

**STATEMENT OF
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**ON
2015 CHANGES TO THE
MEDICARE ADVANTAGE AND THE MEDICARE
PRESCRIPTION DRUG BENEFIT PROGRAMS**

**BEFORE THE
U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE,
SUBCOMMITTEE ON HEALTH**

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Statement of Jonathan Blum on
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Medicare Prescription Drug Benefit Programs
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Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) work to improve the Medicare Advantage (MA) Program and the Medicare Prescription Drug Program, also known as Medicare Part D, in Contract Year (CY) 2015. CMS is proud of our track record of successfully managing these important programs to ensure that beneficiaries have access to a wide range of high quality MA and Part D plans. We have proposed a number of improvements that will help protect taxpayer dollars and the integrity of the Medicare program while lowering costs, improving care quality, and enhancing protections for Medicare beneficiaries.

Medicare Advantage and Medicare Part D: A Track Record of Success

With Medicare Advantage enrollment at an all-time high and costs remaining stable, concerns that recent changes to the MA program would result in lower enrollment and higher costs now appear unfounded. Nationwide, over 15 million Medicare beneficiaries¹ are now enrolled in an MA plan. This is a 30 percent increase in enrollment since 2010, and enrollment is projected to continue increasing.² Plan participation continues to be robust with 99.1 percent of beneficiaries having access to an MA plan in their area. The average MA premium in 2014 is projected to increase by only \$1.64 from last year, coming to \$32.60.³ At the same time, the average number of plan choices will remain about the same in 2014, and access to supplemental benefits remains stable.⁴ Additionally, since passage of the Affordable Care Act, average MA premiums are down by 9.8 percent.⁵

¹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2014-01.html?DLPage=1&DLSort=1&DLSortDir=descending>

² 2013 Trustees Report pp. 166, 198. <http://downloads.cms.gov/files/TR2013.pdf>

³ <http://www.hhs.gov/news/press/2013pres/09/20130919b.html>

⁴ <http://www.hhs.gov/news/press/2013pres/09/20130919b.html>

⁵ <http://www.hhs.gov/news/press/2013pres/09/20130919b.html>

Medicare Advantage plan quality continues to improve. Last year, CMS announced that over one-third of CY 2014 MA contracts will receive four or more stars, which is an increase from 28 percent in 2013.⁶ In 2013, over half of MA enrollees were enrolled in plans with four or more stars, a significant increase from 37 percent of enrollees the previous year.⁷ CMS calculates star ratings from 1 to 5 (with 5 being the best) based on quality and performance for MA and Medicare prescription drug plans to help beneficiaries, their families, and caregivers compare plans.

Like Medicare Advantage, the Medicare Part D prescription drug benefit program has been very successful. In its nine years of operation, Part D has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and greater beneficiary satisfaction with their Medicare coverage. In addition, the drug benefit is helping beneficiaries avoid the need for other services that would otherwise be covered under Medicare Parts A and B; the Congressional Budget Office (CBO) has estimated that a one percent increase in the number of prescriptions filled by beneficiaries causes Medicare's overall spending on medical services to fall by roughly one-fifth of one percent.⁸

The Medicare Part D program provides outpatient prescription drug benefits to about 38.5 million Medicare beneficiaries⁹ through a wide range of plan choices, with plans competing to provide drug benefits to Medicare beneficiaries at an average monthly premium of about \$30—a cost that has held steady for four years in a row despite the benefit becoming more generous.¹⁰ According to surveys, 95 percent of Part D enrollees are satisfied with their drug coverage and confident that the level of coverage meets their needs.¹¹

⁶ <http://www.hhs.gov/news/press/2013pres/09/20130919b.html>

⁷ <http://www.hhs.gov/news/press/2013pres/09/20130919b.html>

⁸ <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>.

⁹ As of Jan. 2014. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDEnrolData/index.html?redirect=/MCRAAdvPartDEnrolData/>

¹⁰ <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-07-30.html>

¹¹ MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf.

Meanwhile, the overall costs for the Part D program have risen more slowly than originally projected. According to CBO's data, Part D is on track to cost 45 percent less than projected for the initial 2004-to-2013 forecast period.¹² Additionally, the deductible and out-of-pocket limit in the standard Part D benefit will be lower this year than in 2013.

The quality of Part D plans is also improving. In 2013, the average star rating among standalone Part D plan sponsors, weighted by enrollment, was 3.3 stars out of five, compared with 2.96 stars for 2012.¹³ These ratings are based on quality measures including patient safety and appropriate medication use metrics. Sponsors have incorporated the Medication Therapy Management Programs into their plans' benefit structures to ensure optimum therapeutic outcomes through improved medication use and a reduced risk of adverse outcomes.

