Prepared Testimony of Mike Kolar
Interim President and CEO

Submitted to the U.S. Senate Committee on Finance
Drug Pricing in America: A Prescription for Change, Part III

April 9, 2019

Chairman Grassley, Ranking Member Wyden, and Members of the Committee, thank you for the opportunity to discuss how pharmacy benefit managers (PBMs) and, in particular, Prime Therapeutics LLC, provide value to the health care system.

I am Mike Kolar, and I serve as the Interim President and CEO of Prime. At Prime, our mission is to make health care work better by helping people get the medicine they need to feel better and live well. We do this by managing pharmacy benefits for health insurers, employers, and government programs including Medicare and Medicaid. Our goal is to ensure that the members and beneficiaries of these plans and programs get the medication most appropriate for their condition at a cost that is the most affordable in the context of their overall insurance benefit. This mantra of "right drug, for the right person, at the right time, and at the right cost," guides our actions every day.

We appreciate the Committee's efforts to thoroughly examine issues related to the problem of high drug costs. We see firsthand the challenges that these costs cause for our plans, for their members and beneficiaries and for taxpayers. In 2018, drug costs represented 27 percent of total health care costs for our commercial clients. A portion of this increased spend results from newly introduced therapies, which have the potential to improve outcomes and avoid medical costs for payers and individuals. But it is the price and value of these new therapies as well as existing therapies, as set by pharma and pharma alone, that needs to be effectively questioned, checked and balanced. As a unique, transparent pharmacy benefits manager, our value lies in applying our clinical expertise to serve as an effective hedge against otherwise unmitigated pricing behaviors and to make medication more affordable.

We agree that high drug costs present a problem for individuals and society. We look forward to sharing more about our how our unique, transparent approach and the clinical value we provide addresses the problem as it exists today. We will provide our thoughts on how the key issues of transparency and manufacturer rebates should be viewed in framing solutions to the problem of high drug costs. And we will share our views on other effective means of reducing the high cost of prescription drugs for the benefit of plans, employers, patients and taxpayers.

Prime Represents a Unique PBM Model

Prime Therapeutics was formed in 1998 by two Blue Cross and Blue Shield Plans seeking to more effectively manage plan and member drug costs. Starting with only a few million members, Prime has grown over the last 20 years to provide pharmacy benefits to over 28 million individuals, from 23 Blue Cross Blue Shield plans as well as federal employees served by the Federal Employee Program (FEP®). Prime's growth has been driven by our ability to effectively manage drug costs for these plans and their members as a trusted, transparent partner. Our integration with our Blue Cross and Blue Shield clients allows us to leverage our view into both pharmacy *and* medical data to improve care and reduce costs. This helps our plans to best serve the specific needs of their respective local communities.

Today Prime is owned and controlled solely by 18 not-for-profit Blue Plan clients. This makes us the only major PBM with a primary mission focused on driving savings instead of margins. We are not beholden to the short term, quarterly need to report earnings to Wall Street shareholders. We are free to focus on delivering the lowest net cost on prescription medicines and driving lowest overall cost of care for our clients and their members. We are driven to get the right drug, for the right person, at the right time, and at a cost that is as affordable as possible in the context of a member's overall insurance benefit to help ensure sustainability and optimal health outcomes.

Prime Applies Extensive Clinical Expertise to Reduce Drug Costs

The core value we provide our clients and their beneficiaries is based upon our deep clinical pharmacy expertise. We employ pharmacists and physicians and engage an independent Pharmacy and Therapeutics (P&T) Committee made up of 26 actively practicing, nationally recognized medical and pharmacy experts to evaluate the safety, efficacy and value of existing and emerging drug therapies. This expertise allows us to advise our plan clients regarding drug coverage decisions, utilization policies, and adherence, intervention and therapy management programs to lead to better patient outcomes, ensure quality and patient safety, and manage costs. The common misperception that Prime and other PBM's are simply transactional "middlemen" entirely ignores the immense value we provide in helping to ensure clinically appropriate drug utilization to drive better outcomes.

