

Key Implications of Recent U.S. PBM Reforms

The Trump administration has been ramping up its efforts to reform the pharmacy benefit manager (PBM) industry over the past couple of weeks, with major changes coming out of both new legislation and regulatory developments.

On January 29, the U.S. Department of Labor (DOL) issued a proposed rule that would require PBMs to disclose information about fees and compensation to self-insured group health plans. Days later, President Donald Trump signed the U.S. government’s Fiscal Year 2026 funding package (H.R. 7148) into law, including measures intended to reform PBM business practices. On February 4, the Federal Trade Commission (FTC) and PBM Express Scripts agreed to enter a consent decree which would settle a lawsuit accusing Express Scripts and other PBMs of using its market power to drive up insulin list prices to obtain higher rebates from drug manufacturers.

Key provisions across all three actions are summarized below:

	FY 2026 Spending Bill	Department of Labor Rule	FTC/Express Scripts Settlement
Key Changes	Rebate pass-through, transparency/reporting, pharmacy access, and strengthened plan fiduciary oversight	Increase employer fiduciary visibility into PBM compensation to assess contract reasonableness and guard against prohibited transactions	Offer \$25 insulin cap for all members; break rebate-driven incentives; require net price-based designs, transparency, and pharmacy reimbursement reforms
Scope	ERISA group health plans and Medicare Part D. Delinking provision applies only in Medicare Part D and spread pricing provision applies only in Medicaid	Self-insured ERISA group health plans	To be provided as “standard offering” in Express Scripts’ commercial and Medicare PBM operations
Timeline	Compensation disclosure effective Feb 3, 2026; pass-through/reporting effective for plan years starting on/after Aug 3, 2028 (Jan 1, 2029, for calendar-year plans); Part D reforms phase in 2028-2029	Public comments on the proposed rule are due March 31, 2026	Majority of changes expected January 1, 2028

Taken together, the PBM reform legislation, the proposed DOL rule, and the Express Scripts settlement signal a significant shift toward greater oversight of the middlemen and could shape the beginnings of new business practices. However, it is challenging to predict the long-term impact of these changes and how other industry players might respond.

John Neal, Senior Partner, EVERSANA MANAGEMENT CONSULTING, believes that “PBM reform has been on the horizon for some time,” adding, “It appears that meaningful change to the PBM business model may happen, and that ultimately patients can benefit from lower OOP expenses.”

Neal and Jim Burke, General Manager, Revenue Management, EVERSANA discussed key implications of the recent PBM reforms and what changes manufacturers need to be aware of with NAVLIN Daily:



Most impactful changes stemming from each of the three developments

- ✓ **FY2026 Spending Bill**
The most notable impact is the push toward standardization and transparency across PBM contracting and rebate definitions. While these measures don't overhaul the PBM economic model, they reduce ambiguity and give plan sponsors better visibility and comparability.
- ✓ **DOL Proposed Rule**
If finalized, this is likely the most consequential change. Treating PBMs as fiduciaries for ERISA plans would materially shift obligations, forcing greater alignment with sponsor interests and potentially altering formulary and contracting strategies.
- ✓ **FTC/Express Scripts Settlement**
This establishes new regulatory precedent around access and non-exclusionary contracting, particularly with the requirement to offer "covered access" to TrumpRx. This creates the first real enforcement mechanism in this set of reforms.

Biggest limitations of the three measures

All three actions consist of focused line-item changes to individual business practices, rather than comprehensive reforms to the core PBM revenue engines such as rebates or formulary control. Additionally, some of the practices, such as spread-based models, can still be offered, just not as part of a "standard" offering.

Cigna's stock remained largely unaffected following the settlement announcement. When discussions of imminent change first happened around the company's October earnings call, the market reaction was severe; since then, the price has recovered somewhat, and that recovery was neither slowed nor accelerated by this announcement. Investors seem to believe that the financial underpinnings remain largely intact, and that PBMs will be able to adapt operationally without sacrificing significant margin. Remaining flexibility around definitions and fee structures also leaves room for continued maneuvering.