In addition, the Part D program is even stronger since the enactment of the Affordable Care Act because beneficiary costs will be further reduced as coverage in the prescription drug coverage gap, or "donut hole," continues to expand. Since the Affordable Care Act was enacted, more than 7.3 million seniors and people with disabilities who reached the coverage gap in their Medicare Part D plans have saved \$8.9 billion on their prescription drugs, an average of \$1,209 per person since the program began.¹⁴ This represents a dramatic reduction in the coverage gap, which will be closed by 2020.

Despite these achievements, in order for the Part D program to remain successful, we have to celebrate its successes and address its vulnerabilities. While beneficiaries are saving money, government subsidies for reinsurance and low-income cost sharing subsidies continue to increase. Moreover, Part D costs are projected to increase with the introduction of new, expensive biologic therapies, making it important for CMS to find ways to reduce costs when possible in order to keep premiums low. CMS is well aware of concerns related to fraud and abuse in the Part D program, as well as concerns that compliance with program requirements

¹² http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205_Medicare_0.pdf

¹³ MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf

¹⁴ <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-11-26.html>

could be improved. CMS appreciates the thoughtful work of the Congress¹⁵ and the Department of Health & Human Services Office of the Inspector General¹⁶ that highlights the potential for fraud, waste, and abuse in Part D. We are working to improve our efforts to reduce fraud and abuse in order to ensure that beneficiaries receive high-quality, appropriate care, while also making sure that we spend every Federal dollar as wisely as possible.

We also have to recognize that in some circumstances, due to current regulations, market-driven competition among Part D sponsors is not bringing down costs as efficiently as it could. For example, the current policy of requiring all Part D plans to include all drugs in the current six protected classes on their formularies significantly limits plan sponsors' ability to obtain price concessions for these drugs despite other redundant protections. This inhibits competition in the marketplace, unnecessarily increasing program costs for taxpayers and beneficiaries. Similarly, some plans with preferred pharmacy networks do not appear to result in savings—instead of passing along savings achieved through economies of scale, these Part D plans instead charge the Part D program higher prices, increasing taxpayer costs. Part D plans should earn a fair rate of return, but taxpayers and beneficiaries should benefit as well.

Key CY 2015 Improvements to the Medicare Advantage and Part D Programs

CMS strives to continually improve these programs to strengthen beneficiary protections, improve health care quality, and reduce costs. We do so by periodically revising the regulations governing the MA and Part D programs to implement statutory directives and to incorporate knowledge obtained through experience with each program. On January 6, 2014, CMS released a proposed rule with a comment period that includes provisions designed to reduce program costs, increase transparency, ensure consistent compliance with program rules by plan sponsors, and improve the quality of care for MA and Part D enrollees. The proposed rule also includes new Part D program integrity provisions that, if finalized, would give CMS new tools to help us combat fraud, waste, and abuse in Part D. These proposed regulations would implement MA and Part D technical and program changes, as well as provisions under the Affordable Care Act.

¹⁵ For example, <http://www.hsgac.senate.gov/subcommittees/Federal-financial-management/hearings/costs-of-prescription-drug-abuse-in-the-medicare-part-d-program>

¹⁶ HHS OIG has a large body of work examining Part D billing including: OEI-02-09-00603, OEI-02-09-00608, OEI-02-09-00140, OEI-03-11-00310, OEI-07-09-00150, OEI-07-10-06004

Most of the proposed provisions for the contract year 2015 result from insights obtained through practical experience with the programs—not only our experience but also that of stakeholders, whose questions and requests for further direction we address in many of the proposed regulations. This proposed rule is the latest of CMS’ periodic revisions of MA and Part D regulations, and is a continuation of a multi-year strategy to simplify choices, make benefits more meaningful and transparent to beneficiaries, and lower overall costs.

Enhanced Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse

As the Part D program matures, CMS is broadening its initial focus of ensuring beneficiaries have access to prescribed drugs to also ensure that Part D includes effective safeguards to prevent fraud and drug abuse. CMS is aware of the growing problems of prescription drug abuse and inappropriate prescribing, and unfortunately, the Medicare Part D prescription drug program is not immune from the abuses associated with these nationwide epidemics. CMS takes these problems seriously. To combat prescription drug waste, fraud, and abuse more effectively, CMS evaluates Part D sponsors’ operations to ensure that they are compliant with regulations, as well as the guidance in the Prescription Drug Benefit Manual. As part of program oversight, CMS uses the Fraud Prevention System (FPS) in Medicare fee-for-service to target investigative resources to suspicious claims and providers and swiftly impose administrative action when warranted.

