

Damaging Medicare Part D:
CMS Proposes Unnecessary Changes to a Successful Program

U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

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Chairman Pitts, Ranking Member Pallone, and members of the Committee, thank you for the opportunity to share my thoughts on the Part D program and the administration's proposed changes. In what follows, I hope to convey the following major points:

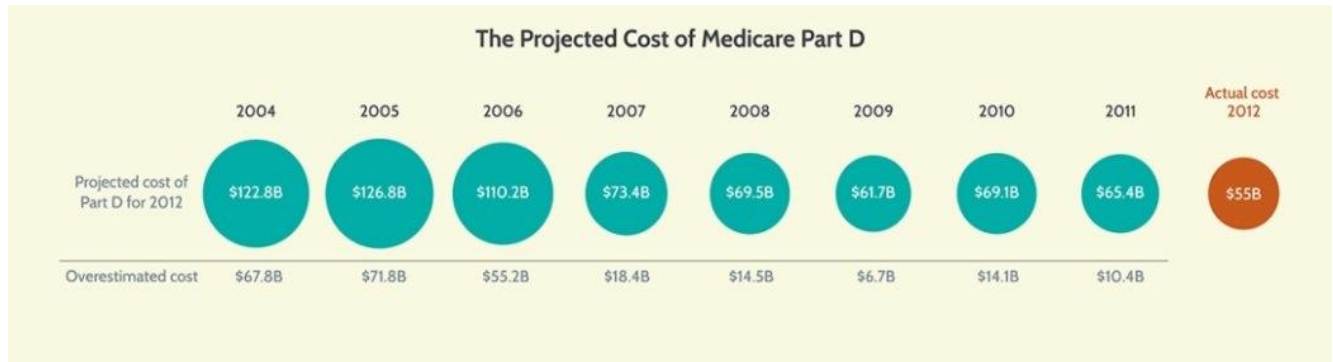
1. The Medicare Part D program is a proven success story of bipartisan Medicare reform, making affordable prescription drug coverage available to seniors and the disabled;
2. The proposed new rule entitled "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" clearly violates the intent of Congress when it passed the Medicare Modernization Act (MMA) and rests on a questionable legal foundation by interfering with the established negotiation processes;
3. Policy analyses show that the proposed rule is likely to raise costs for seniors, programs, and the federal taxpayers, unnecessarily harming the superb record that the competition-based design of Part D has built; and
4. The rule imposes requirements that will decrease seniors' access to vital prescription drugs.

Choice, Competition, and the Success of Part D

Since its enactment, the Part D program has continually proven its ability to control beneficiary and budget costs, provide consistently high quality drug plans and exemplify market-based competition within an entitlement program. Established as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Part D was designed to increase seniors' access to outpatient prescription drugs through the Medicare program. The goal of the policymakers who developed Part D was to provide a stable mechanism for competing insurance issuers to offer prescription drugs at negotiated prices to Medicare beneficiaries.¹ In the past ten years, the program has more than achieved its goals: costing taxpayers much less than the original budgetary projections, providing a wide variety of low cost plan options, and maintaining member satisfaction.²

The Medicare Part D program has consistently performed under budget, coming in at a cost of \$55 billion in 2012 – that is down from an estimated 2012 cost of \$122.88 billion as predicted in 2004³ (see Graphic 1). Much of the observed savings come from the program's competitive design, unhampered negotiations and consumer choice, serving as the backbone policies of the Part D program. Unlike many government programs, plan issuers have the flexibility to develop a wide range of products and as long as a benchmark standard is met, tiered cost-sharing, additional benefits, and savings from using a preferred network of pharmacies can all be utilized to appeal to consumers.

Graphic 1: Decrease in Projected 2012 Costs of Medicare Part D



The annual Part D bidding process allows issuers to place bids for plans in any or all of the thirty four regions in the country. These issuers submit a bid displaying the potential per member per month (PMPM) cost of providing benefits to members in any (or all) of the established regions. All bids contain a rate for the basic benefit or “standard plan” as well as an enhanced benefit plan that goes above and beyond the minimum plan requirements. Part D members can choose whether they would like to participate in a plan that contracts with nearby pharmacies as part of a preferred pharmacy network (PPN), pay a higher premium for plans with enhanced benefits, or save money by selecting a standard plan.

Despite initial worries about plan participation, this process of bidding and selection has led to a large number of available plans, giving seniors in every region at least 23 plan choices in 2013.⁴ The open competition for beneficiaries has resulted in a robust market. The ability for plan issuers to negotiate with preferred pharmacy networks, pharmaceutical companies and pharmacy benefit managers has allowed plans to utilize their market share to obtain lower prices and thus charge lower premiums. For example, a plan may offer drug A at a lower copayment than an equivalent drug B, and in exchange for doing so they negotiate rebates from the manufacturer of drug A. As a result, patients who have a condition that warrants drug A or B are able to obtain A at a lower out of pocket cost, and the Part D plan receives the rebate for every purchase, and thus allows them to price their plan more affordably.

