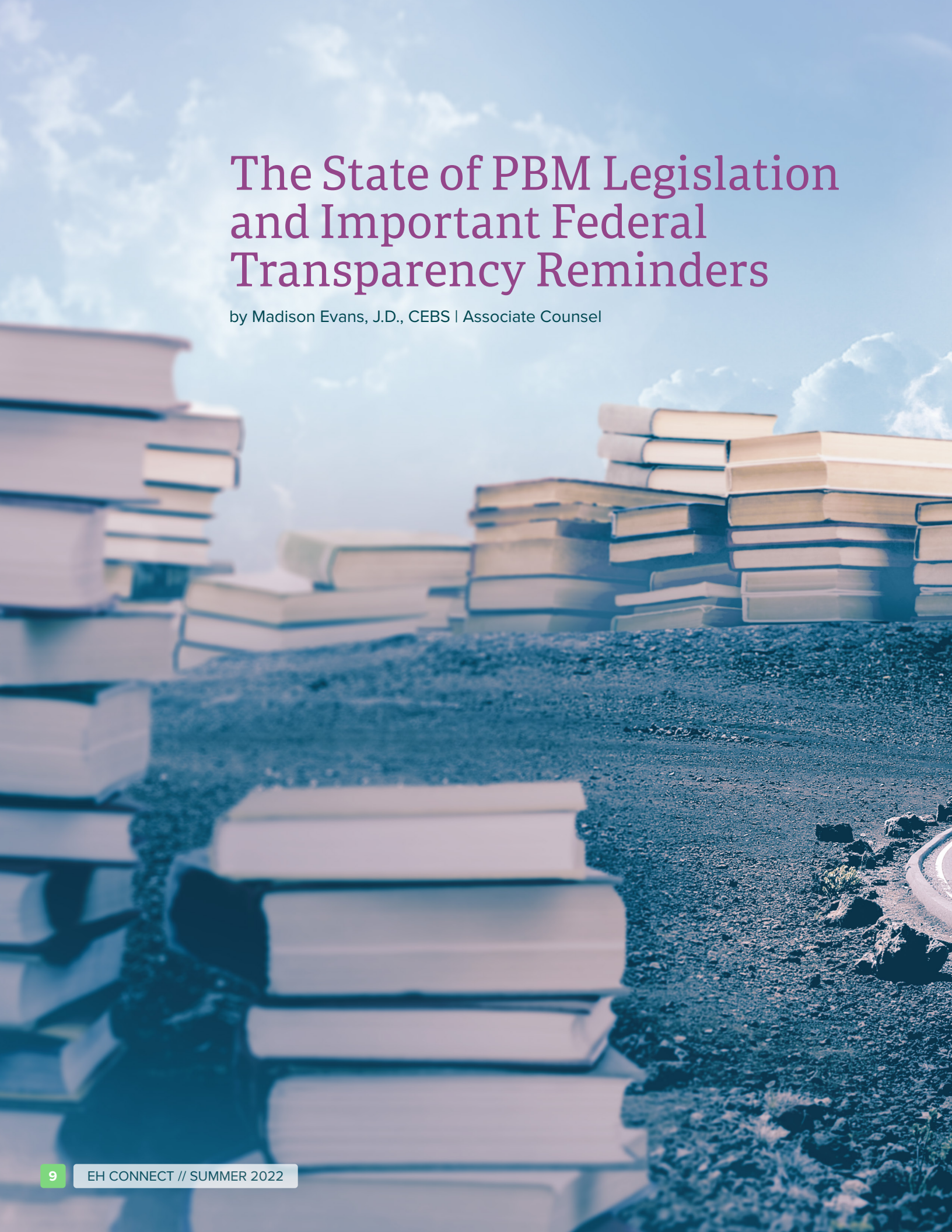

State Legislative Update: Rutledge and Its Aftermath

The last time this publication addressed state pharmacy benefit manager (PBM) legislation, readers were anticipating the final disposition of Rutledge v. Pharmaceutical Care Management Association (PCMA). As a background, Rutledge v. PCMA was a legal challenge to an Arkansas statute that set a pharmacy's reimbursement at a rate that, at a minimum, reflected the pharmacy's acquisition cost for the drug. The law also provided a robust appeals process to determine if reimbursement fell below that acquisition cost and even allowed a pharmacy to decline to dispense a drug to a participant in cases where the pharmacy determined the PBM's reimbursement would be less than the acquisition cost. The PCMA challenged the law arguing that it was preempted by the Employee Retirement Income Security Act (ERISA). ERISA is a federal law that regulates employer-sponsored benefit plans and provides express federal preemption of state laws that relate to an employee benefit plan. Plan sponsors rely on ERISA as it protects sponsors from having to comply with an irregular patchwork of state laws and supports nationally uniform plan administration.

