April 8, 2019

Submitted electronically via: https://www.regulations.gov


Dear Mr. Levinson:

The National Business Group on Health appreciates the opportunity to comment on the proposal to expressly exclude from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations; and, create new safe harbors that protect 1) discounts offered to patients at the pharmacy counter and 2) fixed fee services arrangements between manufacturers and PBMs.

The National Business Group on Health (NBGH or the “Business Group”) represents 440 of the nation’s largest employers, including 74 of the Fortune 100, who voluntarily provide group health plans, prescription drug coverage and other employee benefits to over 55 million American employees, retirees, and their families.

We applaud the department’s effort to make changes in Medicare policy, with an aim at redesigning how drugs are priced at the pharmacy counter. As noted in the department’s own fact sheet, The National Business Group on Health’s Large Employer 2019 Health Care Strategy and Plan Design Survey revealed that three quarters of large employers do not believe drug manufacturer rebates are an effective tool to drive down pharmaceutical costs and over 90% of employers would welcome an alternative to the rebate-driven approach to managing drug costs.

While the Business Group is supportive of elements of the proposal that seek to remove the gross-to-net incentive gap with upfront discounts, we have several serious concerns with the proposal including 1) a weighted focus on out-of-pocket (OOP) costs; 2) the potential to increase list prices by passively incenting price collusion; 3) the potential to increase list prices by failing to address antitrust law; 4) a financial windfall to manufacturers; 5) a disincentive for the promulgation of value and/or risk-based payment models; 6) an unworkable implementation timeline; and 7) an increase in beneficiary premiums.
Evaluating alternatives to the current manufacturer rebate-driven model is an important step toward deescalating drug prices and we support the primary goals of the department’s proposal to redesign AKS safe harbors for manufacturer rebates, which include 1) lowering list prices of prescription drugs; and, 2) OOP spending on prescription drugs.

However, when taken in context with other proposals being contemplated by the Administration, such as the various components of the American Patients First Blueprint, we urge the department to remain open to there likely being multiple concurrent solutions that improve upon the current model within the private and public sector.

Adopting a model that seeks to more closely align patient cost with net drug prices is a step toward improved transparency and affordability but, focusing only on rebates is a diversionary tactic from the real pricing conundrum created by the dynamics of the supply chain, starting from initial pricing all the way to the sale at the pharmacy counter.

As efforts continue to explore levers to achieve lower list prices and reduced OOP spending, primary concerns for our members include:

1. Continuing to develop market-based solutions that prioritize consumers’ affordability, improve clinical outcomes, and simplify a complex system, which include but are not limited to point-of-sale (POS) rebate/discount programs.

2. Improving transparency of the total cost of pharmaceutical and medical spending, including through data integration between the medical and pharmacy benefits to better understand drug value.

3. Correcting misaligned financial incentives within the pharmaceutical supply chain, particularly as specialty pharmacy costs remain among the top three drivers of overall health care trend.

4. Promoting a policy environment that encourages a more competitive and dynamic prescription drug market with correspondingly more affordable prices and one that embraces value and risk-based payment arrangements.

5. Maintaining the ability to design formularies based on the cost-effectiveness of pharmaceuticals.

The Business Group agrees with the idea of removing the gross-to-net gap incentive with upfront discounts.

- In the absence of rebate-optimizing formularies, consumers’ cost-sharing would be linked to a lower list price, which would reduce OOP costs and could improve adherence and outcomes.

- POS discounts 1) increase transparency of net price, 2) remove the link between list price and revenue for supply chain intermediaries, 3) encourage manufacturers to favor lower list prices, and 4) eliminate incentives for PBMs to favor higher list prices for increased rebate revenue streams.
The Business Group has several serious concerns with the proposal.

(1) The proposal focuses on out-of-pocket costs.
   • While we support the proposed increased transparency and pricing relief for patients, we urge policy makers to avoid “quick fixes” that focus only on OOP costs, as opposed to total cost to the system.
   • Focusing only on OOP costs has the potential to mask root causes of high list prices and price increases, potentially lead to even higher increases over time, and drive the escalating trend on drug expenditures.

(2) The proposal may increase list prices by passively incenting price collusion.
   • The potential for collusion among manufacturers, if exact amounts of rebates are disclosed, has been documented by the Federal Trade Commission (FTC) and the Congressional Budget Office (CBO), which could increase list prices, particularly in classes where there are only a few drugs available – this is a phenomenon that could also apply to the disclosure of upfront discounts.