Included in the proposed rule are a number of proposals that will, if finalized, provide the agency with new tools to employ when problematic prescribers and pharmacies are identified. One proposal would require prescribers of Part D drugs to enroll in Medicare in order for their prescriptions to be covered under Part D. Another provision would provide CMS the authority to revoke the Medicare enrollment of a prescriber for abusive patterns and practices of prescribing, or if the prescriber lacks a valid DEA Certificate of Registration. These two provisions, combined, will serve as an important safeguard that will help CMS ensure that Part D drugs are only prescribed by qualified individuals and provide CMS the authority to remove bad actors from the Medicare program, when appropriate, protecting beneficiaries and the Medicare Trust Fund from fraud, waste, and abuse.

New Criteria for Drug Classes of Clinical Concern

In the first year of the Medicare prescription drug benefit, CMS implemented a policy that required all Part D plans to include on their formularies “all or substantially all” Part D drugs within six drug classes—antineoplastics, anticonvulsants, antiretrovirals, antipsychotics, antidepressants, and immunosuppressants. CMS implemented the policy through subregulatory guidance in order to help smooth the transition of 6 million dual eligibles from Medicaid drug coverage to Part D in 2006. The Congress later directed CMS to identify categories and classes of Part D drugs for which all Part D drugs must be on the formulary using criteria established by CMS through notice and comment rulemaking.

Under the proposed rule, extensive beneficiary protections would continue and access to drugs in these classes would be ensured through adequate Part D formularies because CMS’ formulary review is a clinically rigorous protection that ensures that each Part D formulary will meet the needs of most Medicare beneficiaries, and any beneficiary with atypical needs may submit a formulary exceptions request. Any beneficiary whose current medication is being removed from a formulary in the following coverage year will receive advance notice of this change, and that beneficiary will have an opportunity to choose a new plan during the annual election period that will cover that medication. However, it would be a mistake to assume that any current medications, especially brand-name medications, would no longer be broadly available on beneficiaries’ current Part D plans as a result of our proposed policy change. This is not what we observe in drug classes today that are not subject to guaranteed formulary placement, and there is no reason to expect that manufacturer and purchaser behavior would be significantly different for historically “protected class” drugs. For example, when we look at 2014 formularies across drug classes that have as many products as are included in the antipsychotic and antidepressants classes, we see a 79 percent inclusion rate on average. Once the requirement to cover all drugs in a class was removed, we would expect manufacturers to negotiate for their products to remain on many formularies in order to retain as much market share as possible.

If, however, a beneficiary wishes to remain in a plan that will no longer cover a medication that he or she has been successfully stabilized on, that beneficiary will receive a transition supply and will have time to request a formulary exception. Under our transition requirements, the

beneficiary must receive at least 30 days of medication during the first 90 days of the plan year to allow for effectuation of the exception request or conversion to a formulary alternative. Fulfilling that exception request requires his or her prescriber to provide written or verbal attestation of why the formulary alternatives would jeopardize the patient's health, which under these circumstances should be supported by the patient's history. Importantly, the exceptions process is part of the upfront coverage determination process managed by the sponsors, and exception requests never need to progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative. Any time a beneficiary is going to leave a pharmacy without their prescription being filled, that beneficiary receives a printed notice of how to use these exception and appeals rights. Through complaint monitoring and both routine and risk-based audits, CMS has effective oversight of plans' compliance with the coverage determination/redetermination process. Where deficiencies are identified, we have been successful in bringing plans into compliance.

Under the proposed criteria for identifying categories and classes of drugs for which all Part D drugs must be on formulary, CMS would continue to require formulary inclusion of all drugs within the antineoplastic, anticonvulsant, and antiretroviral drug classes. However, CMS would no longer require all drugs from the antidepressant and immunosuppressant drug classes to be on all Part D formularies. The proposed change would not result in only two drugs on a formulary, but would result in at least the *minimum* required by our formulary inclusion reviews, which have been successful in ensuring access for other critical disease groups, including cardiac diseases, diabetes, lung diseases, and stroke. In the specific case of immunosuppressants, the proposed change in policy would not change our formulary requirements—we would require six drugs in this class, just as we do under current formulary review standards. CMS is also proposing to delay removing the protections from the antipsychotic class pending consideration of comments on whether there are any special transitional considerations that should be addressed prior to doing so. CMS recognizes that this would represent a change, and we will carefully review the comments before making any final decision.