The success of the program is not an accident; Part D is designed to provide seniors with affordable choices. Competitive bidding and plan selection have led to high-quality products, as measured through member satisfaction rates. Despite initial concerns about plan enrollment and member participation, 31 million⁵ individuals were enrolled in the Part D program in 2012, with 85 percent reporting that they are “satisfied” with their coverage and nearly 80 percent of members felt that they made a “good choice” with their coverage option.⁶ The satisfaction reported by seniors displays the use of an efficient, high quality program that continues to come in under cost projections and maintain popularity among its members.

Proposed Regulations and the Future Success of Part D

The proposed rule posted by CMS on January 10, 2014, would alter the program operations, jeopardizing Part D's success and quality. The CMS initiative may increase premiums and co-payments, disrupt continuity of care and impact access for Part D beneficiaries. If implemented, the rule will drive up costs by interfering with the ability of plans to negotiate prices, decrease access to services and reduce the number of existing plans.

Violating Statutory Non-Interference. The Part D statute contains a non-interference provision that prohibits the Secretary of Health and Human Services (HHS) from interfering with the negotiations between drug manufacturers and pharmacies and sponsors of prescription drug plans, and from requiring a specific price structure for Part D reimbursement.⁷ The clear Congressional intent of the noninterference provision was to allow for free negotiations between drug manufacturers and pharmacies and plan sponsors. This is exemplified by the letter I signed as Director of the Congressional Budget Office immediately after the passage of MMA.⁸

As the letter makes clear, plans, manufacturers and pharmacies were all covered by the non-interference provision. CMS has changed the agency's interpretation of the law to permit CMS intervention in pharmacy and plan sponsor negotiations. I believe this is a clear violation of Congressional intent.

It is also bad policy. CBO noted at the time of the law's enactment that the involvement of the HHS Secretary in price negotiations will not create any additional benefits during the negotiation process.⁹ Plans have enough leverage with their high number of potential beneficiaries to negotiate effectively, and the Secretary would not be able to significantly reduce prices. The Secretary cannot improve the current state of the price negotiation process, and federal price fixing would prove detrimental to the current competitive price negotiations.

Finally, its legal foundation is questionable as legal experts find this rule to directly conflict with previous HHS interpretations of the MMA. According to a legal opinion produced by the firm Boyden Gray and Associates, PLLC, the legislative history, previous regulatory interpretations and subsequent repeal proposals all point to the clarity of the "non-interference provision".¹⁰ As the opinion states, the non-interference provision was particularly controversial during the legislative debate as all policymakers understood that it barred HHS from inserting itself in pharmaceutical negotiations as they occurred between plan sponsors, drug manufacturers and pharmacies.¹¹ As it exists today these contracts are negotiated freely and in line with the established understanding of strict non-interference. Should HHS choose to ignore the "undisputed understanding" of this law, the regulatory overreach sets a disconcerting precedent for further administrative intrusion. If the agency moves forward with its novel interpretation of noninterference, then this overreach should be vacated by the federal courts.

Placing PPNs at Risk. The proposed rule works to undercut the established preferred pharmacy network (PPN) plans. As proposed in the regulation, the "any willing pharmacy" requirement forces plans to accept any pharmacy that is willing to meet the terms of their contract.¹² These preferred networks are not intended to be exclusionary, but instead are agreements between specific pharmacies in order to ensure a members-only discount. This requirement could cause millions of seniors to lose their plans that provide discounted prices through a preferred

pharmacy network, a part of the program that is projected to save \$9.3 billion over the next ten years.¹³

Placing the Taxpayer at Risk. The loss of preferred pharmacy networks will increase costs for Part D through the removal of discounted membership rates, interfere with seniors' continuity of care, and decrease the quality of coverage. Seniors losing their current, preferred pharmacy network (PPN) plan would no longer experience the savings associated with these networks. In 2014, the average premium for a basic PDP within a preferred network was 21 percent lower than the average premium for non-preferred network plans.¹⁴ Table 1 displays the number of enrollees in every state that stand to lose their Part D prescription drug coverage and could experience premium increases in 2015 if the CMS proposal is implemented.

Budget estimates produced by the actuarial firm Milliman show that the regulation, if implemented, will raise program costs up to \$1.6 billion for the federal government in 2015 alone, increase plan bids by 10 percent, and drive up enrollee cost-sharing, tarnishing the Part D track record of competitive pricing.¹⁵ According to their study, the proposed regulation would increase the out of pocket costs for 6.9 million seniors that do not qualify for low-income subsidies and would increase federal costs for roughly 6 million low-income beneficiaries.¹⁶ Due to the program design, an increase in the plan bids would be borne by both the Medicare beneficiary as well as the federal government.

