

Drug Transparency Act

On March 5th, U.S. Senator Mike Braun (R-IN) introduced the [Drug Price Transparency Act](#) (“the Braun bill”). The goal of the Braun bill is to encourage pharmacy benefits managers to pass discounts from drug manufacturers directly to consumers and bring transparency to the prescription drug market. The Braun bill would prohibit pharmacy benefits managers from receiving any rebates or reductions in price from drug manufacturers, and would require any rebates or reduction in price from a drug manufacturer for any drug be made transparent and reflected at the point of sale to the consumer.

In late February, HHS issued a proposed rule that, if finalized, would eliminate drug rebates in government programs. Initially, private purchasers were happy to see the potential for [elimination of the rebate system](#), but confusion soon set in while we awaited further clarification on how this would affect private purchasers. On its face, the proposed rule applies only to government programs. And while HHS cannot directly regulate private purchasers (i.e. employers with ERISA plans), the HHS Office of Inspector General has in place a ruling that drug rebates must apply equally to all purchasers. The Braun bill is an attempt to clarify this issue and eliminate confusion by making the anti-rebate requirement apply to private purchasers.

There now is the potential for some interesting legal posturing given that there are now concurrent processes moving through the executive and legislative branches of government. The proposed rule is currently out for comment and HHS will presumably eventually issue a final rule, and according to established law, has a fair amount of latitude in deciding what and how to finalize their proposals. But the Braun bill is on a completely separate and distinct path. Neither the proposed rule nor the Braun bill can be dependent on the other.

There are now essentially three things that can happen: 1) the proposed rule is finalized as proposed, but this Braun bill goes nowhere, and the confusion we have now remains, 2) the Braun bill passes and is enacted but the final rule either is not published, or is different from the proposed rule, so even more confusion results, or 3) the proposed rule is finalized as proposed and the Braun bill passes and is enacted, which means things are pretty clear when it comes to rebates.

Obviously, #3 is the ideal state, but the chances are slim that the processes will run that smoothly and things will fall into place from a timing perspective. Stakeholder groups have directly asked HHS and OIG for clarification on how these policies would be interpreted and enforced, but neither agency has responded.

Purchaser Implications

Implications for purchasers will depend on how the proposed rule is finalized, and whether the Braun bill passes and when. Ideally, the question of how private purchasers are impacted will be clarified in the preamble to the final rule when it is published. If the proposed rule is finalized as is, but without any additional explanation of the effects on private purchasers, and Senator Braun's bill does not move forward, employer purchasers will need to be proactive in approaching their PBMs to discuss how rebates will be handled.

If, through either the regulatory or legislative process, we receive more clarity on how rebates apply in the private sector, employer purchasers would still be wise to engage with their PBMs to discuss rebates and how they will be used. The National Alliance and its partner organizations will continue to monitor this issue closely and disseminate any additional clarifying guidance as we learn it.