

Drug Pricing in America: A Prescription for Change III

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Drug Pricing in America: A Prescription for Change, Part III

**Submitted to the United States Senate Committee on Finance
April 9, 2019**

Chairman Grassley, Ranking Member Wyden, and the members of the Committee, thank you for the opportunity to be here today. My name is Dr. William Fleming and I am a pharmacist. I have spent nearly 30 years working in a variety of pharmacist roles, including 25 years with Humana. I currently serve as Segment President of Humana’s clinical organization, which includes pharmacy, home health, and behavioral health.

I am honored to join you today, and I look forward to working with the Committee to achieve our shared goals of reducing prescription drug prices for Americans and improving the Medicare Part D prescription drug program for current and future beneficiaries.

Humana is an integrated health and wellness company focused on providing value to seniors by operating a holistic, health outcomes-driven model that is beneficiary-centric, and which focuses on chronic care and contains locally-integrated health capabilities. Humana currently provides Medicare prescription drug coverage for more than 8.4 million seniors across all 50 states, with approximately 4 million Medicare Advantage (MA) members and 4.4 million Medicare Prescription Drug Plan (PDP) members. We also provide medical coverage for approximately 1.5 million commercial customers, more than 340,000 Medicaid beneficiaries, and 5.9 million TRICARE enrollees in the eastern United States. Humana is unique in that our pharmacy and medical teams are tightly integrated and focused solely on serving our own members – not those of other payers. As a result, the savings we achieve through our pharmacy programs, such as manufacturer rebates and discounts, accrue directly to our members through lower premiums and improved benefits.

Humana’s integrated approach to serving seniors delivers a personalized and simplified experience through a value-based health ecosystem that improves clinical outcomes. This ecosystem includes 233 owned, jointly-owned, or allied primary care facilities; an ownership interest in the nation’s largest home health and hospice providers;¹ as well as initiatives to address social determinants of health.

Humana’s Transparency and Clinical Innovation Tools

Humana is focused on providing seniors with the best care possible. As part of that goal, Humana has developed innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs to reduce costs and improve health outcomes including:

- ***IntelligentRx***: Humana was the first Part D plan to provide real-time access to drug cost and formulary information to physicians and their patients through our *IntelligentRx* tool. *IntelligentRx* enables physicians and their patients to make joint treatment decisions based upon efficacy *and*

¹ 40 percent stake in Kindred At Home and CURO Health Services

cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.

- **Maximize Your Benefits (MYB) Program:** Humana continuously analyzes our members' prescription drug claims to identify opportunities for them to save money by switching to a lower-cost drug or by pointing them to other savings programs such as foundation-based cost-sharing assistance. Based upon that analysis, we proactively reach out to our members and provide instructions on how to maximize their savings opportunities. We estimate that the program saved our members almost \$200 million in 2018.
- **Clinical Pharmacy Programs:** Humana also ensures that seniors are taking the right combination of drugs necessary to improve their health through our clinical programs – medication therapy management (MTM) and medication reconciliation during transitions of care from facility to home. Through these programs, we help seniors by eliminating duplicative drugs, identifying lower-cost options, supporting medication adherence, and identifying possible adverse drug interactions. As a result of these initiatives, beneficiaries have increased medication adherence by as much as 13 percent and have experienced reduced emergency room visits, urgent care visits, and hospital admissions.

I appreciate the Committee's keen interest in working to understand better the root causes of high drug costs and advancing policy solutions.

Evolution of the Medicare Part D Program

Less than 15 years ago, Americans did not have access to an outpatient prescription drug benefit under Medicare. Today, more than 43 million seniors have access to life-improving medicines through Part D.²

At the inception of the Medicare Part D program, Congress designed a competitive marketplace where prescription drug plan sponsors competed based upon premium. As a result, seniors enrolled in prescription drug coverage have gained significant value from the program's focus on market competition including:

- Stable premiums through the 13 years of the program averaging approximately \$30 per month by negotiating rebates to lower costs for all seniors;³
- Generic dispensing rates near 90 percent;⁴
- Medicare beneficiaries average more than 26 Part D plan sponsor options;⁵
- A 50 percent reduction in medication non-adherence due to affordability;⁶ and
- Beneficiary satisfaction rates near 90 percent.⁷

² March 2019 Report to the Congress: Medicare Payment Policy: http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