Potential plan sponsor response

Sponsors will likely leverage these developments to demand more transparency and alignment. Potential changes include increased scrutiny of line-item fees, more influence over formulary decisions, and expanded interest in carve-out or hybrid PBM models. Overall, sponsors may become more assertive buyers, expecting clearer rationales for utilization management and pricing strategies.

How might these three approaches work together (assuming DOL rule is finalized)?

If the DOL rule is finalized, the three actions form a cohesive framework. The spending bill establishes transparency and definitional clarity, the DOL rule adds fiduciary accountability, and the FTC settlement provides enforcement and practical precedent. In combination, they narrow PBMs' discretion and increase consistency across the ecosystem.

Settlement provision requiring Express Scripts to provide "covered access" to TrumpRx

In practice, this likely means Express Scripts must treat TrumpRx as a standard formulary offering—avoiding exclusionary practices and providing reasonable commercial terms. Additional regulatory guidance will likely be needed for operational details, but new legislation may not be required. Other PBMs may follow only if pressured by regulators, large employers, or if future FTC action suggests similar settlements are coming. Notably, both CVS Caremark and OptumRx have also been sued by the FTC for similar business practices. The Express Scripts settlement is the first outcome among the three and likely provides a precedent on how the remaining two PBMs could change their business models.

Although direct-to-patient (DTP) platforms like those supported by TrumpRx have the potential to make some medications more affordable for a subset of cash-paying patients with inadequate insurance coverage, the price of many high-cost and specialty drugs will likely remain out of reach for many patients. Additionally, payments made through DTP channels do not currently count toward a patient's health insurance deductible or out-of-pocket maximum, further disincentivizing the use of DTP arrangements.



If Express Scripts adds the platform to its standard offering, direct purchases of medicines through the service could occur within insurance and count toward patient deductibles or out-of-pocket maximums.

Potential for future PBM reforms

It is likely that PBMs will remain in the political spotlight, even as the effects of these current actions unfold. Potential future actions could include expansion of fiduciary expectations, stricter limits on formulary exclusions, greater oversight of vertically integrated specialty pharmacy operations, and further transparency requirements at the product level. None would dismantle the PBM model, but each would further narrow practices that have historically raised scrutiny.

With increased transparency into fee structures and pricing models being explored, the potential exists for the market to begin to move away from an obscured rebate model to a more direct point-of-sale price concession. This would require significant changes to the technology engines that adjudicate pharmacy claims but could eventually pave the way for greater savings for plan sponsors and patients, as well as simplification to the existing gross-to-net waterfall.

What should manufacturers know about the changes?

Key implications for manufacturers that stem from these three actions include the following:

- Rebate-driven contracting weakens, as PBMs may now be required to pass through 100% of rebates and related remuneration to payers, limiting manufacturers' ability to use rebates to secure favorable formulary status
- Pressure on list prices increases, driven by the shift in Medicare Part D toward flat PBM administrative fees and away from rebate-linked compensation
- Greater transparency into gross-to-net dynamics, with expanded PBM reporting revealing drug level gross spending, net spending, rebates, spread pricing, and formulary decision rationale. This exposes manufacturer pricing strategies to far more scrutiny by plan sponsors as well as therapeutic competitors

- Manufacturers are likely to experience additional pressure from PBMs with greater service fee requirements, and potential increased requests for Off Invoice Discounts (OIDs) through affiliated specialty pharmacies
- Reduced ability to differentiate via PBM-specific formulary contracting, given more standardized access requirements (including the "covered access" obligations in the Express Scripts settlement)
- Manufacturers should evaluate their existing product portfolios under new pricing dynamics:
 - Older branded products nearing patent expiry may become uneconomical to maintain
 - Generic/biosimilar strategies may need acceleration
 - Launch pricing strategies for new products must account for post-reform economics from day one

However, even with these considerations, it is important to note that the recent reforms have limitations and will not change the way PBMs operate overnight. If you have any questions or would like to get in touch with John Neal or Jim Burke to discuss these issues and what they could mean for your team, reach out to connect@navlin.com.

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