The retail prices of some of the most popular prescription drugs older Americans take to treat everything from diabetes to high blood pressure to asthma increased by an average of 8.4 percent in 2017, far exceeding the 2.1 percent inflation rate for other consumer goods and service.[i] Rising costs from specialty drugs and high prices of new specialty drugs have had an even more significant impact on overall drug prices. These specialty drugs treat complex, chronic conditions, like multiple sclerosis and rheumatoid arthritis. These drugs are usually injected or infused. They require careful oversight from a health care provider and require special handling. Over half of all drugs approved by the FDA in 2018 were specialty drugs.[ii] According to a recent report from the Pharmacy Benefit Management Institute, less than 5 percent of commercially insured patients use specialty medications, but they constitute half of overall drug costs.[iii] Prime predicts that specialty drugs will be 60 percent of all drug spend by 2021.

While pharmaceutical companies keep introducing new drugs at high prices and raising prices on existing drugs, we work hard to counter these rising costs by appropriately managing utilization and negotiating for lower net reimbursement. Prime's management tools are critical to managing both drug trend and quality. The results of our efforts can be shown by the savings we generate. Despite rising costs overall, Prime's programs delivered nearly $3.4 billion in incremental value to our health plan clients in 2018. In an environment of rising prices and new, high cost drug introductions, Prime has a long track record of successfully managing overall drug trend. Trend defines the difference of drug spend between one year and the next. It is affected by the number of people using which drugs (utilization) and the prices of those drugs. Prime's commercial clients experienced a drug trend of only 3.3 percent in 2018, and experienced a negative trend in 2017. Prime was similarly successful in managing drug trend in government program markets. Here, where full utilization of our clinical and negotiating tools is significantly limited by current regulations, we achieved a 4.7 percent trend in Medicare and 7.3 percent in Medicaid for 2018, and -0.8 percent and -5.4 percent, respectively for 2017.[iv,v]

We achieve these results by leveraging our clinical expertise to advance quality, optimize utilization and manage net price for our clients and their members and beneficiaries through:

- **Formulary management**, including pipeline management and formulary development. Our P&T Committee evaluates the clinical efficacy and safety of new and existing medications and approves and regularly reviews our clinical recommendations for each drug, including coverage, clinical appropriateness and safety. Our P&T Committee meets quarterly and reviews all drug categories annually. We also make formulary recommendations regarding preference or "tiering" using a lowest net drug cost approach. That occurs only after our initial clinical safety and efficacy determinations, and with an additional concern for minimizing member impacts across any transitions.

- **Utilization management**, including prior authorization, step therapy and quantity limits.

    - When a provider prescribes a drug that could potentially be misused in an unsafe or ineffective manner, prior authorization serves as an additional check, in collaboration with the care provider, to confirm that the drug is appropriate for the particular patient and their condition. This is done to ensure safety and avoid unnecessary costs for the plan and the patient.

    - Step therapy programs similarly help avoid unnecessary costs for the payer and patient by recommending effective, lower cost, "first line" therapies prior to administration of a costlier alternative.

    - Quantity limits also help avoid waste and manage cost for all parties by recommending limited initial trial quantities of a medication to ensure it achieves the intended outcome and/or does not result in harmful side effects before additional doses are dispensed and paid for by the plan and patient.

- Our **GuidedHealth™ program,** promoting optimal member medication management through retrospective drug utilization reviews. GuidedHealth (GH360) is a population health database and clinical rules engine that uses integrated medical and pharmacy data to identify opportunities to lower drug and medical costs. Prime identifies these opportunities and intervenes with doctors, members and pharmacies through a multi-channel communication strategy (e.g. pharmacist case management, direct messaging to prescribers via electronic medical records (EMR), phone, text, email, mail) to help guide better drug therapy. Examples of opportunities include medication non-adherence, gaps in care, drug safety concerns, drug/condition management issues, high cost specialty drug management interventions and chronic disease management programs. In our experience, each dollar spent on these types of programs yields up to $8 in cost savings for our plan clients and their members or beneficiaries, totaling more than $350M in savings, and growing, each year.

