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GUEST COLUMN

Direct-to-consumer prescription drug programs: Plan sponsors beware!

In 2024, Eli Lilly launched LillyDirect, a direct-to-consumer platform providing affordable access to various drugs, bypassing pharmacy benefit managers (PBMs) and raising concerns for employers about potential contract violations and the design of legal reimbursement programs.

By Mary E. Powell

n 2024, Eli Lilly and Company announced LillyDirect, which is an online platform that offers individuals direct access to certain drugs, including Zepbound, a GLP-1 drug that is used to treat obesity. Eli Lilly partnered with telehealth companies that connect individuals with healthcare professionals who can prescribe Zepbound for the treatment of obesity. The prescription for Zepbound is sent from the telehealth provider to Eli Lilly, which then contracts with Amazon to have that drug sent directly to the individual's home. The cost of obtaining Zepbound through this direct-to-consumer (DTC) program is approximately \$500 for a month's supply, which is often far less than the cost of that drug when available under an employer-sponsored health plan. Pfizer has launched a similar program for certain drugs - PfizerForAll. These DTC programs cutout the middleman - the pharmacy benefit manager (PBM).

Who are the PBMs? PBMs are the entities that administer the prescription drug portion of a health plan. They are the middlemen between the health plans, plan participants and pharmaceutical companies. For an employer-sponsored plan, the employer contracts with the PBM to



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manage and administer the prescription drug portion of a health plan, including negotiating drug prices, creating drug formularies, creating pharmacy networks and administering claims and appeals. Separately, the PBM enters into contracts with pharmacies that dispense the drugs, and those contracts address the amount the pharmacies will be paid for the drugs dispensed to health plan participants.

Over the last year, plaintiffs have bought lawsuits against employers (in their capacity as fiduciaries of the health plans offered to their employees) alleging that they have entered into contracts with PBMs that allow the PBMs to overinflate the cost of drugs - causing health plans and their participants to pay "excessive" prices for drugs.

Direct-to-consumer programs. Given the decreased costs of certain drugs offered through these DTC programs, employers are considering ways to utilize these programs. For example, an employer may amend its health plan to eliminate coverage for GLP-1s for the treatment of

obesity. Instead, the employer will reimburse an employee for the cost of that drug obtained through the DTC program under a health reimbursement account (HRA). (HRAs that reimburse drugs obtained through DTC programs must be specifically designed to meet all applicable legal requirements. Those legal requirements are not addressed in this article.)

Plan sponsors beware. In addition to the legal issues that could arise with an HRA that reimburses drugs obtained under these DTC programs

(the "DTC HRA"), another concern for employers is whether such DTC HRA would violate the terms of the contract between the PBM and the plan sponsor. Almost all PBM agreements contain an exclusivity provision - meaning that the employer agrees that its health plan will only cover drugs that are provided through the PBM. If this provision is violated, the contract often states that the PBM can void all of the pricing guarantees

in the agreement. In addition, most PBM agreements contain a provision that if certain drugs are removed from the formulary, the PBM has the right to renegotiate all of the drug pricing provisions in the agreement.

Before a plan sponsor considers adopting any program that reimburses the cost of drugs obtained by an employee through a DTC program, it should first review its agreement with the PBM to ensure such a program would not violate the terms of the agreement. If it can get over that hurdle, it will then need to carefully design a reimbursement program that meets all applicable legal requirements.

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