³ Ibid

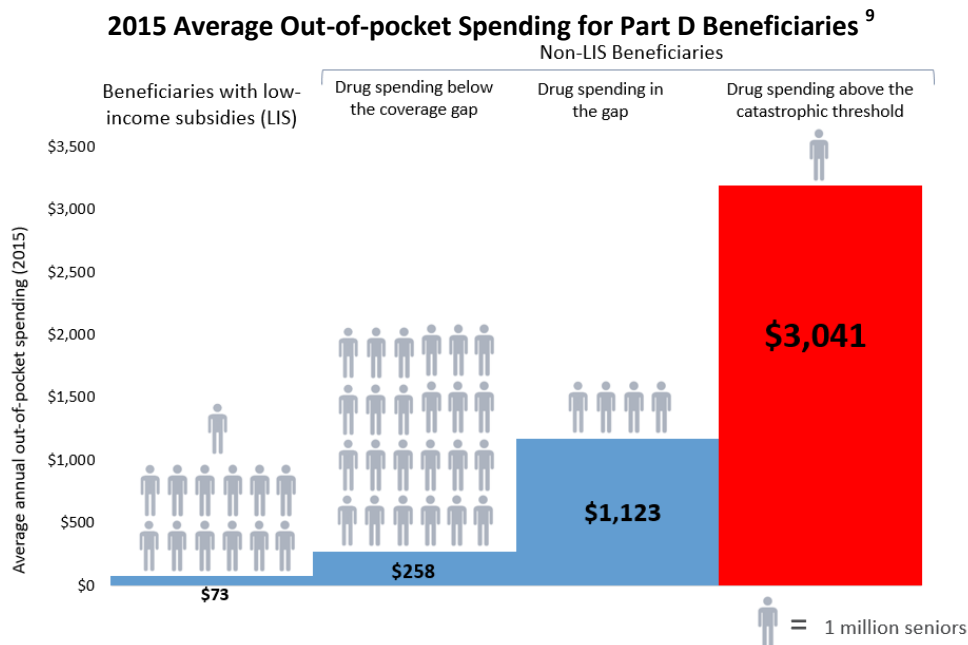
⁴ Ibid

⁵ Ibid

⁶ Diebold, Jeffrey. The Effects of Medicare Part D on Health Outcomes of Newly Covered Medicare Beneficiaries. *The Journals of Gerontology: Series B, Volume 73, Issue 5, July 2018, Pages 890–900*: <https://academic.oup.com/psychsocgerontology/article/73/5/890/2631953>

⁷ 2018 Medicare Today Senior Satisfaction Survey: <http://medicaretoday.org/resources/senior-satisfaction-survey/>

Despite the benefits realized by Part D beneficiaries, there are still seniors who struggle with the increasing cost of prescription drugs. This is especially true for the one million beneficiaries who are not eligible for the low-income subsidy who reach the catastrophic phase of the benefit each year and generally spend more than \$3,041 in out-of-pocket costs for their prescription drug needs.⁸



The most recent Medicare Payment Advisory Commission (MedPAC) Report to the Congress from March 2019 echoed the challenges for the populations of seniors with high drug costs:¹⁰

- **Beneficiaries in the catastrophic phase continue to see increasing costs:** Spending for high-cost beneficiaries (those who reached the catastrophic phase) increased from 40 percent of Part D spending in 2011 to 58 percent in 2016.
- **The average list price increased 10 percent annually:** MedPAC cites the growth in the average price of drugs filled by high-cost beneficiaries as the most significant factor for spending growth among high-cost beneficiaries. The price per standardized, 30-day prescription for high-cost beneficiaries grew annually at 10 percent from 2010-2016.
- **Ten times the number of seniors reached the catastrophic phase on first fill in 2016:** The number of seniors who reached the catastrophic phase through a single claim increased from

⁸ See Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter available here <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>

⁹ Kaiser Family Foundation. No Limit Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs without a Hard Cap on Spending. <https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/>; Kaiser Family Foundation. 10 Essential Facts About Medicare and Prescription Drug Spending. Jan 29, 2019: <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>; Kaiser Family Foundation. Medicare Part D in 2016 and Trends over Time. Sep 16, 2016: <https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program/>. Part D enrollment figures reflect 2016 enrollment.

¹⁰ March 2019 Report to the Congress: Medicare Payment Policy: http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

33,000 in 2010 to 360,000 in 2016. Non-LIS beneficiaries were more likely to have this claim than LIS beneficiaries.

- **Spending on specialty drugs accounted for four times the share since 2007:** Specialty-tier drugs accounted for 25 percent of Part D overall gross spending in 2017, an increase from 6 percent in 2007.

Humana’s experience reflects the challenges faced throughout the Part D program. In 2018, two percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending. In two years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending.

Ultimately, policymakers are faced with the challenge of preserving the benefits of the Part D program – which has been successful for many – while modernizing the program to address the new challenges in the prescription drug market since the program’s inception in 2003.

Anti-competitive Behavior by Drug Manufacturers

As members of the Committee have highlighted in previous drug pricing hearings, a major factor contributing to the increase in drug spending is the list price of prescription drugs. **Drug manufacturers alone set the list price of prescription drugs.** Drug manufacturers have also historically engaged in a host of tactics meant to delay generic competition, including preventing generic manufacturers from obtaining drug samples, utilizing the Risk Evaluation and Mitigation Strategy (REMS) process to block timely entry of generics, utilizing loopholes in the patent system to delay and thwart the market entry of lower cost competitors, and paying generic manufacturers to delay market entry. According to the Federal Trade Commission (FTC), these anti-competitive “pay-for-delay” actions alone increase costs for seniors and American taxpayers by \$3.5 billion annually.¹¹

Blocking entry of generic competitors

One tactic for blocking competition is the practice commonly known as patent “evergreening” or “product hopping” where drug manufacturers extend a brand drug’s patent exclusivity through the development of new formulations or products that offer clinically insignificant additional benefits. This practice is inherently anti-competitive and is designed to outright block or challenge the legitimate market entry of generic competitors, raising drug costs for seniors. For example, Forest Laboratories’ Namenda (memantine HCl) is indicated for the treatment of moderate to severe Alzheimer’s disease. When the 5/10 mg tablets were scheduled to go off-patent in April 2015, Forest responded by creating a “new” version marketed as Namenda XR (an extended release version of the drug) and obtained a new patent, providing the manufacturer with an additional 14 years without generic competition.¹² In 2015, the first year with generic memantine HCl tablets, the annual per-user cost decreased 23.8 percent in Part D, consistent with Calendar Year (CY) 2011 levels. In contrast, the per-user cost of patent-protected Namenda XR increased 52.2 percent from CY 2014 to CY 2015.

¹¹ See <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>

¹² Michael Carrier & Steve Shadowen, *Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis*, HEALTH AFFAIRS BLOG (June 1, 2017); Letter from Patrick G. Boen, Senior Director, Clinical Development at Forest Research Institute to providers (Feb. 2014) (announcing plans “to discontinue the sale of NAMENDA” (memantine HCl) tablets on August 15, 2014).