(3) The proposal may increase list prices by failing to address antitrust law.
   • Absent Congressional action, antitrust law may prohibit manufacturers from offering the same level of price concessions through an upfront discounting system that they do currently by way of market share-based rebates.
   • This sentiment was echoed at the February 26, 2019 hearing of the Senate Committee on Finance by CEOs of several major pharmaceutical manufacturers.

(4) The proposal as written results in a financial windfall to manufacturers.
   • Reduced OOP costs would lead to fewer patients reaching the coverage gap phase, where manufacturers must provide a discount of 70%.
   • It has been estimated that brand drug manufacturers would pay out nearly $10 billion to $29 billion less in price discounts in the Part D coverage gap over ten years because fewer patients reach the coverage gap.
   • While savings is expected, that savings should be realized comprehensively across both the supply and demand sides of the pharmaceutical supply chain and not disproportionately benefit or disadvantage any stakeholder.

(5) The proposal does not an exception for any retrospective remuneration from a manufacturer to a PBM/insurer.
   • An alternative rebate model should provide a broad safe harbor for outcomes-based contracts and indication-specific pricing agreements to allow for experimentation that can lead to the establishment of best practices.

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2 Orszag P. Letter to House Committee on Ways and Means; and House Committee on Energy and Commerce. March 2007.
4 Senate Committee on Finance. Hearing: Drug Pricing in America: A Prescription for Change, Part II. February 26, 2019
• These types of contracts generally need to have an option for a “true-up” payment that, if not called a rebate, would function in a similar manner.

(6) The proposal seeks to implement a timeline that is arguably too aggressive.
• PBMs have largely already concluded negotiations on price concessions for plan year 2020 and are in the middle of actuarial analysis to prepare bids.
• There is little ability to properly renegotiate bids in time to know the associated costs of implementation of the proposal.

(7) The proposal will result in premium increases.
• The proposal is projected to increase the cost of healthcare for those who don’t use drugs with upfront discounts, through premium increases, while disproportionately decreasing costs for those who do use drugs with upfront discounts.
• According to the proposal, absent any behavioral changes that would reduce net prices, Part D premiums are projected to increase in 2020 and beyond, ranging from $3.20 per beneficiary per month to $5.64 per beneficiary per month (PBPM).
• HHS actuaries have estimated that the policy could cost taxpayers between $27 billion to $82 billion over ten years, depending on the minimum rebate amount, as increasing premiums would require more federal subsidy for enrollees.  

Nearly all employers believe the pharmaceutical supply chain model needs to change. Increased employer scrutiny of the pharmaceutical supply chain is precipitated by the growth of high-deductible health plans over the past decade; a plan design change that illuminated for consumers, policymakers and the media what plan sponsors have observed for years – trends of high and rising drug prices. Previously, consumers were insulated from high drug prices when pharmacy plan designs were built around copays.

Simultaneously, this structural change also revealed the deficiencies of the complex, opaque and antiquated design of the pharmaceutical supply chain, which could be described as a “rebate-driven” contracting model. Employers are eager for change within the supply chain:

• 14% Believe it needs to be more transparent;
• 35% Believe rebates need to be reduced; and
• 49% Believe the model needs to be overhauled and simplified.

Most employers do not believe rebates are an effective mechanism of controlling drug costs. Rebates, while historically have served as a negotiating lever with manufacturers, especially in drug classes with multiple bioequivalent alternatives, have become less efficient overtime and create financial burden for patients when list prices increase but net prices after rebates are more modest. As a result, nearly half of large employers are “concerned” or “very concerned” that in today’s high-deductible plan environment, the rebate-driven model does not benefit patients at the POS.

This phenomenon – the “gross-to-net bubble” – underscores the perverse nature of rebates negotiated as a percentage of list prices, which have had the impact of reducing price efficiency

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7 2019 Large Employers’ Health Care Strategy and Plan Design Survey, National Business Group on Health
for both patients and plans sponsors who seek to provide affordable, quality health coverage for employees.

- 75% of employers do not believe drug manufacturer rebates are an effective tool for helping to drive down pharmaceutical costs; and
- 91% would welcome an alternative to the rebate-driven approach to managing drug costs.

Large employers recognize consumer benefit of POS rebates, but they’re not a comprehensive solution for controlling drug prices.

Although POS rebate models are not a silver bullet for drug pricing concerns, as PBMs have developed market capability to pull the value of rebates forward to benefit consumers at the POS, employers have begun including them as part of their plan offerings to reduce OOP costs for employees.

- 27% of large employers will have a POS rebate program in place in 2019; and,
- Another 31% are considering implementation by 2021.

