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Evaluation of Drug Pricing Policies Under a Potential Reconciliation Package

Introduction

As Republicans begin 2025 in control of the White House, Senate and House of Representatives, it is widely anticipated that the new GOP Congressional majorities will leverage the budget reconciliation process to enact many of their priorities without the need for bipartisan support from Democrats. Budget reconciliation is an optional, special procedure outlined in the Congressional Budget Act (CBA) to expedite the consideration of a narrow category of spending and tax legislation; Congress intended reconciliation bills to fulfill fiscal goals set out in annual budget resolutions. The most important feature of a budget reconciliation bill is that it is not subject to the filibuster in the Senate and, thus, can be enacted by simple majority (51 votes), rather than the 60-vote threshold typically required to end a filibuster. However, the CBA places strict limits on this unique procedural mechanism. The most restrictive of these limits is the so-called "Byrd rule," which allows Senators to block provisions of reconciliation bills that are "extraneous" to a policy's federal budgetary effects. The Senate Parliamentarian is the neutral referee of the process, determining whether CBA guardrails like the Byrd Rule are followed; reconciliation proponents must make the case for each provision to the Parliamentarian and her team for their consideration and review (the "Byrd bath"). Notably, this procedure is not self-executing; a Senator must assert a point of order against a provision on the floor in order for it to be struck from the reconciliation bill.

In anticipation of the 119th Congress and expected activity leveraging the federal budget reconciliation process to advance drug pricing and supply chain reforms, Manatt analyzed 40 individual pieces of legislation encompassing a range of drug pricing and supply chain policy proposals from the 118th Congress to assess which of these might be eligible for enactment through the budget reconciliation process. Manatt examined the legislative text of these policy proposals and the Congressional Budget Office's (CBO) cost estimates to determine whether these provisions would survive the so-called "Byrd bath."

The table below describes the policies and relevant legislation, a CBO estimate (if one exists), the health insurance markets to which these policies would apply, and our assessment of whether these are appropriate for reconciliation.[i] Of the 40 pieces of legislation reviewed, only 12 of these bills (consisting of nine policies) appear to be appropriate for reconciliation at this time.

i. A three-fifths majority (60 votes) can waive a point of order against a provision under the Byrd rule and permit it to proceed. Too many provisions that waive the Byrd rule can jeopardize the privileged protections of the reconciliation bill altogether (also known as "fatal" to privilege). However, "too many" is subjective and based on the assessment of the Parliamentarian.

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Delinking	Part D	PBM may only charge flat fees not tied to price, discounts, rebates, fees or other remuneration with respect to prescription drug products.	Patients Before Middlemen (PBM) Act (S. 1967) Protecting Patients Against PBM Abuses Act (H.R. 2880) Modernizing and Ensuring PBM Accountability Act (S. 2973) Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261)	Close call.	In the case of H.R. 2880 (the only CBO-scored bill in this category), CBO has made clear that the federal budgetary savings stem from increased scrutiny by CMS and Office of Inspector General (OIG) of the fair market value standard, since current law requires PBMs to report fees exceeding fair market value. As a result of this increased scrutiny, PBMs will correctly classify more direct and indirect remuneration which would be passed on to plan sponsors, who will then submit lower bids, reducing Part D spending. While the Parliamentarian has ruled in the past that similar provisions involving oversight and program integrity are permissible in reconciliation, she has also ruled the other way, finding the budgetary impact "merely incidental" to the core policy operation of program integrity provisions. The success of this provision proceeding via reconciliation will depend on the strength of proponents' argument that the savings stemming from the transparency provisions of the bill are inextricably related to the provisions defining terms in the contracts between plans and PBMs.	(H.R. 2880) $226 million saver.	
	Commercial	PBM may only charge flat fees not tied to price, discounts, rebates, fees or other remuneration with respect to prescription drug products.	Delinking Revenue from Unfair Gouging (DRUG) Act (H.R. 6283/S. 1542)	Likely no.	While CBO is likely to score budgetary savings from this policy (see notes), the Parliamentarian has historically not found these savings sufficiently causally related to the operation of the policy, triggering the "merely incidental" bar.	No public score.	CBO is likely to score savings of this policy stemming from lower costs to plan sponsors, who will pass those savings along in the form of lower premiums. That change will raise cash wages, thus increasing tax collections.