There are numerous additional examples where a brand drug manufacturer has delayed competition to preserve its monopoly, resulting in astronomically high drug prices:

- Humira, the highest-selling drug in the world, has received six different orphan drug designations since 2005. Its drug price increased by 200 percent from 2012-2018 to \$38,000 per patient.¹³
- The REMS for Thalomid, an earlier iteration of Celgene's top-selling cancer drug Revlimid, has been patented over 14 times in order to delay the development of generics. The price for Revlimid rose from \$6,195 in 2006 to \$16,691 in 2017.¹⁴ The Medicare program spent an average of \$88,437 per beneficiary for a year of Revlimid treatment in 2017.¹⁵
- The price of Evzio, a drug manufactured by Kalèo and utilized for emergency treatment of known or suspected opioid overdoses with a novel delivery mechanism, has risen by approximately 600 percent since 2014.¹⁶

These actions from brand drug manufacturers weaken the ability of plan sponsors to negotiate lower costs for prescription drugs. Plan sponsors have been most successful negotiating lower drug costs on behalf of beneficiaries when there is sufficient competition in the market. According to the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT), the:

- **Federal spending on retail prescription drugs is flat:** For the second consecutive year, retail prescription drug growth has decreased; the 0.4 percent growth has been driven by a continued shift to lower-cost generic drugs and declines in generic drug prices.¹⁷
- **Cost of drugs with limited competition has increased at double the rate:** Conversely, there have been significant price increases for drugs subject to limited or no competition. In 2016, the cost of single-source drugs with no generic alternatives increased at more than double the rate of average annual drug spending.¹⁸

The trend of increasing list prices for prescription drugs with limited competition is seen for prescription drugs administered in both clinical settings, which are typically covered by Medicare Part B and are generally considered specialty drugs, and dispensed at the pharmacy counter, which are typically covered by Medicare Part D.

- **90 percent of the Medicare B drugs with the highest expenditure have no generic:** A 2017 study performed by the Government Accountability Office (GAO) found that Medicare Part B drugs with the highest expenditures are predominantly single-sourced (84 percent) without a

¹³ FDA <https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm>

¹⁴ Alison Kodjak, "How A Drugmaker Gamed The System To Keep Generic Competition Away," NPR, 5/17/18

¹⁵ CMS 2017 Part D Drug Spending Dashboard available here: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

¹⁶ Ken Alltucker, "Drug Company Raised Price Of Lifesaving Opioid Overdose Antidote More Than 600 Percent," USA Today, 11/19/18)

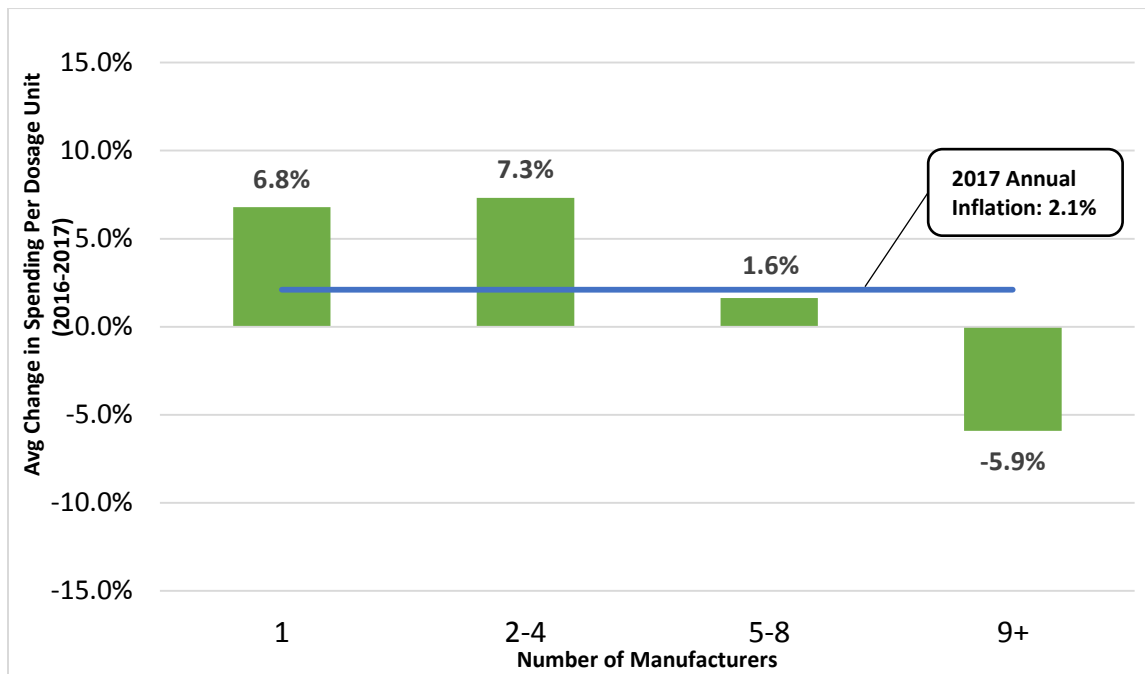
¹⁷ CMS Office of the Actuary Releases 2017 National Health Expenditures, available online at <https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures>

¹⁸ Ibid.

generic option (90 percent).¹⁹ This has resulted in a market where eight of the top ten Part B top-expenditure drugs have an annual cost of \$10,000 to \$30,000.²⁰

- **List prices increase beyond inflation for Part D drugs with fewer than five manufacturers:** An analysis of 2017 Part D prescription drug spending found that prescription drugs with less competition were more likely to have list price increases than drugs with five or more manufacturers.²¹

Year over Year Growth in Prescription Drug Costs Decreases with Competition in Part D²²



¹⁹ GAO, Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015 GAO-18-83: Published: Dec 18, 2017, available online at <https://www.gao.gov/assets/690/689082.pdf>

²⁰ MedPAC, Medicare and the Healthcare Delivery System, available online at http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0

²¹ Based on Humana analysis of the CMS 2017 Part D Drug Spending Dashboard & Data, available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>. The CMS dashboard includes all Part D organizations and plan types. Part D PDE records were summarized by drug by linking National Drug Codes (NDCs) available in the PDE data to a commercially available database and aggregated across all strengths, dosage forms, and routes of administration to the drug brand name and generic name. CMS did not provide NDCs in the public use file. Over-the-counter drugs in the PDE data are excluded as well as NDCs with fewer than 50 claims in the current (2017) or previous year (2016). In addition, NDCs with large variations in reported units from year to year were reviewed by CMS on a case-by-case basis and data anomalies were excluded. Drug spending metrics for Part D drugs are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees. Part D drug spending represents total spending for the prescription claim, including amounts paid by the Medicare Part D plan and beneficiary payments. The Part D spending metrics do not reflect any manufacturers' rebates. For purposes of this analysis, we removed Part D covered supplies, such as syringes and alcohol swipes for diabetics, and weighted average change in spending per dosage unit by 2017 claim volume. Average 2017 inflation rate is sourced from the Bureau of Labor Statistics website.

