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“Messing with Success: How CMS’ Attack on the Part D Program Will
Increase Costs and Reduce Choices for Seniors”

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Introduction:

Chairman Pitts, Ranking Member Pallone, and distinguished members of the Subcommittee on Health, I am Joe Baker, President of the Medicare Rights Center (Medicare Rights). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

Thank you for the opportunity to testify on the “Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (CY 2015 Part C and D Rule) recently proposed by the Centers for Medicare & Medicaid Services (CMS).¹

We believe that each of the proposed policies reflected in the rule should be evaluated on its own merits—as opposed to supporting or opposing the proposed rule as a whole. The draft rule reflects CMS’ interpretation of multiple statutory mandates as well as updates to existing rules that have become necessary in the two years since a comprehensive Part C and D contract rule has been released.

In short, the evaluation of this rule should not be a zero-sum game, as the rule represents a varied array of changes to Part C and Part D plans that should be assessed on a case-by-case basis. Our testimony will detail proposed policies that Medicare Rights strongly supports, those that we support with suggested changes, those that we approach with caution, and those that we oppose altogether.

Many of the proposed policies that we support reflect CMS’ acknowledgement that increased oversight and monitoring is required to ensure that plans and providers serve beneficiaries in a way that is consistent with the purpose and intent of the Medicare program. There are several provisions in the proposed rule where we appreciate CMS’ intentions, though we may not agree with the specifics of CMS’ proposed policy solutions. In these instances, we offer suggestions to both CMS and Congress that are aligned with the best interests of people with Medicare.

A Direct Line to Medicare Beneficiary Experiences and Challenges:

Medicare Rights answers 15,000 questions on our national helpline each year, serving older adults, people with disabilities, and those that help them—family caregivers, social workers, attorneys, and other service providers. Through our educational initiatives, we touch the lives of another 140,000 people with Medicare and their families. In addition, Medicare Interactive, our online learning tool, receives approximately 1.1 million visits annually.

Problems presented by callers to the Medicare Rights helpline are varied and complex. In 2012, the most common questions heard on the helpline centered on three themes: affording basic health care costs, appealing denials of coverage, and enrolling in Medicare. In all of these areas, we see that Medicare beneficiaries lack needed support.²

¹ “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule” 79 Fed. Reg. 7 (Jan. 10, 2014) pp. 1918-2073 (to be codified at 42 CFR Parts 409, 417, 422, et al.) (Here and after as proposed rule)

² Sutton, C., Bennett, R., Sanders, S., and F. Riccardi, “Medicare Trends and Recommendations: An Analysis of 2012 Call Data from the Medicare Rights Center’s National Helpline,” (Medicare Rights Center: January 2014), available at: <http://www.medicarerights.org/policy/priorities/2012-medicare-trends/>

As an acknowledgement of our counseling expertise, the Medicare Rights helpline is referenced on a number of standardized beneficiary notices approved by CMS. These include the Medicare Advantage (MA) notice of denial of payment, the MA notice of denial of medical coverage, the Part D notice of coverage denial, and most recently the integrated denials notice developed for use by health plans serving dually eligible beneficiaries.³

Medicare Rights regularly provides comment on proposed regulation and educational content developed by CMS, such as the annual Medicare & You handbook. Our commentary on the proposed CY 2015 Part C and D rule draws directly from 25 years of experience serving older adults and people with disabilities who rely on Medicare for basic health security.

Proposed Policies We Strongly Support:

Ensuring meaningful differences between Part D plans. Under Part III, A, Section 20 of the rule, CMS proposes to limit the number of prescription drug plans (PDPs) that can be offered by a plan sponsor to one basic and one enhanced plan per region. We have been consistently supportive of CMS's efforts to consolidate Part D plan offerings and to require meaningful differences among plans, and we strongly endorse the proposed change.

Like CMS, we believe that an appropriate offering of plans in a given region must reflect a balance between meeting the needs of diverse beneficiaries and avoiding undue confusion resulting from the availability of too many plans. Based on our experience, the current multitude of plan choices does not adequately strike the desired balance. In 2013, on average, beneficiaries had a choice among 31 PDPs.⁴

We observe that older adults and people with disabilities find choosing among a large number of Part D plans a dizzying experience. We urge people with Part D to revisit their plan's coverage each year, as annual changes to plan premiums, cost sharing, utilization tools, and formularies are commonplace. Yet, research and our one-on-one counseling of people with Medicare suggest that inertia is widespread.