- **Pharmacy network management**, designed to ensure access, quality and affordability for beneficiaries and plans. Prime maintains contracts with over 60,000 retail pharmacies nationwide representing in aggregate over 91 percent of all pharmacies in the United States. Prime highly values the role of the local pharmacist in serving patients and ensuring appropriate medication therapy, including pharmacists' role in counseling patients on drug administration, interactions, adherence and safety. We partner closely with pharmacists and local pharmacies in these activities. In constructing networks of local pharmacies to serve members and beneficiaries, we drive both higher quality and more affordable costs for the benefit of patient.

- **Fraud, waste and abuse** (FWA) programs that aggressively combat activities that burden plans, members and taxpayers with costs that are wholly unnecessary, and not infrequently, have a basis in criminal activity. Our activities in rooting out fraud, waste and abuse resulted in $268M in savings in 2018 alone for our clients, their members and beneficiaries.

- **Value-based contracting** (VBC), designed to hold a pharmaceutical manufacturer accountable for the overall effectiveness of its drug. Prime's goal with VBC strategies includes evaluating the effectiveness and value that a drug has on a member's total cost of care, including both pharmacy and medical costs. Our value-based contracts focus on all aspects of care, including channel management, persistency and compliance, health monitoring, diagnostic testing, and health outcomes assessments. We signed our first VBC contract in 2010. Since then, we have contracted with pharmaceutical manufacturers for value-based arrangements in therapeutic areas that affect large groups and gaps in care (e.g. diabetes, cardiovascular disease, chronic migraine) as well as those that are high cost for our clients' members (e.g. hepatitis, rheumatoid arthritis, ulcerative colitis, multiple sclerosis).

- One example of our value-based contracting is our arrangement with the manufacturer of an oral type 2 diabetes medicine indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. Our contract evaluates the incidence and total cost of care for certain cardiac events among patients taking this medication and links payment for the drug to improved outcomes. We believe that this type of evidence-based, outcome-driven reimbursement model underscores the unique value that Prime can bring in the drug market to ensure that prices become more aligned with quality and economic value.

We believe that these capabilities and additional capabilities under development provide significant value for our clients and their members and beneficiaries. We welcome opportunities to expand the application of our programs to drive additional savings in government programs. Specifically, Prime supports the August 2018 CMS change that allows plans to create indication-based formularies – formularies that cover specific drugs for specific indications – for Medicare beginning in 2020. Indication based formularies are currently used in our commercial business. The ability to bring this expertise to Medicare will provide plans additional flexibility and choice in formulary design, and will improve drug affordability for plans and beneficiaries.

Beyond cost control, our clinical expertise plays a key role in patient safety. PBMs are the entities in the health care system that are best situated to know and to coordinate all the medications that a patient takes. Neither pharmacies nor physicians are currently guaranteed to see the entire spectrum of a patient's prescriptions. A 2012 study found slightly more than one-third of patients use multiple pharmacies to fill their prescriptions.[vi] A more recent study of Part D patients reported that even more – 38 percent - used multiple pharmacies.[vii] Individual physicians may also not know all the medication their patients use. According to a recent *Consumer Reports* survey, over half (53 percent) of Americans who take prescription drugs get them from more than one health care provider, which increases the risk of adverse drug effects.[viii] PBMs like Prime play an important role in identifying inappropriate utilization and adverse drug interactions. Prime's concurrent drug utilization program screens medicines at the point of sale for potential drug therapy problems such as drug-to-drug interactions, inappropriate refill timing and potential overuse or misuse. If an issue is flagged, Prime collaborates with the local pharmacist to address the issue with the patient and to provide clinically appropriate guidance on how to proceed.

As health care becomes more complicated, and as personalized medicine and companion diagnostics (i.e. a laboratory genomic test whose result determines therapy) become more prevalent, we see additional opportunities to use our clinical expertise to collaborate with physicians and allied health professionals to manage medication therapies. The clinical expertise and tools of a PBM like Prime can help to continue to ensure the right patient gets the right therapy at the right time even as science and research continue to advance.