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Transparency in Coverage Rule	Commercial	Requires PBMs to report specific measures both to plans and to the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS) and the Departments of Labor and Treasury.	Pharmacy Benefit Manager Reform Act (S. 1339)	No.	No budgetary impact.	No effect.	Generally, codifying a rule has no fiscal impact and thus is impermissible for reconciliation.
Enhanced Compensation Reporting for PBMs/TPAs	Commercial	Requires PBMs to report on direct and indirect compensation and on direct and indirect compensation for brokers and consultants to employer-sponsored health plans.	Pharmacy Benefit Manager Reform Act (S. 1339) Lower Costs, More Transparency Act (H.R. 5378) Pharmacy Benefit Manager Transparency Act (S. 127)	Likely no.	CBO describes the operation of this policy as similar to that of the pricing and fee transparency provision described below, in which increased disclosure of compensation and other fees will give plans more leverage to negotiate with PBMs. For the reasons described below, the Parliamentarian is likely to find that the budgetary impact of this provision is too causally remote from the operation of the core policy, making the budgetary effect "merely incidental" to its policy impact and thus impermissible.	If enacted alone, CBO projects savings of $1.3 billion.	
	Part D	Requires PBMs to report on direct and indirect compensation and on direct and indirect compensation for brokers and third-party administrators.	Protecting Patients Against PBM Abuses Act (H.R. 2880) Modernizing and Ensuring PBM Accountability Act (S. 2973) Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261)	Likely no.	Similar analysis as commercial market provision above	No score.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Spread Pricing Ban	Medicaid	Amount that PBM charges the plan must equal amount paid to the pharmacy.	Drug Price Transparency in Medicaid (H.R. 1613/S. 1038) Lower Costs, More Transparency Act, Sec. 202 (H.R. 5378) Modernizing and Ensuring PBM Accountability Act (S. 2973)	Likely yes.	This provision prohibits state Medicaid programs from contracting with PBMs or related entities unless the contract prohibits spread pricing. Since such provision is a "term or condition" of a federal payment, it is likely to survive scrutiny under reconciliation rules.	~$1 billion saver.	
	Commercial	Amount that PBM charges the plan must equal amount paid to the pharmacy.	Pharmacy Benefit Manager Reform Act (S. 1339) Pharmacy Benefit Manager Transparency Act (S. 127)	Likely no.	Unlike the Medicaid provision above, regulating the commercial market does not have the same direct nexus to federal spending. Thus, it is likely to fail reconciliation scrutiny on the same "merely incidental" grounds as the other commercial market regulations described here (see, e.g., "fee transparency to plans/sponsors").	No budgetary impact.	Section 2 of S. 1339 includes requirements pertaining to PBMs' contract provisions, such as banning spread pricing and requiring full pass-through of manufacturer rebates. CBO does not expect those provisions to affect the profits that PBMs would share with group health plans, unlike the amounts that would be affected as a result of the information disclosure mandate alone. PBMs derive compensation for their services in many ways, and the amounts they lose because any individual practice is regulated can be recovered by charging higher fees.

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Rebate Pass-Through	Medicaid	PBMs must remit all rebates to the plan.	Lower Costs, More Transparency Act, Sec. 202 (H.R. 5378) Modernizing and Ensuring PBM Accountability Act (S. 2973)	Likely yes.	Same analysis as Medicaid spread pricing ban.	No score.	
	Commercial	PBMs must remit all rebates to the plan.	Pharmacy Benefit Manager Reform Act (S. 1339)	Likely no.	No budgetary impact.	No budgetary impact.	Section 2 of S. 1339 also includes requirements pertaining to PBMs' contract provisions, such as banning spread pricing and requiring full pass-through of manufacturer rebates. CBO does not expect those provisions to affect the profits that PBMs would share with group health plans, unlike the amounts that would be affected as a result of the information disclosure mandate alone. PBMs derive compensation for their services in many ways, and the amounts they lose because any individual practice is regulated can be recovered by charging higher fees.