²² Ibid

HHS OIG proposed rule does not address anti-competitive behavior

The recently proposed regulatory changes to the Anti-Kickback Statute's Safe Harbors from the Office of the Inspector General (OIG) at the Department of Health and Human Services (HHS) will not address any of the anti-competitive actions from drug manufacturers detailed above and, in some cases, will only increase the bargaining power of manufacturers. Drug manufacturers alone set the list price of prescription drugs; nothing in the proposed rule compels drug manufacturers to lower the list price of drugs.

Recommended legislative actions

The examples of anti-competitive pricing detailed above and the importance of competition require innovative policy approaches to enhance competition in the market, especially for specialty drugs. Humana strongly supports the introduction of S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, as well as S. 64, the Preserve Access to Affordable Generics and Biosimilars Act, developed under Chairman Grassley's leadership. We believe the enactment of these bills will encourage the development of generic and biosimilar drugs that will infuse additional competition into the market, prevent brand drug manufacturer REMS abuses that block generic competition, and penalize brand drug manufacturers for engaging in pay-for-delay agreements.

The Food and Drug Administration (FDA) is taking proactive steps within its regulatory authority

Humana applauds the FDA's efforts to bring additional competition and transparency to the prescription drug market. In particular, Humana supports the FDA's Drug Competition Action Plan and the goal of removing barriers to generic development and market entry to increase competition, improve access, and lower costs.

Policymakers within Congress and the Administration have been focused on addressing the rising prices of prescription drugs. In January, the HHS OIG proposed a rule that modifies the current Discount Safe Harbor under the Anti-Kickback Statute to exclude from discounts protected by the Safe Harbor rebates negotiated by PBMs, Part D plan sponsors, and Medicaid managed care plan sponsors.²³ The OIG's proposed rule also establishes a new Safe Harbor allowing those rebates to be applied to reduce the price at the pharmacy counter.

Through the proposed rule, HHS ultimately seeks to reduce out-of-pocket cost of prescription drugs for those currently covered by Medicare and Medicaid and ultimately to reduce the list price of prescription drugs. *However*, the rule fails to take into account the role of rebates in reducing the price of premiums for all beneficiaries and in reducing costs to the federal government. The proposed rule also fails to consider the complexity of operationalizing the new requirements by the proposed January 1, 2020, implementation date and the downstream behavioral impacts of beneficiaries, drug manufacturers, and plan sponsors.

Rebates are currently used to lower premiums

Currently, plan sponsors utilize rebates as a tool to ensure that beneficiaries are obtaining the greatest possible value from their Medicare coverage. Savings that are obtained by Humana through rebate negotiations with drug manufacturers are distributed to our entire beneficiary population through reduced premiums for Part D coverage, resulting in lower costs for seniors in PDP and MA plans.

²³ Available here: <https://www.regulations.gov/document?D=HHSIG-2019-0001-0001>

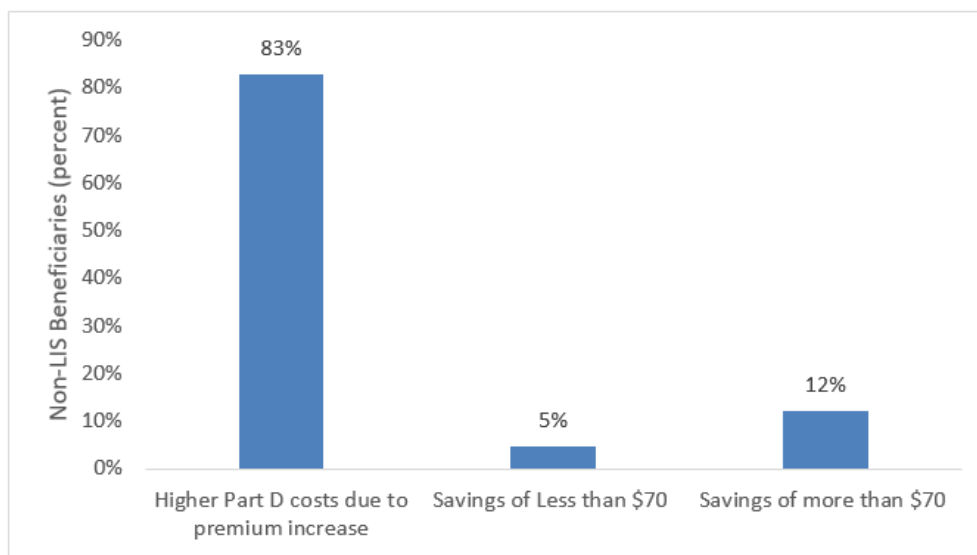
Additionally, rebates have resulted in significant savings to the government. As cited in the Medicare Trustees Report, rebates have played a critical role in keeping the overall cost of Part D lower than projected when the program was first launched in 2006.²⁴

The proposed rule will lead to higher premiums and increase costs to the government while creating a windfall for drug manufacturers

If the proposed rule is finalized as written, all Part D beneficiaries will pay higher premiums. Rebates that have historically been utilized to lower premiums across the program will no longer be applied to the entire population and will instead be utilized to reduce out-of-pocket costs for a small number of seniors. The analysis performed by the CMS OACT indicates that shifting cost savings from rebates to a beneficiary's co-pay will increase the overall cost of the Part D program for the majority of beneficiaries, the government, and Part D plan sponsors.