While the rebate-driven contracting model is ripe for reform, and there are perhaps few who would defend it, simply passing the rebates (or discounts) through to either payers or patients will not meaningfully reduce overall pharmaceutical spending without other policies that drive toward value. In addition to contracting concerns within the rebate-driven model, there remains substantial opportunity for policy change relative to prescription drug prices, most of which would encourage a more competitive and dynamic market with correspondingly more affordable prices.

Advance Policies to Promote More Affordable, Financially Sustainable Prescription Drug Pricing.

Many of the recommendations below are directed toward various agencies in the Administration and several of them require Congressional action. All of these policy recommendations are highlighted in the National Business Group on Health’s Issue Brief on Policy Recommendations to Promote Sustainable, Affordable Pricing for Specialty Pharmaceuticals.

1. Remove Uncertainties Surrounding Risk-based and Value-Oriented Contracting and Implement Indication Specific Pricing and Reference Pricing in Public Programs.
   - Consider exemptions for value-based contracts from Medicaid best price requirements and clarify how drug makers and payers can conceive of value-based contracts without triggering broader Medicaid best price program implications.
   - Allow for variable pricing, where the price better reflects the evidence for benefit.
   - Evaluate the usefulness and application of the existing developed value frameworks and their potential to impact drug pricing in public programs, as well as their overall utility to the health care system.
   - Directly link reimbursement and improved patient outcomes.
   - Consider how drug makers and payers can enter into other types of innovative value-based payment (VBP) arrangements, such as indication-specific pricing.
   - Implement reference pricing policies supported by clinical evidence consistently across public programs, where possible.
(2) Limit Reach of Medicare Part D Protected Classes.

- Following the MedPAC’s recommendations, the Congress and CMS should limit legislative and regulatory restrictions on formulary design within protected classes by modifying the Medicare Part D rules to remove those protected classes where enough generic competition exists, a change that would give private plans more freedom to control their formularies and negotiate for expanded manufacturer rebates.

- Specifically, CMS should resubmit its proposal to remove antidepressants, antipsychotics, and immunosuppressants for transplant rejection from the list of protected classes because, in these classes, price reductions have been more closely linked with the availability of generics than to their status as “protected” and stand firm against industry-funded campaigns that seek to undermine the agency’s data-driven proposal to increase competitive pricing.

- At a minimum, policy makers should evaluate the potential anticompetitive influence of protected classes on the commercial market and, specifically, evaluate the limitations imposed on private payers’ ability to negotiate competitive prices for drugs in the protected classes due to market spillover.

(3) Eliminate Perverse Payment Incentives Under Medicare Part B.

- Eliminate financial incentives for prescribing more expensive medicines, in more expensive settings.

- Establish direct links between reimbursement and improved patient outcomes.

- Encourage manufacturers to assume some financial risk for use of high-priced drugs.

(4) Encourage the Uptake of Biosimilars.

- Consider the utility of having an “interchangeability” distinction and potential alignment with the European biosimilars model, which has no such distinction.

- Work with stakeholders to disseminate provider and patient education to firmly establish the safety and efficacy of biosimilar drugs to their reference products, recognizing that key successes to the uptake of biosimilar medicines in other countries was predicated on the creation of trust and confidence among all the stakeholders involved, such as prescribers, pharmacists and patients.

- Maintain payer autonomy to implement utilization management tools for specialty pharmaceuticals, including tools that pertain to biosimilar products.


- Reduce the market exclusivity period for biologics from 12 years to 7 years.

- Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited, or no additional company investment or patient value produced.

- Develop sound policy that would discourage patent abuses such as “evergreening” and “product hopping.” These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.

- Refine the biosimilars patent dance to effectively incentivize the use of the section 351(l) patent dispute resolution provisions.

(6) Reject Anticompetitive “Quick Fixes.”
As consumers find themselves paying more of their drug costs, it’s tempting to be lured into new policies which may only further contribute to an anticompetitive climate. These policies may include specialty drug price caps, OOP payment caps, limitations on utilization management tools and mandated disclosure of propriety information.

Additionally, a federal law permitting importation nationwide could lead to some price reductions for both payors and patients in the short-term but, as markets adapt, it is unclear what the long-term effect on prices would be. It would also likely require a significant boost in resources for the Food and Drug Administration (FDA) to monitor imports and assure safety.

We thank you for the opportunity to comment and look forward to working with you on our shared goals for health care: lower costs, improved access, and higher quality – umbrella goals inclusive of prescription drugs. Please contact Steven Wojcik, the National Business Group on Health’s Vice President of Public Policy, at (202) 558-3012, if you would like to discuss our comments in more detail or if we can provide additional information as the department continues its evaluation of drug pricing.

Sincerely,

Brian J. Marcotte
President and CEO