Prime Believes in Transparency

From our inception 20 years ago, our business model was built on transparency, and we understand the importance of transparency in the health care system overall. We believe that the right kind of transparency within the PBM model can improve outcomes and lower costs for members and beneficiaries. We would caution, however, that the wrong kind of transparency will ultimately lead to higher drug prices.

In Prime's view, there are five audiences for the right kind of transparency:

(1) client transparency
(2) patient transparency
(3) government transparency
(4) physician/prescriber transparency; and
(5) pharmacy transparency

Client Transparency: Client transparency is the hallmark of Prime's unique business model. Unlike the clients of other PBMs, Prime's clients see their respective drug costs at a unit cost level. Prime also shows clients *all* the savings Prime generates on their behalf, including pharmacy savings and rebates. Savings are passed back to clients to offset the cost of services and to help keep premiums affordable. To be clear, Prime's model is to send the *entire* rebate back to our clients.

Enrollee/Patient Transparency*:* Prime believes it is vitally important that its members make informed choices. Presently, Prime has tools that are available to patients to enable them to more easily understand their pharmacy benefits. We maintain a website at *MyPrime.com* that allows members access to pharmacy benefit information. *MyPrime.com* is a personalized platform where members can find pharmacies, understand coverage and tiering, and find actual prices for prescription drugs, including their applicable cost share. We share information about *MyPrime.com* with members upon plan enrollment and thereafter in other beneficiary communications.

We also support efforts to advance adoption of a real-time benefit tool (RTBT). This provides an easy-to-use, complete view of a beneficiary's prescription benefit information including cost, formulary alternatives, and utilization management requirements at the point of prescribing. This allows both the patient and his or her prescriber to make informed decisions using both clinical and pricing information. To drive rapid adoption and widespread use, we believe that RTBTs should be based upon a standardized platform, such as the in-process standard being finalized by the National Council for Prescription Drug Programs (NCPDP). This standard will provide the guardrails to ensure consistent, thorough, and quality communication of prescription benefit information. This will aid practitioners and patients in making informed, real-time drug decisions at the point of prescription, eliminating surprises and delays that adversely impact medication utilization and adherence, and, ultimately, health outcomes.

Government Transparency: The Center for Medicare & Medicaid Services (CMS) collects very detailed information from PBMs about Part D transactions through its mandatory Direct and Indirect Remuneration (DIR) reporting. CMS has a thorough line of sight into all rebates, fees and payment adjustments, which are reported to CMS as DIR on a drug by drug basis. Further, each plan submits bids annually to CMS by the first Monday in June. Those bids reflect the plan's expected benefit payments plus administrative costs after they deduct expected federal reinsurance subsidies, and the level of CMS payment to plan sponsors is derived from actual plan bids.

Prime supports legislation recently introduced by Senators Cornyn, Cortez Masto, Carper and Cassidy that would allow the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission access to CMS's DIR data to inform Congress' decision-making on Part D policy. Our support is based upon the important protections for proprietary data included in the legislation that will mitigate the risk of adverse, anti-competitive consequences that could cause drug prices to increase.

Physician and Allied Health Professional Prescriber Transparency*:* Prime provides prescribers with access to formularies and regularly communicates changes in formularies and other coverage information, and we believe that adoption of RTBTs will provide an enhanced user experience and more rapid transparency to aid prescribers in making informed prescription decisions.

In addition to supporting RTBTs, we also support electronic prescribing directly to patients' pharmacies. This vastly improves efficiency for health care professionals and pharmacy interactions for patients. We were pleased that last year's SUPPORT Act, P.L. 115-271, included a requirement that Part D plans use electronic prior authorization (ePA).

Pharmacy Transparency: In our relationships with pharmacies we seek to ensure quality by scoring pharmacy performance on key metrics as such as medication adherence and generic dispensing rates, which aid in improving a member's health outcomes and reduce costs. Prime provides quarterly results to the pharmacies and includes data for reconciliation. In our quality based networks, pharmacies earn incentives based upon their performance on key metrics that are relevant to the CMS Stars ratings. Prime uses EQUIPP, an industry standard dashboard that allows pharmacists to track their performance and predict their likely results. Prime meets with pharmacies monthly to review their performance and discuss improvement options. Price concessions earned because of underperformance on quality metrics are remitted in full to our plans for member-facing premium reductions and quality programs, and for reporting to CMS.