Humana's analysis found that approximately 17 percent of beneficiaries would see savings at the pharmacy counter, with only 12 percent saving more than \$70 annually.²⁵ The remaining 83 percent of beneficiaries will see an *increase* in costs for prescription drug coverage due to premium increases that will exceed any potential savings the beneficiary may have experienced at the pharmacy.²⁶

Impact of Proposed Rule on Part D Beneficiary Premiums²⁷



The small number of beneficiaries who will benefit from the rule will do so at a significant cost to the government. The projections developed by the OACT estimate that government outlays for the Part D program would increase by approximately \$200 billion while beneficiaries would save approximately

²⁴ 2018 Medicare Trustees Report: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

²⁵ Based upon internal analysis of estimated premium impacts for CY 2020 resulting from the proposed rule.

²⁶ Ibid.

²⁷ Based on internal analysis of estimated premium impacts resulting from the proposed rule.

\$25 billion; this means that government spending will increase approximately \$7 for every one dollar of savings realized by beneficiaries.²⁸

The rule also creates a significant windfall for drug manufacturers through reduced liability in the Coverage Gap Discount Program (CGDP). According to the analysis performed by OACT, drug manufacturers will realize savings of \$44 billion over a ten-year period.²⁹

The proposed rule will lower out-of-pocket costs for a limited number of seniors

The proposed rule will have a limited impact on seniors at the pharmacy counter. An analysis based upon 2017 claims data for prescription drugs from CMS found that only 7.8 percent of total prescriptions filled were for drugs for which Humana has a rebate agreement in 2019.³⁰ This is due to the high utilization of generic drugs, which are not eligible for rebates, and a large number of brand drugs where the manufacturer does not offer rebates.

Put another way, fewer than one in ten prescriptions will have a lower out-of-pocket cost as a result of the proposed rule while premiums for all beneficiaries will increase and costs to the government will rise significantly. Humana believes that there are alternative policy options that could modernize the Part D program and also reduce out-of-pocket spending on prescription drugs. These options are discussed in detail at the end of this testimony.

List prices for all brand drugs will need to decrease by 28 percent to keep beneficiaries whole

One of the underlying assumptions in the proposed rule is that the changes will result in drug manufacturers lowering their list prices. *However*, when asked by Chairman Grassley, “Should the Administration finalize this [OIG] rule, would you commit to lowering your drug prices?”, the CEOs of AstraZeneca, AbbVie, Bristol-Myers Squibb, Johnson and Johnson, Pfizer, Merck and Sanofi all testified that they would only lower list prices if the same rules were applied in the commercial sector or they failed to answer the question. The proposed rule only applies to federal health care programs and does not extend to ERISA or the Public Health Service Act which governs much of the commercial market.

This will result in increased drug prices that will cause some beneficiaries to pay more out of pocket. Based upon Humana’s actuarial analysis, the only way to achieve the same costs for the Part D program and maintain beneficiary premiums comparable to the current system is if all brand drug manufacturers – including those who do not currently offer rebates – elect to decrease their list prices by at least 28 percent. Alternatively, if brand drug manufacturers refuse to reduce their list prices for products not currently rebated, manufacturers of the remaining branded products would need to drop their list prices by at least 45 percent in order to avoid higher costs for CMS, taxpayers, and beneficiaries.

²⁸ Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (RIN 0936-AA08)

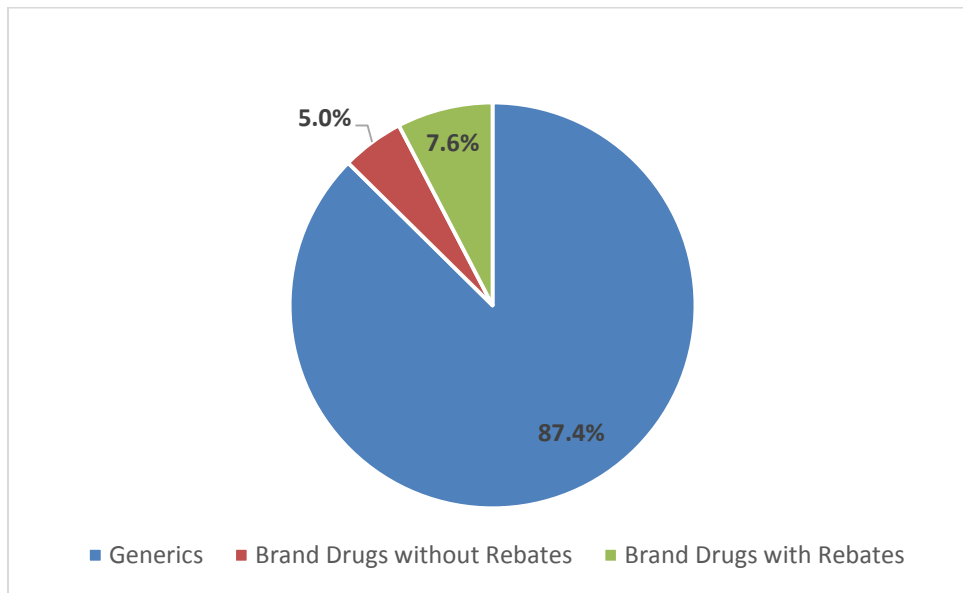
²⁹ Ibid.

³⁰ Based on Humana’s analysis of CMS Part D Drug Spending Dashboard & Data, available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>. Products in the dashboard were categorized as generic if the generic name listed matched the brand name. The remaining products were categorized as brand and then segmented based on whether Humana has a rebate contract for that product in 2019. Finally, “Total Claims” was summed across all products in each category.