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Any Willing Pharmacy (Part D)	Part D	Specifies that a Part D plan sponsor must permit any pharmacy willing to meet its terms and conditions into its network.	Better Mental Health Care, Lower Cost Drugs, and Extenders Act, Section 201 (S. 3430)	Likely no on AWP, likely yes on NADAC "floor."	While CBO did not provide a narrative explanation, it's likely that they project a budgetary cost to this provision because it reduces Part D plan sponsors' bargaining leverage by requiring certain pharmacies to be included in networks. Proponents are likely to argue that the link between the policy's operation and its "downstream" fiscal impact is tighter than it would be in the commercial context, but it is still likely that that Parliamentarian finds this to be a regulatory change for which the downstream effect on raising Part D plan bids is "merely incidental" and thus impermissible. However, MEPA also requires (starting in 2028) Part D plans to reimburse certain independent community pharmacies not less than average NADAC. That requirement draws a more direct link between the policy and Part D plans' higher premium bids (as a result of the new reimbursement levels) and is more likely to survive Byrd rule scrutiny.	~$1 billion coster.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Pharmacy Reimbursement	Part D, Medicaid	Requires HHS to survey retail community pharmacies' drug prices to determine national average drug acquisition costs.	Better Mental Health Care, Lower Cost Drugs, and Extenders Act, Section 202 (S. 3430)	Likely no.	Requiring HHS to survey national average drug acquisition costs is a regulatory provision at its core, albeit one with significant savings due to projected lower reimbursement rates for drugs. On the Medicaid side, states must use the data in a specific way for the savings to materialize—exactly the kind of separate entity involvement that the Parliamentarian has found attenuates the connection between the operation of the policy and its savings.	~$2 billion saver.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
PBM Pricing and Fee Transparency to Plans/ Sponsors	Commercial	Requires annual reporting to plan sponsors on specific metrics for PBM services, including the amount of copayment assistance funded by drug manufacturers, a list of covered drugs billed under the plan during the reporting period and total net spending by the health plan on prescription drugs.	Pharmacy Benefit Manager Reform Act (S. 1339) Lower Costs, More Transparency Act (H.R. 5378) Pharmacy Benefit Manager Transparency Act (S. 127)	Likely no.	The budgetary savings arise from increased bargaining leverage by plan sponsors who would not otherwise have access to certain drug pricing and PBM remuneration information, enabling them to negotiate with PBMs for a larger share of those proceeds. CBO assumes those proceeds will go towards reducing premium, which, in turn, increases taxable income and, thus, revenue. The Parliamentarian is likely to find this increased revenue to be causally remote from the operation of the core policy, especially given the involvement of an independent entity (the plan), making the budgetary effect "merely incidental" to its policy effects.	~$2.7 billion saver.	
	Part D	Requires PBMs report to a PDP sponsor or an MA-PD plan sponsor on rebates and fees PBMs receive from drug manufacturers, which CMS must publish publicly and online at least annually.	Protecting Patients Against PBM Abuses Act (H.R. 2880) Modernizing and Ensuring PBM Accountability Act (S. 2973) Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261)	Likely no.	The analysis of this policy is similar to that described above, but proponents are likely to argue that the link between the policy's operation and its "downstream" fiscal impact is tighter than in the commercial context—primarily because Part D plan sponsors have less flexibility to decide how to use additional revenue.	~$720 million saver.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Cost-sharing for highly rebated drugs	Commercial	Implements cost-sharing limits for highly rebated drugs to reduce patient out-of-pocket costs.	Fairness for Patient Medications Act (H.R. 3285) PATIENT Act, Section 304 (H.R. 3561)	Likely no.	The federal budgetary impact of a change in commercial insurance regulation enacted by, for example, the Griffith Amendment in the House Committee on Energy and Commerce (E&C) markup is more attenuated than a Part D change (described below) and is thus unlikely to survive reconciliation scrutiny. Specifically, the Parliamentarian has previously found that a decrease (or increase) in tax revenue attributable to an increase (or decrease) in plan benefit generosity is "merely incidental" to the policy effects of the regulatory provision itself and has disallowed such a policy in reconciliation.	~$312 million cost for "highly rebated drugs."	
	Part D	Calculate post-deductible enrollee coinsurance for certain covered Part D drugs ("discount-eligible drugs") on their net prices inclusive of projected manufacturer rebates, rather than their Part D negotiated prices or other list price derivative.	Better Mental Health Care, Lower Cost Drugs, and Extenders Act, Section 203 (S. 3430)	Likely yes.	Given the precedent of including Part D redesign in the Inflation Reduction Act (IRA), it seems very likely that adjusting cost sharing limits for certain categories of drugs is permissible in reconciliation.	Costs $1.15 billion.	