Misguided Transparency: Many aspects of transparency are laudable. These are already fully present in Prime's business model, and aid in better managing drug spend for clients and their members and beneficiaries. But we believe proposals that would require disclosure or visibility into *actual* negotiated rebates would have an adverse impact and would likely result in an increase in overall drug costs.

Our view is supported by the Federal Trade Commission (FTC), which has studied the issue and found that such disclosure creates a risk for anti-competitive behavior by manufacturers that would increase prices. Currently, manufacturer rebates to PBMs are confidential, and competing manufacturers do not know the rebate offered by their competitors. When rebates are disclosed, the FTC warns that this type of price transparency may "allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price or increases the likelihood that they can coordinate on higher prices."[ix] In the brand drug market, where a limited number of manufacturers offer similar products within a therapeutic class, net price transparency may cause these manufacturers to raise prices.

Rebates Effectively Offset, Rather Than Cause, High List Prices

One of the key PBM levers for creating competition and value is drug rebates. A rebate is an after-the-fact (usually quarterly), percent reduction off the full list price of a drug given to the end purchaser whether that be a government entity, an employer or an insurer. They are a powerful tool used by PBMs to offset the list prices set by pharma. The 2018 Medicare Trustees' report credited PBM-negotiated rebates, in part, for bringing Part D spending lower than in the Trustees' 2017 Report.[x] Similarly, a recent Oliver Wyman study found that Part D plan-negotiated manufacturer rebates have resulted in $34.9 billion in premium savings for enrollees from 2014 to 2018.[xi] As rebates are an effective tool to manage and mitigate pharma pricing behaviors for the benefit of plans and members, we strongly believe that they cannot and should not be curtailed or eliminated without viable, concrete and equally effective means of placing similar competitive pressure on manufacturers and holding them accountable for drug pricing.

While rebates are an important savings tool, they are not Prime's first consideration in making formulary recommendations. Prime's formulary selection process is tied to safety and efficacy consideration *before* accounting for competitive pricing. In considering competitive pricing, we take a "low net cost" approach: Prime will often forgo rebates on a certain drug in favor of a clinically equivalent, lower-cost medication. In Medicare Part D, Prime has more than a 90 percent generic dispensing rate, and generic drugs generally do not offer rebates. In situations in which a rebated drug is covered and rebates are earned, Prime's model is to pass back 100 percent of the value of rebates we negotiate to our clients.

The relationship of rebates to drug prices and the role of rebates is very much misunderstood. Prime disputes the idea that rebates are the primary cause of high list prices. Indeed, many drugs have high and significantly increasing list prices *without* offering any rebates. The HHS OIG found that 39 percent of Part D drugs offered no rebates in 2015.[xii] Additionally, there are very limited rebates in Part B, and Part B has nonetheless seen significant price increases in the drugs the program covers, including drugs that increased in price from 2012 to 2017 by between 76 and 3,449 percent.[xiii] Pharmaceutical companies could lower list prices on these drugs today but have generally not chosen to do so. Where pharmaceutical companies have lowered list prices, there is generally little effect on net costs to the payer or the products are "minor."[xiv]

Instead of rebates making drugs less affordable, the lack of rebates for certain drugs makes them less affordable. In general, pharmaceutical manufacturers do *not* pay rebates on cancer drugs since plans typically do not implement traditional formulary management tools for these therapies. However, we continue to experience increases in price. As an example, in Medicare Part D in 2018, Prime's clients saw the greatest increase in spending for oral cancer drugs stemming from both an increase in price and utilization. The trend grew from 3.3 percent in 2017 to 19.4 percent in in 2018 for this class.