Drug manufacturers raise list prices to boost their revenue

Drug manufacturers alone set the list price of prescription drugs. However, some in the pharmaceutical industry cite rebates and other price concessions as the driver of increasing list prices for all brand drugs. Currently, there are few brand drugs with a rebate agreement in comparison to the total number of drugs in the market. For the 2019 benefit year, Humana will only receive rebates on 255 brand drugs, or seven percent of the potential drugs on its Medicare formulary.

Prescriptions Filled by Part D Beneficiaries in 2017 ³¹



Additionally, there are many examples of increasing list prices for brand drugs where the manufacturer does not offer rebates. To highlight this, Humana analyzed the historical list prices of three brand drugs – Revlimid, Imbruvica, and Isentress – which accounted for over \$4 billion in taxpayer spending in Part D for 2017.³²

³¹ Based on Humana’s rebate experience applied to an analysis of the “total claims” in the CMS 2017 Part D Drug Spending Dashboard & Data public use file, available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>. Note, CMS excludes over-the-counter drugs and National Drug Codes (NDCs) with fewer than 50 claims per year from the public file. Drug spending metrics for Part D drugs are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees, but does not reflect any manufacturers’ rebates. For purposes of this analysis, we removed Part D covered supplies, such as syringes and alcohol swipes for diabetics.

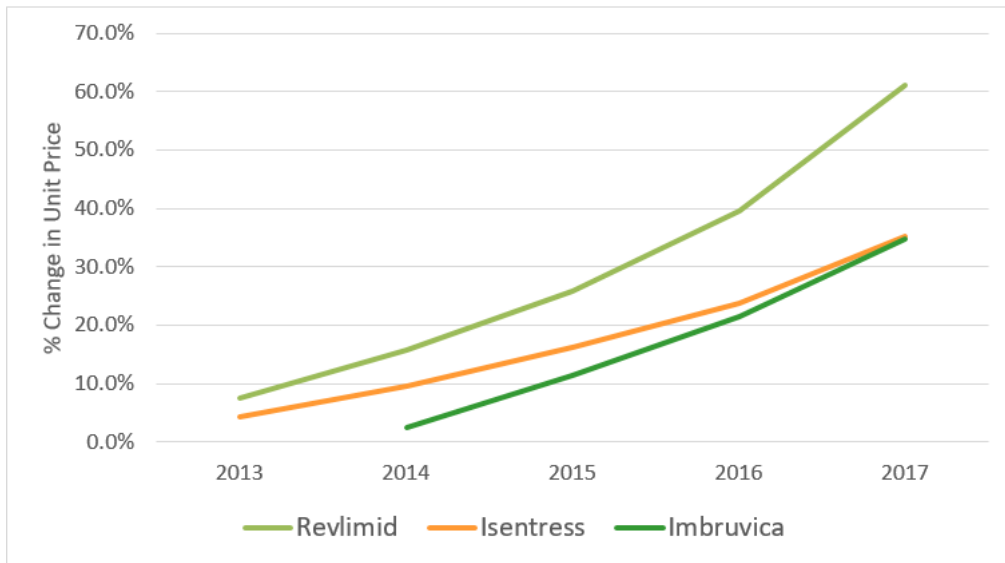
³² CMS 2017 Part D Drug Spending Dashboard & Data, available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

Examples of Brand-name Drugs with No Rebate

Product	Condition	Manufacturer	Overall Part D Spending in 2017
Revlimid	Cancer	Celgene	\$2.3 billion
Imbruvica	Cancer	AbbVie	\$1.4 billion
Isentress	HIV	Merck	\$320.9 million

None of these drugs were subject to rebate agreements during the 2013-2017 time period examined. However, each drug’s list price increased annually by as much as 64 percent. This analysis, utilizing publicly available CMS data, directly refutes the suggestion that rebates are the driver of increasing drug list prices. Ultimately, this is further evidence that the proposed changes to the Anti-Kickback regulations will not result in HHS’s desired outcome of lower list prices for prescription drugs and lower out-of-pocket costs for beneficiaries.

Percent Change in Unit List Price Compared to Base Year ³³



The HHS’s OIG Proposed Rule Will Inject New Uncertainties into the Part D Market That Will Put Upward Pressure on Part D Premiums

Consistent with the Administration’s own analysis, Humana’s actuaries project that Part D premiums will increase for all beneficiaries as a result of the HHS’s OIG proposed rule, with out-of-pocket costs reduced for a subset of beneficiaries that utilize rebated brand drugs. We project that those premium increases will lead to changes in beneficiary behavior that will have premium and beneficiary impacts

³³ Based on Humana’s analysis of the CMS Part D Drug Spending Dashboard & Data, available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>. Chart reflects the percent change in the unit price of each product in 2013-2017 compared to a base year. Base year is 2012 for Revlimid and Isentress. Base year is 2013 for Imbruvica, which was launched in November 2013.

not contemplated in the proposed rule. We have outlined several potential consequences of the OIG HHS proposed rule – none of which are contemplated in the regulation.