Restricting Mail Order Pharmacies. Many preferred pharmacy networks create a portion of the savings described above by utilizing or owning a mail order pharmacy. Mail order pharmacies ship prescriptions directly to Part D enrollees, providing an efficient supply chain and eliminating costs associated with brick and mortar pharmacies. According to CMS itself, pharmaceuticals ordered through mail order pharmacies are estimated to cost 16 percent less on average than retail pharmacies.¹⁷ In addition to the cost savings, having prescriptions delivered by mail is often more convenient for patients and as a result may increase medication adherence. A study performed by Kaiser Permanente found that among diabetes patients, those receiving their medication via mail order pharmacy had fewer emergency department visits.¹⁸

CMS' proposal includes new requirements for mail order pharmacies that establish a mandated date of shipment and causes complexities with existing beneficiary outreach requirements. In the proposed regulation, CMS requires mail order pharmacies to ship prescriptions within three or five days. Prescriptions that do not have any issues or discrepancies must be shipped within three days and prescriptions that are unclear or require a prior authorization must be shipped within five days. This provision directly conflicts with the requirement of mail order pharmacies to receive patient approval prior to shipment of medications, which can interfere with the proposed time limits. These new requirements add another layer of complexity to the mail order process and impose regulations that do not regard patient/prescription specific circumstances.

Creating Issuer Limitations. Part D enrollees would experience a decrease in the number of available plans along with their increased premiums if the proposed rule is implemented. The intricate negotiations between Part D plan issuers and provider pharmacies have resulted in 1,169 plans in 2014,¹⁹ offering a variety of premium levels and benefits. However, the proposed rule would limit the number of plans per issuer that can be offered in each of the 34 Part D regions in 2016. All issuers would be limited to offering two plans per region: one plan that provides the

standard benefit package and a plan that provides enhanced benefits.²⁰ According to a study conducted by Avalere, the rule would cause issuers to roll enhanced plans with richer benefits into less generous plans, increasing premiums for existing plans and decreasing the variety of benefits offered.²¹ This proposal will greatly impact those enrolled in enhanced benefit plans; the termination and consolidation of enhanced plans may disrupt the Part D benefits for 7.4 million, or 94 percent of individuals enrolled in enhanced plans.²² According to Milliman, the reduced plan offerings would result in 50 percent of Part D enrollees seeing their plans cancelled or “materially changed.”²³

This provision is the result of concern that seniors have “too many” choices of Part D plans, and can get confused. It is not a result of concern that some of these choices are poor or inadequate. There is likely some truth to the fact that it may take some research for a Medicare beneficiary to figure out which plans provide the best (and least expensive) coverage for the medications they use, but there are plenty of resources to help individuals make these choices. Interfering in a well-functioning market system simply to reduce choices—not to eliminate poor choices, is not good policy.

Conclusion

The proposed rule damages the policy foundations of the Medicare Part D program, creating major changes to the program’s operations. CMS should not be able to radically rework a successful program that impacts so many individuals on a whim. A group of 200 stakeholders and industry leaders have publicly stated their resistance to these changes, showing a broad support for the current status of the program. I am urging Congress not to allow for the finalization of this unneeded rule.

The interpretation of the noninterference provision, changes to preferred pharmacy negotiations, and placing absolute requirements on portions of the program will increase costs, impede the effectiveness, and create dissatisfaction among plan enrollees. Federal involvement will only hinder negotiating practices and increase costs. Allowing any willing pharmacy to participate in preferred networks will increase premiums for enrollees, many of which are seniors on a fixed income. Creating mandates on turnaround times for mail order pharmacies and the number of plans offered in a region blindly restricts mechanisms in the program that create savings. Limiting issuers to offering only two plans per region will increase plan costs, and requiring mail order pharmacies to adhere to specific timelines show a disregard for consumer choice and access. Through this testimony, I am encouraging the roll-back of an unnecessary rule that inhibits a competitively driven, financially successful, popular program.

Table 1: Medicare Beneficiaries in Preferred Network Plans by State

State	Medicare Beneficiaries in Preferred Network Plans		State	Medicare Beneficiaries in Preferred Network Plans
Alabama	249,530		Montana	56,988
Alaska	21,006		Nebraska	112,141
Arizona	233,826		Nevada	102,284
Arkansas	174,711		New Hampshire	102,747
California	1,200,074		New Jersey	446,486
Colorado	181,349		New Mexico	71,173
Connecticut	170,142		New York	659,179
Delaware	68,294		North Carolina	572,525
District of Columbia	27,004		North Dakota	41,265
Florida	1,007,077		Ohio	490,416
Georgia	425,401		Oklahoma	198,138
Hawaii	17,431		Oregon	124,151
Idaho	61,975		Pennsylvania	515,000
Illinois	76,1137		Rhode Island	50,690
Indiana	401,452		South Carolina	270,856
Iowa	177,282		South Dakota	56,795
Kansas	211,465		Tennessee	328,983
Kentucky	297,432		Texas	946,557
Louisiana	167,474		Utah	58,482
Maine	132,415		Vermont	50,528
Maryland	285,479		Virginia	412,826
Massachusetts	342,840		Washington	240,145
Michigan	537,086		West Virginia	115,704
Minnesota	172,809		Wisconsin	231,236
Mississippi	209,577		Wyoming	36,342
Missouri	330,673			