The U.S. Court of Appeals for the 8th Circuit held that the law was preempted and thus unenforceable as applied to ERISA covered health plans. The Arkansas Attorney General appealed the 8th Circuit's decision to the United States Supreme Court. After multiple COVID-19 related delays, the court heard oral arguments in October 2020. In January 2021, the court released its highly anticipated opinion which ultimately reversed the lower court's decision. In a unanimous 8-0 ruling, the court held against ERISA preemption for the first time in decades. The court characterized the Arkansas law at issue as merely, "cost regulation." The court said that states were allowed to regulate reimbursement even if an ERISA plan experienced indirect increases in the costs of plan administration. The court acknowledged, however, that certain indirect economic effects of a law may necessitate preemption if such a law, "effectively dictate(s) plan choices." The court declined to describe an example of a situation that would warrant preemption of the state law.

This broad ruling has immediate implications for the regulation of PBMs and health benefit plans alike. Rutledge gives states expanded authority to regulate aspects of an ERISA plan, without defining the boundaries of such authority. In the aftermath of Rutledge, states continue to pass numerous bills seeking to regulate PBMs and the health benefit plans they administer benefits on behalf of.

States have introduced PBM legislation in the following areas:

- Restriction of mail service
- Restriction of specialty network options
- Banning preferred pharmacy arrangements
- Payment mandates/National Drug Acquisition Cost (NADAC) based pharmacy reimbursement
- Plan design restrictions including prohibition of copay accumulator programs
- Transparency disclosures

While many of these types of laws are distinguishable from the reimbursement law at issue in Rutledge, states may still be able to rely on Rutledge's precedent and general reasoning. For example, an Oklahoma district court recently upheld the state's Patient's Right to Pharmacy Choice Act using similar reasoning. The Oklahoma law went beyond merely cost regulation; the law required a PBM to allow any retail pharmacy the option to participate in its network if the pharmacy accepted the terms and conditions of the network and prohibited a PBM from incentivizing participants to use preferred in-network pharmacy providers. The district court said that, "while these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices."

As anticipated, the 2022 state legislative sessions have been just as active. Many PBM bills that did not pass during the 2021 sessions (when legislatures were largely concerned with COVID-19 related issues) were reintroduced. State sessions follow a variety of schedules; many general assemblies will adjourn in spring or early summer, while others will remain in session through the end of the year. As employer-sponsored prescription drug benefit plans experience increased scrutiny at the state level, Employers Health will continue to monitor these developments and advocate for the interests of self-funded plan sponsors. Plan sponsors should pay special attention to these state developments and work with their current vendors and advisors to understand the financial and administrative implications of these limitations and, once armed with that knowledge, advocate for the interests of their organizations.

Now turning to an area that most plan sponsors are more attuned to monitoring...

Federal Regulatory Update:

Key Transparency Deadlines and Updates on Reporting Requirements

Transparency in Coverage Final Rule

What it is

The Transparency in Coverage Final Rule was released in October of 2020 by the Department of Health and Human Services, the Department of Labor and the Department of the Treasury (the departments) in response to the Trump Administration's Executive Order on Improving Price and Quality Transparency to Put Patients First. The rule aims to give consumers knowledge and access to pricing information through their health plans. It has a two-part approach: access to a member cost comparison tool and publication of three machine-readable files.

COMPONENT ONE

Member Price Comparison Tool

Plans must provide members with real-time accurate estimates of their cost-sharing liability for health care items and services from different providers. This information is to be provided via telephone and an internet-based cost estimator tool. The departments released a list of 500 initial items and services that are required to be available via the self-service tool for plan years that begin on or after January 1, 2023. Most of the items and services included in the initial wave are covered under the medical benefit. The remainder of all items and services covered by a plan will be required to be available via these self-service tools for plan years beginning on or after January 1, 2024. Most medical carriers have an existing cost estimator tool that meets the requirements of the rule and others will continue updating their systems to ensure that all required services are available by the rule's applicable effective date.