- **POS rebates will lead to changes in prescription drug manufacturer pricing and market access behaviors that will be difficult for plan sponsors to project** – POS transparency also impacts prescription drug manufacturer pricing and market access behaviors. Each brand drug manufacturer will naturally seek to develop pricing strategies that maximize market share without deflating their profit margins. Some manufacturers are considering authorized generic drug pricing strategies, while others are examining an average net of rebate pricing strategy with minimal or no price segmentation between Part D plan sponsors. We expect many other variations on these pricing strategies moving forward. The challenge plan sponsors face when preparing 2020 Part D bids is that these constantly evolving market/pricing dynamics further increase the difficulty of projecting Part D plan costs if POS rebates are implemented in 2020. This enhanced unpredictability will either lead to greater pricing misestimates in Part D bids or conservatism in pricing (and thus higher premiums).
- **Some beneficiaries with high drug costs will likely make plan choices based primarily on POS drug costs, which may result in migration to those specific plans, thus increasing the likelihood of adverse risk selection**– We anticipate that beneficiaries shopping for Part D coverage in 2020 and beyond will be choosing a plan based on different criteria than in previous years. With greater transparency of drug prices inclusive of manufacturer rebates, we anticipate that more consumers will be selecting plans based on POS costs versus the traditional focus on premiums, formulary, and pharmacy network. While there are numerous long-term advantages to this change in beneficiary shopping behavior, in the near term, this shift will lead to increased membership movement between plans. Increased beneficiary movement will place further upward pressure on premiums because, historically, newly-enrolled beneficiaries are less likely to enroll and engage in clinical programs. In addition, as beneficiaries increasingly select plans based on POS costs, it will place plan sponsors at an increased risk of adverse selection. The current Part D risk adjustment model is not built to sufficiently mitigate this risk, because it assumes that high cost beneficiaries will be evenly spread across all Part D plan sponsors.

Proposals to Mitigate Beneficiary Disruption in 2020

Plan sponsors are in the process of preparing Part D bids to CMS for the 2020 benefit year and will be submitted to CMS by June 3rd. If the Administration elects to move forward with the proposed changes to the Anti-Kickback Safe Harbor regulations, it is absolutely critical that CMS take immediate steps to mitigate inevitable premium increases and beneficiary disruption. The proposed rule will make it exceedingly difficult for plan sponsors offering Part D coverage to project costs and set accurate beneficiary premiums.³⁴

Mandatory point-of-sale rebates would be the most significant regulatory change to the Part D program since its inception. This actuarial uncertainty, coupled with the lack of guidance to date from the CMS OACT, will lead to more conservative (i.e., higher) rate setting, potentially resulting in significant beneficiary disruption.

³⁴ For a more detailed discussion of the actuarial challenges posed by the HHS OIG proposed rule, please consult public comments submitted by the American Academy of Actuaries, available online at: https://www.actuary.org/sites/default/files/2019-04/Rx_Rebate_Timeline_04032019.pdf

The following steps would be necessary to help preserve stability and predictability in the Part D market in 2020. We would respectfully suggest members of the Committee and other members of Congress to encourage CMS to take the following actions:

- **Implement interim adjustments to the Part D risk adjustment model immediately** – The current Part D risk adjustment model cannot sufficiently mitigate the actuarial uncertainties posed by the Anti-Kickback Safe Harbor proposed regulation. Historically, it has taken CMS multiple years to recalibrate the Part D risk adjustment model to reflect changes in Part D utilization and spending. We strongly urge CMS to work with plan sponsor actuaries immediately on methods for potentially making interim adjustments and to implement a model recalibration as soon as possible to reflect a mandatory point-of-sale rebate market.
- **Require all Part D Plan Sponsors to offer a plan designed specifically for LIS auto-enrollees as part of a new, fourth plan option** - Part D LIS-eligible beneficiaries will prove to be the most challenging population for plan sponsors to predict pricing and drug utilization for 2020, primarily because LIS beneficiaries are more likely than the general Part D population to utilize rebated brand-name drugs.³⁵ Our recommendation would encourage population-based formulary design; enhance the value of manufacturer price concessions for CMS; establish parity across the market; and preserve competition and beneficiary choice. We note that there is precedent for this approach; MA dual-eligible special needs plans (D-SNP) are specifically structured for the dual-eligible population both in cost-sharing and formulary design. In order to accommodate the new LIS-only plan, CMS would need to allow plan sponsors to offer a fourth plan, because they are currently limited by CMS sub-regulatory guidance to no more than three plans in any market.
- **Narrow Part D risk corridors for 2020** – In order to manage the transition to the new Part D rebate model contemplated by the HHS OIG proposed rule and mitigate premium increases, we recommend that CMS narrow the Part D risk sharing corridors for 2020 consistent with risk corridors applicable during the first two years of the Part D program (2006-2007).³⁶
- **Increase the 2020 De Minimis Premium policy for LIS-eligible beneficiaries** – In order to avoid disruption, movement between plans, and confusion for LIS beneficiaries, we recommend that CMS permit plan sponsors to voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is up to a de minimis amount of \$10 during the 2020 transition to the new Part D rebate model.³⁷
- **Allow plan sponsors to facilitate chargebacks and pharmacy reimbursement** – A 2020 implementation date does not provide sufficient time for stakeholders to develop, test, and deploy the new system for processing chargebacks and pharmacy reimbursement

³⁵ MedPAC Report to Congress: Medicare Payment Policy, March 2017 available at: http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf

³⁶ CMS used its demonstration authority to smooth the premium impacts to protect beneficiaries from negative aspects at the start of the Part D benefit. It announced the Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries on June 8, 2006 as well as implementing a one-year payment demonstration, the “Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans.” Those are potential examples of the agency’s ability to minimize disruption.

³⁷ Ibid.

contemplated in the HHS OIG proposed rule. Rather than trying to reinvent the wheel in a matter of months, CMS should continue allowing plan sponsors to process and facilitate chargebacks in order to ensure that pharmacies receive timely and accurate payment for their services.