As this cancer example illustrates, there *is no correlation between rebate levels* and manufacturer list prices.[xv] The determining factor of whether a given brand drug will offer a rebate is the competitiveness of the therapeutic class.[xvi] As MedPAC states in its March 2019 report:

> "*In general, the extent to which a manufacturer of a specific drug can raise its price depends on many factors - for example, whether there are generics or brand therapeutic alternatives, how many competitors there are in the given market, and whether their competitors cover all the same indications. Competition within a therapeutic class can result in restraint in list-price growth or in higher post sale rebates and discounts.*"

Where there is no competition in a therapeutic class or if a drug demonstrates clinical superiority over existing therapies, there may either be no rebate or just a very small rebate.[xvii] In Medicare's protected classes, plan sponsors have limited options to not cover or restrict access to certain drugs. When there are limited options to treat a specific disease state, PBMs have little ability to influence pharma pricing. Drugs in high cost specialty classes like oncology, hemophilia and hereditary angioedema generally do not have rebates. In classes where products are deemed clinically interchangeable, such as insulins, diabetes medications (SGLT, DPP-IV), and respiratory drugs to treat asthma and COPD, competition drives greater rebates that can be leveraged for the benefit of payers, members and beneficiaries.

One of the concerns over rebates is that patient cost-sharing in certain plan designs is determined by the list price of a drug rather than the net price. Over the past decade, the patient's role in sharing in prescription drug costs has evolved considerably. The advent of high-deductible health plans and greater use of coinsurance has increased the proportion of health care costs consumers must pay out of pocket. While such benefit designs were intended to give beneficiaries more control, a very real consequence has been increased exposure to the extreme drug pricing behavior of manufacturers. Patients are justifiably frustrated with the unacceptably high drug prices and unjustified price increases set by pharma, which drive up their costs without providing additional health value.

Prime offers commercial health plan clients and employer groups the option to adjust the prices of drugs in their benefit plans to reflect rebate savings, including the option of applying the rebate savings at the point of sale when a member receives a prescription from a pharmacy. This plan offering allows members with high deductibles and coinsurance to benefit from rebates at the point of sale, but there is a trade-off between premiums and a point-of-sale rebates. Point-of-sale rebates help those who face high coinsurance or deductibles but may cause an increase in premium.

In the commercial market, the majority of members served by Prime are not affected by high list price influenced cost-sharing. They pay flat dollar copays rather than coinsurance (i.e. a percentage of the list price). Indeed, only 1 percent of the commercial membership served by Prime is subject to coinsurance with no out of pocket maximum, while 56 percent of the members we serve are enrolled in plans with a flat co-pay without a deductible and 4 percent are in plans with a flat copay with low deductibles. Neither of these latter two groups are meaningfully affected by the list price of a drug.

Similarly, in Medicare Part D, many beneficiaries do not face significant cost-sharing. Cost-sharing is minimized for the 29 percent of Part D beneficiaries that receive low-income subsidies, also called "Extra Help," who pay flat, nominal amounts for drugs including brands.[xviii] Prime realizes that a small percentage of beneficiaries are challenged by the current Part D benefit design due to the high cost of certain medications. As MedPAC reports, in 2016, approximately 360,000 Part D beneficiaries filled a prescription for which a *single* claim would meet the maximum out-of-pocket threshold, up from 33,000 in 2010.[xix] Prime welcomes the opportunities to work with policymakers, beneficiaries and plans to help Part D enrollees who face high cost-sharing. At the same time, we recognize that that Part D enrollees are very premium sensitive, and are generally pleased with their benefit: a recent nationwide survey found that 85 percent of Part D enrollees are satisfied with their Medicare Part D prescription drug coverage, with over eight out of 10 also saying that their Part D plans provide "good value." The same survey research indicates that 78 percent of seniors feel that their copays and coinsurance are affordable.[xx] Another recent survey of seniors in Part D found that they are satisfied with their out-of-pocket costs by a 67 percent to 30 percent margin.[xxi]

As we work towards policy solutions to further address high drug costs, we believe that the important role rebates play in managing cost requires careful study. The lack of a proven link between list price and rebates, the need for plan flexibility in designing benefits and keeping premiums low, and the need for an equally effective means of holding pharma accountable must all be considered before enacting measures that would mandate redirection or cause rebates to be curtailed or eliminated.