¹ Medicare Improvement and Modernization Act of 2003. Section 101 (a)(1)(A).

² Book, Robert A. Ph.D., Holtz-Eakin, Douglas, Ph.D., Competition in the Medicare Part D Program. September 2013.

³ Book, Robert A. Ph.D., Holtz-Eakin, Douglas, Ph.D., Competition in the Medicare Part D Program. September 2013.

⁴ Andrew Stocking, "Competition and Bids in Medicare's Prescription Drug Program," Congressional Budget Office, June 23, 2013, p.8-9

⁵ 2013 Statistical Supplement." *Center for Medicare and Medicaid Services*. Chapter 14: Medicare Part D, Web. <<http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2013.html>>.

⁶ Report on Access, Satisfaction, and Cost," AARP, November 2007. http://assets.aarp.org/rgcenter/health/rx_medicaid.pdf

⁷ The Medicare Improvement and Modernization Act of 2003, 33 § 1860-D (2003). <http://www.gpo.gov/fdsys/pkg/BILLS-108hr1enr/pdf/BILLS-108hr1enr.pdf>

⁸ CBO Letter to Congress. 2004. <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf>

⁹ CBO Letter to Congress. 2004. <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf>

¹⁰ Boyden Gray and Associates, PLLC. "The Medicare Modernization Act's Prohibition Against Federal Negotiation of Drug Prices." February 24, 2014. <http://americanactionforum.org/insights/legal-analysis-of-proposed-part-d-rule-finds-hhs-acting-unlawfully>

¹¹ Boyden Gray and Associates, PLLC. "The Medicare Modernization Act's Prohibition Against Federal Negotiation of Drug Prices." February 24, 2014. <http://americanactionforum.org/insights/legal-analysis-of-proposed-part-d-rule-finds-hhs-acting-unlawfully>

¹² 79 FR 1978. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, CMS-4159-P § 3, 2014. <https://www.federalregister.gov/articles/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the#p-790>.

¹³ Kaczmarek, Stephen J., Andrea Sheldon, and David M. Liner. "The Impact Of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023." Milliman, Oct. 2013. Web.

¹⁴ Based on 2014 enrollment in Medicare Part D prescription drug plans with preferred pharmacy networks as reported by the Drug Channels Institute. <http://www.drugchannels.net/2014/01/for-2014-3-out-of-4-seniors-choose.html>, and "2014 Premiums and Star Ratings for Medicare Part D Prescription Drug Plans with Preferred Pharmacy Networks" Avalere Health. 2014.

¹⁵ Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.

¹⁶ Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.

¹⁷ Centers for Medicare and Medicaid Services, "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," December, 2013.

¹⁸ CPatients with Diabetes who use Mail Order Pharmacy are Less Likely to Visit Emergency Rooms." Kaiser Permanente. November 2013. <http://share.kaiserpermanente.org/article/patients-with-diabetes-who-use-mail-order-pharmacy-are-less-likely-to-visit-emergency-rooms/>.

¹⁹ Hoadley, Jack, Juliette Cubanski, and Laura Summer. "Medicare Part D: A First Look at Plan Offerings in 2014 « » The Henry J. Kaiser Family Foundation." *Kaiser Family Foundation*. N.p., Oct. 2013. Web. <<http://kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-plan-offerings-in-2014/>>.

²⁰ 79 FR 1963. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, CMS-4159-P § 3 (2014). <https://www.federalregister.gov/articles/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the#p-689>.

²¹ Eyles, Matthew. "7.4 Million Beneficiaries Could Be Affected by Proposed Meaningful Differences Policy." *Avalere Health*. N.p., Feb. 2014. Web. <<http://avalerehealth.net/expertise/managed-care/insights/7.4m-medicare-beneficiaries-could-be-affected-by-proposed-meaningful-differ>>.

²² Eyles, Matthew. "7.4 Million Beneficiaries Could Be Affected by Proposed Meaningful Differences Policy." *Avalere Health*. N.p., Feb. 2014. Web. <<http://avalerehealth.net/expertise/managed-care/insights/7.4m-medicare-beneficiaries-could-be-affected-by-proposed-meaningful-differ>>.

²³ Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.