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Changes in the Federal Regulatory Landscape: What Matters for Plan Sponsors

Dear Client,

You may have seen recent coverage of the TrumpRx "43 drug list," which highlights brand-name medications offered at manufacturer-negotiated prices outside of the traditional PBM model.

While the program has attracted attention, it's important to separate visibility from value.

A meaningful portion of the drugs on the TrumpRx list already have FDA-approved generic equivalents that are broadly available today. In those cases, steering members to a brand drug, regardless of a negotiated direct price, often results in higher overall plan spend compared to existing PBM pricing or generic utilization. In short, a lower advertised price does not automatically translate to a lower *net* cost.

LucyRx is actively evaluating the TrumpRx list to assess the true cost impact across multiple dimensions, including:

- Manufacturer-stated direct pricing
- PBM-negotiated net brand cost (inclusive of rebates)
- Available generic alternatives and dispensing channel economics

This analysis will allow us to provide fact-based guidance on when programs like TrumpRx may be additive and when they are unlikely to outperform existing plan strategies.

More broadly, LucyRx continues to advance a formulary strategy that is less dependent on rebates and instead prioritizes high-value therapies with the lowest achievable net cost. This includes optimization of generics, biosimilars, and clinically appropriate therapeutic alternatives, all designed to align utilization with true economic value. That approach is intended to improve the overall cost position for plans seeking greater transparency, predictability, and alignment between utilization and spend.

Separately, as part of the Consolidated Appropriations Act (CAA) of 2026, signed into law last week, Congress made changes to ERISA that affect both PBMs and plan sponsors:

- The ERISA amendments are scheduled to go into effect in the summer of 2028, approximately 30 months from now.

- The ERISA changes for PBMs fall into two categories: a rebate pass-through mandate and PBM plan reporting requirements.
- The reporting requirements range from sharing drug pricing data to PBM compensation disclosures, as well as reporting on PBM relationships with other entities involved in the provision of pharmacy benefit management services, including affiliated entities.
- PBMs will face liability for not meeting the Act's requirements. Employers may also face liability if they do not take appropriate steps to require PBM compliance and ensure that their contracts meet the new legal requirements.

In parallel, the Department of Labor has passed a related rule calling for expanded disclosures and reporting, including disclosure of spread pricing, which is expected to go into effect later this year.

LucyRx is fully prepared to meet these federal reporting requirements, support clients through compliance readiness, and maintain clear visibility into pharmacy spend.

We will continue to share updates as our TrumpRx analysis progresses and are happy to discuss how these developments may apply to your plan design, formulary strategy, and member population.

Best regards,

Susan

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