Increased Competition

In light of our experience managing the Part D benefit and consistent with the Congress’ directive to promote market competition in order to lower costs for the program and beneficiaries, CMS has proposed a number of interrelated regulatory provisions that are designed to improve price transparency and expand access to market-driven price competition. The proposed rule would require that all pharmacy price concessions are reflected in the drug prices paid by beneficiaries and the government, and it would ensure that any amounts rebated by pharmacies to Part D sponsors are used to lower the “negotiated price.” The proposal would also put all Part D sponsors on a level playing field regarding how they report drug prices, improving the transparency of drug prices used on the Medicare plan finder and in the bids submitted by Part D sponsors.

To further improve market-driven price competition, the proposed rule would require that the lower copayments some Part D sponsors make available in a limited number of “preferred” network pharmacies steer beneficiaries toward lower priced drugs. While CMS agrees that preferred pharmacy networks can offer savings to Part D beneficiaries, we have found that a few sponsors have actually offered little or no savings on aggregate drug prices in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs. Instead of passing through lower costs available through economies of scale or steeper discounts, some sponsors are actually charging the program higher negotiated prices and retaining any “savings” as higher profit. When these higher prices are combined with significantly lower cost sharing offered in preferred pharmacy pricing, such pricing increases the costs borne by the government. CMS supports maintaining or expanding access to preferred cost sharing levels, provided that there is better alignment between lower cost sharing levels for beneficiaries and lower negotiated prices for the program.

The proposed rule would also require Part D sponsors to allow any retail pharmacy willing to receive reimbursement at lower negotiated drug prices to contract with a Part D sponsor to have preferred cost sharing levels offered at the pharmacy. This proposal would allow more pharmacies—not just the pharmacies selected by Part D plans sponsor—to offer the most competitive drug prices, particularly for widely available low-cost generics, in order to be able to

attract customers with lower copayments offered under preferred cost sharing. As a result, the proposal, if finalized, should expand access for beneficiaries, particularly beneficiaries in rural areas, to more pharmacies that charge lower copayments for lower priced drugs. Expanding access to lower priced drugs also has the potential to reduce government expenditures on Part D. That said, we welcome comments on the implications of this policy.

More Meaningful Plan Choices

In order to ensure that beneficiaries have better ability to compare prescription drug plans with meaningfully different benefits and transparent costs, and because the Affordable Care Act's closing of the coverage gap has reduced the need for plans offering enhanced benefits, in the CY 2015 rule, CMS proposes that prescription drug plan (PDP) sponsors offer no more than two Part D plans in the same service area. On average, in 2014, every region has 17 basic plans and 17 enhanced standalone plans. Under the proposal, each organization would continue to be able to offer two plans in each area—one basic and one enhanced. CMS believes that the proposed policy would promote needed clarity of plan choices for beneficiaries without denying sponsors access to any truly innovative approaches they may take to designing plan benefit packages that meet Part D requirements.

To meet Part D requirements, all PDP sponsors must offer at least one basic plan per PDP Region, and all plans offered by the sponsor in a region must be meaningfully different from each other. Historically, sponsors, in addition to their basic plan offering, have used coverage for drugs in the coverage gap to distinguish their second and third plans. With the gradual reduction and closing of the coverage gap mandated by the Affordable Care Act that began in 2011, a feature of the Part D benefit that previously afforded sponsors greater opportunity to differentiate their own plans from each other and from the products of their competitors has largely been eliminated. As a result, sponsors' third plans represent little enhanced value over their second plans and have little appeal in the Part D market. Today, the enrollment in all "third" plans combined represents only two percent of the total enrollment in all stand-alone PDPs.

CMS believes beneficiaries will be better served by encouraging sponsors to focus on quality rather than quantity by developing innovative plan designs that have broad beneficiary appeal. In

addition, CMS believes this policy could help CMS use the bid review process to prevent plans from tailoring benefits in enhanced plans to attract healthier, lower-cost beneficiaries. This policy also could make it easier for beneficiaries to compare their options and select the Part D plans that best meet their needs. As with all proposals, we welcome comments on this policy.

Conclusion

CMS' role in managing the MA and Part D programs is to ensure strong choices and protect beneficiaries, while ensuring the fiscal integrity of the trust funds. To accomplish these goals, CMS has and will continue to take steps to make improvements. The proposed rule is a continuation of CMS' periodic strengthening of the regulations governing the MA and Part D programs and, as in the past, CMS will listen carefully to the comments from all stakeholders, reserving judgment until the comment period is closed and all stakeholders have had the chance to weigh in. CMS will continue to work with the Congress and this Committee in protecting taxpayer dollars, beneficiary health, and the integrity of the Medicare program.