Prime Offers Policy Solutions

Prime welcomes the opportunity to partner with the Committee and other federal policymakers to advance initiatives to lower drug prices and improve health care. For instance, we support changes to anti-kickback law and Medicaid best price that would catalyze further value-based contracting and provide greater regulatory certainty around such contracts.

We believe that high list prices are the central issue driving the drug cost problem, and that PBMs are the most effective organizations capable of bringing down drug costs for payors and patients. An optimally competitive drug marketplace helps us to fully deploy our tools to lower costs for our plans, for their members and beneficiaries and for taxpayers. We therefore support such policies as:

- *Addressing Part D's protected classes:* Designating "classes of clinical concern" in Part D, where all or substantially all drugs in a class must be covered allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage in all drug classes. Prime supports a CMS proposal to moderate the effect of protected classes—not eliminate them—that would save $2 billion over 10 years.[xxii]

- *Modify the requirement for two drugs per class*. The requirement that Part D plans cover two drugs per class is outmoded. It has encouraged manufacturers to argue for ever more granular classes and reduced competition, increasing Part D costs. Modifying the requirement by requiring plans to ensure access to therapies based on conditions or disease states instead would reduce costs without reducing access to needed drugs.

- *Apply Part D management tools to Part B drugs.* PBM tools such as value-based formularies, manufacturer negotiation, prior authorization, and step therapy have proven indispensable in improving patient safety and lowering costs in outpatient prescription drug plans like Part D. Adding Part D management tools to the Medicare fee-for-service program and building on efforts in Medicare Advantage for Part B drugs would make drugs more affordable on Medicare's medical side. We also believe policymakers should explore using economic value assessments to ensure that payments for drugs are based on cost savings and quality outcomes for patients.

- *Eliminate pay-for-delay agreements:* Patent settlements involving "pay-for-delay" agreements allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic or biosimilar drug. These anti-competitive agreements should be eliminated.

- *End risk evaluation and mitigation strategy (REMS) abuses.* Brand drug manufacturers have withheld drug samples from would-be generic manufacturers by citing REMS compliance as an excuse. Enacting the CREATES Act or similar legislation would prohibit these abusive practices used by a small minority of brand drug manufacturers to keep competitors off the market.

- *Address orphan drug exclusivity abuses.* Orphan drug exclusivities are meant to encourage research into therapies to address rare diseases. However, the exclusivities afforded by orphan status have been abused. In fact, six of the eight best-selling biologic drugs in 2017 have orphan approvals, but the drugs have been widely used for non-orphan indications. Orphan exclusivity periods should apply to only those drugs originally approved by FDA under an orphan indication and only for the orphan indication itself.

- *Tackle patent "ever-greening"* or patenting a small change in an existing drug to prevent generic competition. The advent of generic drugs, and particularly multiple generic drugs brings down drug prices, and ever-greening blocks this competition, keeping prices unnecessarily high. Brand patents should not result in near-permanent exclusivity.

- *Encourage faster FDA approval of "me-too" brands:* Increasingly the drugs FDA reviews and approves are reviewed under accelerated approval to address "unmet needs." The imperative for greater competition to lower drug prices should also be considered a type of unmet need.

- *Promote biosimilar interchangeability:* The FDA has yet to finalize guidance on interchangeability. Such guidance would allow substitution of biologics with biosimilars just as pharmacists do today with brand name drugs to lower costs for patients.

- *Eliminate the tax deduction for direct-to-consumer (DTC) drug ads.* While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of drug benefits and often encourage patients to demand a brand name over a generic. Tax deductions should end for ads mentioning a specific product.

Conclusion

We appreciate the Committee's interest in our perspectives on the problem of high drug costs, the role that PBMs and Prime play in helping to manage those costs, and our views on the issues of transparency, rebates and potential policy solutions that can effectively address the drug cost issue.

We believe that the clinical expertise and solutions we offer create significant value for our clients and their members and beneficiaries by ensuring that the right drugs are accessible and affordable, in the context of overall benefit designs, at the right time and for the right patients.

