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New Prescription Drug Oversight, Transparency, and Opioid Abuse Legislation

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Throughout September and October 2018, the government enacted laws and issued proposed guidance aimed at the prescription drug market. These bills and regulatory actions follow the Trump administration's "American Patients First" blueprint, with the objective to bring down prescription drug prices and out-of-pocket costs, along with combatting the opioid epidemic.

The recent actions on prescription drugs seek to:

- Eradicate the use of "gag clauses" by PBMs and insurance carriers in contracts with pharmacists so information regarding pricing through insurance versus on a direct-buy basis is more readily available to consumers;
- Require pricing information in drug advertising; and
- Address opioid abuse.

Below is a discussion of the new laws and regulations on this topic. Except as it applies to "gag clauses," the direct effect of these changes will be felt predominantly in the Medicare and Medicaid marketplaces.

New Bills Prohibit "Gag Clauses" in Pharmacy Contracts

On October 10, 2018, President Trump signed legislation that would prohibit "gag clauses" in pharmacy contracts. Often the cash price of a prescription is lower than the copayment based on the plan's formulary. It has been a common practice for insurance plans and/or PBMs to have contractual language with their participating pharmacies that prohibited the pharmacist from disclosing the lower cash price to the enrollee (informally, a "gag clause"). The new legislation prohibits such clauses.

There are two bills that address this requirement:

- The Patient Right to Know Drug Prices Act applies to group health plans and health insurers offering group or individual coverage and is effective immediately.
- The Know the Lowest Price Act of 2018 applies to Medicare Part D plans and is effective for plan years beginning in 2020.

Group health plans sponsored by employers are subject to the Patient Right to Know Drug Prices Act. Generally, the group health plan and insurance carrier:

- cannot restrict any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

- must ensure any entity that provides pharmacy benefit management services under a contract with the health plan or the carrier does not violate the same provisions.

It is important to note however, that the legislation does not require the pharmacist to disclose the lower cash price; it simply prohibits the plan from penalizing the pharmacist from doing so. Consumers may still need to ask the pharmacist if there is a lower cash price when filling prescriptions.

Employer Action

Employers with self-funded health plans or self-funded prescription drug carve-outs managed by a PBM will want to discuss whether such gag clauses are included in contracts with participating pharmacy providers and have them removed as soon as possible.

Proposed Regulation to Require Drug Pricing Transparency on TV

In mid-October, the Centers for Medicare and Medicaid Services (CMS) released draft regulations that, if enacted, would include certain pharmacy pricing information in television advertisements.

Specifically, the draft regulations provide that CMS will publish an annual list of drugs which must provide pricing information if they are featured in a television commercial. Only drugs that are paid for by Medicare or Medicaid would be subject to this requirement.

If finalized, the advertisement must provide the drug's wholesale acquisition cost or "list price." Even though consumers rarely pay the list price of the drug at their pharmacy counter, CMS believes that sharing the list price will create transparency to the consumer as to how much drugs really cost compared to what they pay.

Interestingly, the proposed regulations state that the enforcement mechanism for drug companies that do not comply will be private lawsuits, not direct enforcement from CMS or other government agencies.

It is important to note that these regulations are not yet finalized and are not yet law; they are only in draft form. Therefore, there may be changes that can occur as the draft regulation continues through the regulatory process. Further updates may be available after the comment period closes in December 2018.

Newly Enacted Law Addresses the Opioid Crisis

On October 24, 2018, President Trump signed into law the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). This largely bi-partisan law includes the following objectives:

- Reduce use and supply of opioids;

- Encourage recovery for those with substance use disorders;

- Support caregivers and families impacted by substance use; and

- Drive innovation and long-term solutions (i.e., research for non-addictive painkillers and ensure parity for mental health and substance use disorders benefits).

While the objectives are global, in operation, the law primarily affects Medicare or Medicaid programs and healthcare providers. Group health plans are not directly affected. Some noteworthy provisions of the law are discussed below.

Few Implications for Employers and Group Health Plans

The final text of the bill provides little impact and/or changes for employers and employer-sponsored health plans.

However, in the early stages of the legislation, there was a provision that would have revised the Medicare Secondary Payer rules around payment for end-stage renal disease (ESRD) in order to generate revenue for the program by requiring group health plans to pay primary for an additional three months of care for ESRD patients before Medicare. This provision was not added as a part of the final regulations, and thus the Medicare Secondary Payer Rules are not changed by this law.

Separately, the Act provides that the Department of Labor (DOL) will establish an Advisory Committee on Opioids and the Workplace to review the impact of opioid use in the workplace and to support those in the workplace that abuse opioids.

Medicaid Coverage Expansions

The SUPPORT Act also has several provisions that expand Medicaid-covered services for substance use disorders. For example, the Act expands state Medicaid treatment for substance use disorders to include all FDA-approved drugs, counseling services, and behavioral therapy, beginning in October 2020 through 2025.

Medicare and Medicaid funding for Telemedicine

The Act expands the use of telemedicine for opioid and heroin use treatment and counseling. In the future, states will receive options for providing telehealth services to treat substance use disorders under Medicaid. Medicare coverage will be expanded for telehealth services for treatment of substance use and related mental health conditions.

Future regulations will be enacted for registration of providers to prescribe controlled substances via telemedicine in legitimate emergency situations.

Oversight on Providers and Pharmacists Providing Opioid Prescriptions

The Act also includes new measures of prescription drug oversight for doctors and providers that accept Medicaid. The Act requires states to have drug utilization safety measures to monitor issuing of opioid prescriptions and refills, and similar measures for antipsychotic prescriptions issued to children. There will also be additional federal funding available to states for implementation of prescription drug monitoring programs.

Additionally, the Department of Health and Human Services (HHS) must develop training programs and materials to train pharmacists on when they may refuse to fill a controlled substance prescription. Instances of refusal would include if there is suspicion of forgery, fraud or other prescription abuse.

The bill also seeks to promote communication with families of affected individuals during emergencies and overdoses. To promote this, providers will receive annual updates on privacy restrictions and laws describing what health information is allowed be shared with families and caregivers during an emergency.