Mid-year Biosimilars Formulary Changes	Part D	Under current law, Part D plans may alter formularies from year to year. This policy would enable mid-year formulary changes for biosimilar and biologic products.	Modernizing and Ensuring PBM Accountability Act, Section 608 (S. 2973)	Yes.	Given the precedent of Part B and D provisions in the IRA that adjust cost sharing (e.g., Part D no cost adult vaccine coverage), it seems very likely that allowing a Part D sponsor to change the cost sharing status of a reference biologic and add a lower cost sharing biosimilar is permissible in reconciliation.	$222 million saver.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Limits on Step Therapy	Commercial	Requires exceptions for step therapy protocols, which require patients to try less expensive treatment before accessing a more expensive therapeutic.	Safe Step Act (H.R. 2630/S. 652) Pharmacy Benefit Manager Reform Act (S. 1339)	No.	In spite of its substantial budgetary effect, the Parliamentarian would likely find this provision impermissible on the same grounds as other commercial market regulations (see e.g. "enhanced compensation reporting").	Costs $2 billion.	
Standardized Pharmacy Metrics	Part D	Implementing standard Part D measures for assessing network pharmacy performance.	Modernizing and Ensuring PBM Accountability Act, Section 602 (S. 2973)	No.	Provisions requiring adoption of standardized pharmacy performance measures have no budgetary impact (beyond appropriated implementation dollars) and are thus impermissible in reconciliation.	$4 million implementation funding.	
Anti-Gag	Commercial	Confirms that all private health plans are subject to bans on gag clauses, which prevent pharmacists from communicating lower-cost drug options to patients.	Transparency in Coverage Act (H.R. 4507) Lower Costs, More Transparency Act, Sec. 403 (H.R. 5378)	No.	Like the other commercial market regulations discussed above, the causal linkage (budgetary savings from increased revenues attributable to lower premiums caused by lower prices for prescription drugs) is insufficiently close to pass the "merely incidental" standard for a regulatory provision.	$34 million saver.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Federal PBM Proposals							
Discrimination against 340B Covered Entities	340B	Prohibits PBMs from discriminating against health providers that participate in the 340B drug program, including contract pharmacies.	PROTECT 340B Act (H.R. 2534) 340B PATIENTS Act (S. 5021/H.R. 7635)	Uncertain, but likely no.	CBO has released very little on how policies affecting 340B eligibility and payment terms affect the federal budget. In general, policymakers have assumed that 340B legislation has zero or negligible effect on the federal budget, given that no federal spending is involved—in which case these policies would be ineligible for reconciliation. However, these policies may have budgetary impacts as some remove from their regulatory operation. For example, CBO may find that PROTECT 340B Act's restrictions on PBM and plan reimbursement for 340B drugs has an effect on the volume of drugs purchased by covered entities, which, in turn, could result in increased Medicare spending to reimburse those purchases. CBO may project a similar spending increase associated with the PATIENTS Act's antidiscrimination provisions.	No.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Other Drug Pricing Proposals							
Eliminating the IRA's "Pill Penalty" Provision	Medicare Parts B & D	This policy would equalize the time period for eligibility for negotiation under the IRA for both small and large molecule drugs.	Ensuring Pathways to Innovative Cures (EPIC) Act (H.R. 7174)	Likely no, if not sunset or offset beyond the budget window. If this fiscal constraint is corrected, the measure is appropriate, given that the IRA was enacted via reconciliation, so changes to its provisions are generally permissible via reconciliation.	Across all policies, a reconciliation bill cannot increase the budget deficit outside the budget window—if a policy like this were included, it would need to be sunset at the end of ten years or offset in the out years to CBO's satisfaction. Setting this aside, an adjustment to eligibility for negotiation would be permissible, given that it produces a budgetary effect proximate to the eligibility change.	No score.	
Part B Maximum Fair Price (MFP) Effectuation	Part B	Requires a rebate by manufacturers for Part B drugs products subject to maximum fair price negotiation.	Protecting Patient Access to Cancer and Complex Therapies Act (S. 2764/H.R. 5391)	Yes.	The bill's rebate mechanism would require manufacturers to pay the Supplemental Medical Insurance trust fund, in certain circumstances, specified amounts determined with reference to average sales price (ASP) and MFP. CBO is almost certain to project federal savings from that mechanism, and those savings flow directly from the operation of the rebate requirement.	No score.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Other Drug Pricing Proposals							
Orphan Drugs in Medicare Drug Price Negotiation	Medicare Parts B & D	Under the IRA, orphan drugs are excluded from Medicare price negotiations, but only for drugs treating a single rare disease. Policy proposals to modify this would broaden this exception to permit drugs that treat "one or more rare diseases or conditions" to be excluded from the Medicare drug price negotiations.	Optimizing Research Progress Hope and New Cures (ORPHAN Cures) Act (S. 3131/H.R. 5539)	Likely yes.	While the Orphan Cures Act does not fully repeal any provision of the Medicare drug negotiation program, it straightforwardly changes the number of drugs that qualify for price negotiation. Increasing the number of drugs and biologics excluded from that process, and delaying those products' eligibility for negotiation as compared to current law, will necessarily reduce those cost savings and constitute a sufficient budgetary effect for inclusion. The bill also meets the Byrd Rule test that the provision be predominantly budgetary in nature.[ii] The bill amends a code section enacted through reconciliation; the Parliamentarian permitted that section's inclusion because it directly regulates expenditures by government programs, namely Medicare, by dictating the price terms that the government may pay. In adjusting the terms of that provision, the Orphan Cures Act's budgetary impact is similarly direct, if much smaller—reducing the number of drugs and, subject to negotiation, will increase government spending relative to current law without any intervening steps.	No score.	