We are a unique PBM. We are owned solely by Blue plans and are designed to serve their needs through a transparent, lowest net cost model to enable them to serve their members and communities. We are hopeful that our perspective is useful in the dialogue and in leading to constructive solutions.

---

[i] Bunis, Dena. "Retail Prices of Brand-Name Drugs Continue to Skyrocket," September26, 2018, AARP, https://www.aarp.org/health/drugs-supplements/info-2018/prices-rising-for-name-brand-drugs.html

[ii] Health Insurance.org "*Glossary."* https://www.healthinsurance.org/glossary/specialty-drug/ and https://www.pcmanet.org/pcma-cardstack/what-is-a-specialty-drug/

[iii] Pharmacy Benefit Management Institute, "2019 Trends in Specialty Drug Management," https://www.pbmi.com/ItemDetail?iProductCode=SPECIALTY_2019&Category=SPECIALTY

[iv] "Prime Therapeutics Keeps High Drug Cost Trends at Bay: Annual Trend Reports Released, March 19, 2019, https://www.primetherapeutics.com/en/news/pressreleases/2019/release-2018-drug-trend.html

[v] "Prime Releases Proves PBM's Value: Delivers Negative Drug Trend in 2017," February 20, 2018, https://www.primetherapeutics.com/en/news/pressreleases/2018/drugtrend-2017-release.html

[vi] Eder, Rob, "Why Patients Use Multiple Pharmacies," *Drugstore News,* Ag. 28, 2012 https://www.drugstorenews.com/news/why-patients-use-multiple-pharmacies/

[vii] Z.A. Marcum et al, "Impact of Multiple Pharmacy Use on Medication Adherence and Drug-drug Interactions in Older Adults with Medicare Part D," J Am Geriatr Soc. 2014 Feb; 62(2): 244–252. Downloaded from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115075/

[viii] "Americans Taking More Prescription Drugs Than Ever," *HealthDay Reporter,* Aug. 3, 2017 https://www.webmd.com/drug-medication/news/20170803/americans-taking-more-prescription-drugs-than-ever-survey

[ix] Koslov, TI, Jex, E. "Price transparency or TMI?," Federal Trade Commission, July 2, 2015, https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.

[x] https://www.cms.gov/newsroom/press-releases/medicare-trustees-report-shows-lower-spending-projections-medicare-part-d

[xi] Oliver Wyman, "Premium Impact of Removing Manufacturer Rebates from the Medicare Part D program,' July 6, 2018, downloaded from https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf

[xii] HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," *Data Brief* OEI-03-15-00080, June 4, 2018, downloaded from https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp

[xiii] Visante, "Reconsidering Drug Prices, Rebates, and PBMs," downloaded from https://www.pcmanet.org/wp-content/uploads/2018/08/Reconsidering-Drug-Prices-Rebates-and-PBMs-08-09-18.pdf."

[xiv] Thomas, Katie, "Merck is Lowering Drug Prices. There's a Catch," *New York Times,* July 18, 2018, https://www.nytimes.com/2018/07/19/health/merck-trump-drug-prices.html

[xv] Visante, "Reconsidering Drug Prices, Rebates, and PBMs," downloaded from https://www.pcmanet.org/wp-content/uploads/2018/08/Reconsidering-Drug-Prices-Rebates-and-PBMs-08-09-18.pdf

[xvi] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

[xvii] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

[xviii] J. Cubanski, A. Damico and T. Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," May 17, 2018, downloaded from https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/

[xix] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

[xx] http://medicaretoday.org/2018/08/85-percent-of-u-s-seniors-are-satisfied-with-their-medicare-part-d-prescription-drug-coverage-according-to-nationwide-survey/

[xxi] North Star Opinion Research, National Survey of Seniors Enrolled in Part D, March 2019, https://www.pcmanet.org/wp-content/uploads/2019/03/NSO-PCMA-Senior-Part-D-Survey-Memo-March-6.pdf

[xxii] Owermohle, Sarah, *Politico Prescription Pulse,* "CMS Takes on 'Protected Classes in Part D'", November 27, 2018. https://www.politico.com/newsletters/prescription-pulse/2018/11/27/cms-takes-on-protected-classes-in-part-d-431017