COMPONENT TWO

Publicly Available Machine-Readable Files

This second requirement is more complicated and will require synchronization between plans and their vendors. Plans must publish three machine-readable files in a publicly available format with monthly updates. The first file will include negotiated rates for all covered items and services between the plan and in-network medical providers. The second file must list both the historical payments to and billed charges from out-of-network medical providers. The third file will detail the in-network negotiated rates and historical net prices for all prescription drugs covered through the pharmacy benefit. The files must be posted in a standard format; the departments indicated that a JSON file is an acceptable format while Excel is not.

Deadline Status

The two files detailing the in and out-of-network information for medical providers are required to be publicly available for plan years that begin on or after July 1, 2022. The departments deferred enforcement of the prescription drug file requirement indefinitely pending notice and comment rulemaking regarding whether the requirement remains appropriate in light of the prescription drug reporting requirements under the Consolidated Appropriations Act (below).

Action Items

Plan sponsors should be prepared to work with their medical carriers to coordinate publication of the in and out-of-network files as the carrier is the entity with access to this information. The term "publicly available" means that the information published online must be accessible to any person free of charge and without conditions such as identity verification, credentials, a username or password, etc.

Consolidated Appropriations Act (CAA) Prescription Drug Reporting

What it is

These regulatory requirements implement the drug cost reporting provisions from the Consolidated Appropriations Act of 2021. Plans must provide specific reporting data on prescription drug spending to the departments. Utilizing the reported drug spending information, the departments will biannually release an aggregated report on drug pricing costs and trends beginning in 2023. The types of information that must be provided in the report include the top 50 most costly drugs, top 50 most frequently dispensed drugs, total rebate amounts, specific rebate information for the top 25 drugs with the highest dollar amount of rebates, etc. Readers may recall that the original CAA regulations also called for a member price comparison tool, but this requirement was determined to be duplicative of the comparison tool required for the Transparency in Coverage Final Rule. Thus, compliance with the Transparency in Coverage consumer comparison tool requirement (described above) is also sufficient for purposes of the CAA.

Deadline Status

Last August the departments delayed enforcement of these requirements to allow additional time for rule-making and for plan sponsors and PBMs to prepare for implementation. On November 22, 2021, the departments released an interim final rule (IFR) with a request for comments as well as a draft reporting form with instructions. Comments on the IFR were due January 24, 2022. Per the IFR, plans must submit reports for 2020 and 2021 by December 27, 2022. Reports will then be due each following June, based on information from the prior calendar year.

IFR clarifications

The IFR included some important clarifications for plans sponsors. Although the legal requirements to report under the CAA apply to plans and insurers, the departments recognize that plans will look to PBMs to assemble most, if not all, of the reporting. The departments will allow multiple entities to enter reporting information for a particular plan. This means that both the plan and the PBM can submit information to complete the plan's reporting requirements. Reporting will be done through the online Health Insurance Oversight System (HIOS) run by the Centers for Medicare and Medicaid Services (CMS) as CMS will be collecting the CAA reporting data on behalf of the departments. Readers should note that this is likely the first time that employer-sponsored health plans will have a nexus with this system.

To facilitate efficient reporting and useful data compilation, the departments will allow a PBM to aggregate most of the required data elements at the state and market levels. The original text of the CAA seemed to contemplate reporting on a plan-by-plan basis, but each PBM will now be able to aggregate the report information for all self-insured employer plans that it administers. Plans will still be responsible for some plan-specific inquiries such as plan identifying information, states where coverage is offered, number of participants, etc. While multiple entities can report required information, only the entity reporting will be able to view the file information it uploads and cannot view information reported by any other entity. This lack of visibility means that plans must work with their PBMs to confirm that all pertinent information has been reported in a timely manner. Even if a plan enters into an agreement with its PBM, the plan remains ultimately liable for the reporting.

Action Items

Given the interim nature of the rule and that the departments have requested comments on the rule, the requirements in this IFR are still subject to change. The departments indicated in the IFR that they plan to promptly issue final rules based on the collected public comments. Plan sponsors should anticipate final regulations from the departments this summer and watch for communications on next steps from their PBM. Sample reporting templates and instructions are available on the Prescription Drug Data Collection page of the CMS website.

TO LEARN MORE CONTACT

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