- **Temporarily exclude Part D from the Total Beneficiary Cost (TBC) calculation for MA-PD plans beginning in 2020** - Because drug formularies may change significantly as a result of the proposed rule, there may be large changes in the Part D component of the TBC calculation. We request that Part D be excluded from the TBC calculation until the impact of formulary changes can be adequately evaluated and quantified.
- **Issue guidance on 2020 bid assumptions as soon as possible** – We strongly encourage CMS to provide guidance on 2020 bid assumptions to ensure consistency in approach among plan sponsors. In particular, because direct subsidy and low-income premium subsidy amounts are a function of plan sponsor bids, there needs to be consistency in bidding approaches to avoid wide swings in plan bids and beneficiary premiums.
- **Preserve the ability for plan sponsors to implement value-based purchasing programs for pharmacies** – Given the extraordinary disruption that could occur in the Part D market in 2020, we recommend that CMS not finalize its proposal. It would add yet another layer of complexity by eliminating pharmacy direct and indirect remuneration (DIR), such as value-based purchasing programs. As CMS’ own analysis indicates, prohibiting pharmacy DIR will further increase Part D premiums – amplifying the upward premium trend attributable to POS rebates. In addition, CMS has failed to consider several key unintended consequences of eliminating pharmacy DIR. For example, we anticipate that plan sponsors would respond by lowering pharmacy reimbursement rates and reducing the size of their existing pharmacy networks. All of which would likely result in significant changes in Plan Sponsors’ pharmacy networks occurring at the same time as widespread premium increases and formulary changes.
- **Delay the Health Insurance Tax** – In addition to the projected impact of the rebate rule and value-based pharmacy networks rule (DIR), we are also preparing for the potential return of the Health Insurance Tax in 2020. Under both President Obama and President Trump, bipartisan legislation passed delaying the tax, including in the current calendar year (2019). Without Congressional action, the tax is scheduled to return in 2020, resulting in tens of millions of seniors with Part D coverage paying higher premiums. We strongly urge Congressional action in support of S. 172, the Health Insurance Tax Relief Act of 2019.

Modernizing the Part D Program to Better Serve Medicare Beneficiaries

Given the profound changes that have occurred in the pharmaceutical marketplace since the implementation of Part D, we encourage the Committee to examine potential reforms to the Part D program that would both alleviate the burdens seniors face when paying for high cost drugs and leverage market-based reforms to drive down prescription drug prices.

- **Maximum Out-of-Pocket (MOOP) Cost Protection** – In order to better protect non-LIS beneficiaries from high prescription drug costs, we recommend that the Committee consider establishing an annual maximum out-of-pocket cap for Part D drugs. It is critical that any proposal to cap out-of-pocket costs in Part D be paired with prescription drug pricing reforms that meaningfully reduce prescription drug costs by improving competition in the

pharmaceutical market. Stated another way, the costs of implementing a Part D MOOP should be borne by the pharmaceutical industry.

- **High Cost Specialty Drugs** – As discussed previously, two percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending in 2018. In two years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending. We welcome the opportunity to explore potential solutions for alternative pooling or funding mechanisms for this growing category of products.

Proposals to Increase Drug Market Competition

Humana strongly urges the Committee to encourage CMS and other federal agencies to remove barriers to prescription drug competition and regulations that are abused in anticompetitive ways and are harmful to affordable drug access for beneficiaries. We specifically have recommended to the Administration to take the following actions that would address abuses of regulations and anticompetitive behaviors:

- **Finalize CMS's Proposed Drug Pricing Rules Aimed at Increasing Competition** – Humana urges CMS to finalize the proposed rules on plan sponsor flexibility for protected classes and the Part B step therapy program in “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule”[CMS-4180-P]. Humana has long supported these policy changes and has identified opportunities to create competition in the market and lower drug costs for beneficiaries. Internal analysis estimates that the lack of competition due to the protected class policy collectively increased beneficiary premiums by an estimated \$2.79 per-beneficiary per-month (PBPM, \$34 per-beneficiary-per-year) in 2018. Additionally, 50 percent of Humana’s Part B drug spending is attributable to drug classes with multiple clinically equivalent substances where additional competition can be stimulated through utilization management. Additional flexibility with respect to formulary development will enable sponsors to effectively drive competition in the market and lower drug costs for their beneficiaries.
- **Eliminate the Requirement that Part D Plan sponsors Cover At Least Two Drugs in Each Therapeutic Category or Class** – CMS currently requires Part D plan sponsor formularies to cover at least two drugs in every Part D covered therapeutic category and class as long as there are at least two drugs available. When two drugs are mandated to be covered in a class, manufacturers of a drug with only one other competitor typically refuse to negotiate rebates or discounts in Medicare Part D because they know their products must be covered. The existing policy increases costs to the plan sponsor, which are passed through not only to individuals in the form of higher premiums, but also to the federal government in terms of increased direct subsidy payments.
- **Leverage CMS data to illustrate the cost impacts of anticompetitive behaviors such as patent “evergreening”** – CMS is best-positioned to leverage its claims from Parts A, B, and D to empirically illustrate the Medicare Trust Fund and beneficiary impacts associated with these and other anticompetitive behaviors.
- **Issue information regarding manufacturers’ drug pipelines and anticipated drug prices prior to market launch** – It is critical for Part D and Medicare Advantage (MA) plan sponsors and the CMS OACT to be aware of anticipated new drugs, new drug indications, and their potential

launch prices. These data are necessary to make critical decisions about MA and Part D bidding parameters, making special updates to the MA and Part D risk adjustments models, and for OACT to perform its long-term program cost estimation duties for the Medicare Trustees. With the right information, this decision-making will have a significant impact on our ability to provide lower drug costs and premiums for beneficiaries. While we understand there are proprietary data provisions and there is general uncertainty about approvals of new therapies, we believe that, between clinicaltrials.gov and PubMed, there is a notable opportunity to produce a transparent summary dashboard of the drug pipeline in one place. We ask that HHS ensure that the FDA works toward this goal and provide CMS and plan sponsors with this necessary information.

- **Address Anticompetitive Actions by Drug Manufacturers** – Humana strongly supports the Administration’s continued work to address and prevent anticompetitive actions by drug manufacturers. Again, Congressional action through passage of the CREATES Act and S. 64 will limit these actions, bringing more competition to the market and placing downward pressure on beneficiary drug costs.

Conclusion

We appreciate the Committee’s keen interest in working to better understand the root causes of high drug costs. We look forward to working with you on policy solutions to ensure access to affordable prescription drugs and to foster stability in the 2020 benefit year.