ii. The operative text of the Byrd Rule follows: "…a provision [of a reconciliation bill or reconciliation resolution] shall be considered extraneous if it produces changes in outlays or revenues which are merely incidental to the non-budgetary components of the provision." 2 U.S.C. 644 (b)(1)(D)

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Other Drug Pricing Proposals							
Biosimilars Reimbursement	Part B	Implements a three-year demonstration project in which payment rates for biosimilar drugs under Part B would rise during the demonstration in an effort to increase access to biosimilar biological products.	Increasing Access to Biosimilars Act (H.R. 1352 / S. 3934)	Yes.	This policy is a direct Part B reimbursement increase, for a limited duration, for certain biosimilars. It has a clear and straightforward budgetary cost that is an immediate result of the policy. Given IRA precedent, this is permissible in reconciliation.	~$227 million coster.	
Coverage Determinations	Part D	Requires HHS to determine whether a request for a National Coverage Determination is complete within 90 days of receiving the request.	National Coverage Determination Transparency Act (H.R. 5389)	No.	No budgetary impact.	No score.	
Foreign Actors in the Pharmaceutical Supply Chain	Medicare, Commercial, Medicaid	Prohibiting certain entities that receive federal funds from using biotechnology that is from a company associated with a foreign adversary.	BIOSECURE Act (H.R. 8333)	Likely no.	The Parliamentarian is unlikely to recognize "asterisk" budgetary effects as satisfying the Byrd rule—especially one as policy-heavy as this. Further, the parliamentarian is likely to interpret the savings as "merely incidental" to the core policy a violation of the Byrd rule.	< $500k effect on federal spending (CBO).	
Accumulators	Commercial	Requires health insurance plans to apply third-party payments, including manufacturer coupons, to the calculation of patient's cost sharing limits.	Help Ensure Lower Patient (HELP) Copays Act (S. 1375/ H.R. 830)	Likely no.	Like the other commercial market regulations discussed above, the causal linkage (budgetary cost from decreased revenues attributable to higher premiums caused by a richer prescription drug benefit) is insufficiently tight to pass the "merely incidental" standard for a regulatory provision.	No score.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Other Drug Pricing Proposals							
Formulary Placement Rebates	Medicare, Commercial, Medicaid	Prohibits "kickbacks" or rebates for preferential formulary placement.	Ending of Prescription Drug Kickback Act of 2023 (S. 1217)	Likely yes.	This bill is likely to have the same large budgetary cost that the Trump "rebate ban" rule did. Given that the IRA—a reconciliation bill—postponed the implementation of that rule, this bill would likely be permissible in reconciliation given that precedent.	No score.	
Pay-for-Delay	Medicare, Commercial, Medicaid	Prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug.	Preserve Access to Affordable Generics and Biosimilars Act (S. 142)	Likely no.	The federal budgetary impact of policies that accelerate generic/biosimilar entry arise from the downstream effect of greater price competition and, consequently, lower prices. While the impact on Medicare and Medicaid is more direct (for the reasons described above) than those on commercial payors, neither is proximate enough to the regulatory operation of the provision to pass Byrd rule scrutiny.	$1.6 billion saver.	
Citizen Petitions	Medicare, Commercial, Medicaid	Permit civil action against any person or entity that submits a baseless petition to the Food and Drug Administration (FDA) intended to delay approval of a generic, biosimilar biological product or certain other new drugs.	Stop Stalling Access to Affordable Medications (S. 148)	Likely no.	Same as pay for delay above.	$401 million saver.	
Product Hopping	Medicare, Commercial, Medicaid	Prohibits product-hopping by drug manufacturers and authorizes the FTC to sue in court or institute administrative proceedings to enforce this prohibition.	Affordable Prescriptions for Patients Act of 2024 (H.R. 9070/ S. 150)	Likely no.	Same as pay for delay above.	$3 billion saver.	