Most people with Medicare fail to reevaluate their coverage options on an annual basis, largely because there are *too* many options and *too* many variables to compare. According to one analysis, from 2006 to 2010, only 13% of beneficiaries switched prescription drug plans during each annual enrollment period, despite changes in premiums, cost sharing, and coverage.⁵

In addition, so-called enhanced Part D plans are not always meaningfully enhanced, and in many cases it would serve beneficiaries better for these plans to be consolidated or eliminated. Lower income beneficiaries who are enrolled in the Low-Income Subsidy, or Extra Help, can receive full subsidies for so-called basic plans—but not

³ CMS, "Notice of Denial of Payment," (required use by November 2013), available at: <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/NDP.zip>; CMS, "Notice of Denial of Medical Coverage," available at: <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/NDMCZip.zip>; CMS, "Notice of Denial of Medicare Prescription Drug Services," (last revised February 2013), available at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10146.pdf>; CMS, "Integrated Denial Notice Form," (issued August 2013), available at: <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/MADenialNotices.html>

⁴ Hoadley, J., Summer, L., Hargrave, E., and Cubanski, J., "Medicare Part D Prescription Drug Plans: The Marketplace in 2013 and Key Trends, 2006 – 2013" (Kaiser Family Foundation: December 2013), available at: <http://kff.org/medicare/issue-brief/medicare-part-d-prescription-drug-plans-the-marketplace-in-2013-and-key-trends-2006-2013/>

⁵ Hoadley, J., Hargrave, E., Summer, L., Cubanski, J., and T. Neuman, "To Switch or Not to Switch: Are Medicare Beneficiaries Switch Drug Plans to Save Money?" (Kaiser Family Foundation: October 2013), available at: <http://kff.org/medicare/issue-brief/to-switch-or-not-to-switch-are-medicare-beneficiaries-switching-drug-plans-to-save-money/?special=footnotes-footnote-87213-9>

for enhanced plans. This means that the less robust enhanced plans will tend to attract a wealthier, healthier population, and be able to offer enrollees lower premiums—while basic plans will charge higher premiums to cover the costs of a by and large less affluent and less healthy population.

Additionally, plan sponsors have less competitive incentive to keep basic plan premiums low—premiums which are paid in large part by the federal government through the Extra Help program. This is because plans sponsors are currently able to attract healthier, private-paying individuals to a low-premium enhanced plan. Medicare Rights agrees with CMS that this kind of risk segmentation should be avoided.

Increasing drug pricing transparency, fairness and accuracy: In Part III, A, Sections 25, 26, 27 and 29, CMS proposes a series of interrelated proposals on negotiated drug prices, preferred cost sharing, and preferred pharmacies. We strongly support this series of proposals, and we believe these changes will benefit both taxpayers and Medicare beneficiaries.

Standardizing reporting by drug plans on negotiated prices: In sections 25 and 26, CMS proposes to standardize how PDPs report the negotiated price for particular medications, which in turn affects the amount CMS pays plan sponsors. To justify this change, CMS details inconsistencies in how PDPs report negotiated drug prices. For instance, some PDPs are reporting a negotiated price that includes “concessions” from the network pharmacy, essentially price reductions, while others report a higher negotiated price that excludes concessions, and wait until the payment year reconciliation process to report concessions as one-off discounts. CMS explains that the proposed standardization is needed to ensure that PDPs cannot game the system by failing to report network pharmacy concessions in the negotiated price.

As such, we support CMS’ efforts to ensure that the reported negotiated price accurately reflects the net agreed-upon price between the network pharmacy and PDP. This practice will not only benefit the Medicare program—and taxpayers—but also improve the accuracy of premium and cost amounts in the Medicare Plan Finder, CMS’ online plan comparison tool, allowing beneficiaries to more accurately gauge plan costs and efficiency.

Establishing fair and accurate preferred pharmacy cost sharing: In Section 27, CMS seeks to address existing problems with “preferred pharmacy” arrangements. Medicare Rights’ counseling experience reflects a need for increased oversight, clarity, and beneficiary education around these practices, as evidenced by our experience serving Ms. T, a 72 year-old woman and Maryland resident who called our helpline during the 2013 annual election period.

Ms. T is enrolled in a PDP and has relied on her local pharmacy for 40 years. In November, she was notified that her pharmacy would no longer be a preferred pharmacy for her drug plan. Her pharmacist explained that he was unaware of the reason behind the change, and wished his business could retain preferred status. Ms. T called the helpline seeking assistance with finding a Part D plan that “would allow her to use her pharmacy.”

Our counselor explained that Ms. T’s medications would still be covered at her pharmacy, but that the copayments would likely be higher, because her pharmacy was still in her plan’s network but was not “preferred.” After completing a Plan Finder search, the counselor determined that Ms. T’s cost sharing would increase by over \$300 during the year if she continued to visit her long-standing pharmacy with her current drug plan. Unfortunately, other PDPs offered in Ms. T’s area offered only moderate savings over these new higher costs, and many had deductibles that were simply unaffordable on her fixed income.