Policy	Market	Policy Description	Relevant Legislation	Appropriate for Reconciliation	Rationale on Reconciliation	CBO Score	Other Notes
Other Drug Pricing Proposals							
"Q1/Q2"	Medicare, Commercial, Medicaid	Requires FDA to inform generic drug applicants, upon request or during review, whether the drug is qualitatively and quantitatively the same as the listed brand-name drug (and, if not, the reasons why).	Increasing Transparency in Generic Drug Applications Act (H.R. 3839/ S. 775) Lower Costs, More Transparency Act, Sec. 201 (H.R. 5378)	Likely no.	Same as pay for delay above.	$871 million saver.	
Switching Studies to Qualify for Interchangeability	Medicare, Commercial, Medicaid	Prohibits FDA from requiring that biosimilars undergo switching studies to receive an "interchangeable" designation.	Biosimilar Red Tape Elimination Act (S. 2305)	Likely no.	Same as pay for delay above.	No score.	Sen. Lujan offered this legislation as an amendment to S. 2840, the Bipartisan Primary Care and Health Workforce Act. However, the amendment was not voted on during the HELP Committee markup (9/26/2024)
Patient Experience Data	Medicare, Commercial, Medicaid	Requires FDA to consider relevant patient experience data in the risk-benefit assessment framework used in approving new drugs.	BENEFIT Act (S. 526)	Likely no.	Any savings/spending resulting from accelerating entry of brand or generic drugs to market is likely to be too speculative to pass Byrd rule scrutiny.	No score.	

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