Unfortunately, Ms. T's experience is not uncommon. When Congress enacted Part D it sought to preserve patient access and choice by permitting any willing pharmacy to participate in a network so long as it met the plan's reasonable terms and conditions. In recent years, however, some plan sponsors have formed preferred pharmacy arrangements that are increasingly restrictive and not cost effective. As CMS explains in the proposed rule, the utilization of preferred cost sharing by plan sponsors should reflect a lower total cost for prescriptions to Medicare and to beneficiaries. Currently, however, the promise of savings is not being fully realized.

Numerous CMS studies have found that current sponsors who utilize preferred pharmacy networks, "...have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs..."⁶ CMS also found that numerous plan sponsors, and their Pharmacy Benefit Manager (PBM) intermediaries, have conflicts of interest with respect to these pharmacy arrangements. CMS writes, "...we note that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits."⁷

In this way, plans distort market behavior by lowering beneficiary cost sharing where the full cost of the drug is the same or higher than it would be at a non-preferred pharmacy. Instead of harnessing the power of consumer choice to lower costs overall by aligning lower cost-sharing with lower total cost, the plans divide the interests of individual beneficiaries and the Medicare program in order to increase the profits of related-entity mail order pharmacies. This results in higher Medicare spending overall. Like CMS, we find these facts disturbing, and we agree that these practices reflect inappropriate cost shifting to CMS and taxpayers. As such, we strongly endorse CMS' proposal to revisit the current preferred pharmacy network structure in favor of a minimum savings standard under a preferred cost sharing system.

Medicare Rights also supports CMS' proposed language change to more accurately reflect that preferred cost sharing is applicable to a particular medication at a particular pharmacy, and to avoid confusion about whether non-preferred pharmacies are out-of-network. Understanding how preferred, in-network pricing works is one of the most opaque and confusing aspects of choosing a Part D plan. In our experience, beneficiaries often find the distinction between in-network and out-of-network status difficult to grasp. Preferred and non-preferred status, essentially networks within networks, creates yet another layer that beneficiaries must understand when using their Part D benefits. Given this, we support these efforts by CMS to ensure that plan pricing and cost sharing structures are uniformly explained across plans.

Expanding access to preferred pharmacies and reducing beneficiary costs. Aligned with the proposal to ensure that preferred cost sharing signals consistently lower costs, in Section 29, CMS proposes that any pharmacy willing to meet specified savings goals be allowed to charge preferred cost sharing. Medicare Rights agrees that local pharmacies willing to match competitors' prices should be allowed to charge the applicable cost sharing. For instance, had Ms. T's pharmacy been allowed to participate in preferred cost sharing, she would have retained access to her pharmacy of choice and saved considerably on her annual prescription drug costs.

⁶ Proposed rule at 1975

⁷ Proposed rule at 1976

Enhancing oversight. In many respects the proposed CY 2015 Part C and D rule reflects CMS' belief that enhanced oversight of PDPs and MA plans is needed to improve the delivery of benefits. Medicare Rights supports CMS' determination that strengthened oversight is needed as follows:

Expanded contract termination authority. In Part III, A, Section 2, CMS proposes prohibiting MA plan sponsors from submitting bids for new plans of the same type in regions where the plan was not renewed due to low enrollment. We support this rule, which will discourage plan sponsors from resubmitting bids for plans not well suited to beneficiaries' needs.

Increased audit and inspection authority: In Part III, A, Section 6, CMS details the criteria by which it determines which Part C and Part D plan sponsors are audited each year, and at the same time acknowledges that limited resources allow the agency to perform annual audits on only 10% of plan sponsors, or 30 of 300 Part D and MA sponsors. We strongly agree that more regular auditing of plan sponsors is needed. Additionally, we urge members of Congress to make the resources available to allow CMS to perform its own independent audits on an appropriate scale.

New requirements for continuity and disaster planning: In Part III, A, Section 16, CMS highlights the experience of beneficiaries affected by Hurricane Sandy as the basis for new planning and service continuity requirements. Medicare Rights' main offices are located in New York City, and we heard directly from beneficiaries unable to secure needed prescriptions and other services in the aftermath of Hurricane Sandy. As such, we strongly support CMS' determination that these continuity plans should be developed and tested to ensure that beneficiary needs are met.

Required experience for new plan contracts: In Part III, A, Section 17, CMS develops new requirements for first-time applications to the Part D program. Under the proposed rule, plan sponsors or related entities must have at least one year of experience delivering the Part D benefit in order to secure a Part D contract. We support these requirements, as beneficiaries will be better protected and served by Part D plan sponsors and entities with experience operating this specific benefit.

Enforcing plan improvement via star rating metrics. In Part III, C, Section 1, CMS proposes including the requirement that MA and Part D plan sponsors achieve good or improving scores on CMS performance standards for outcomes, intermediate outcomes, process, patient experience, and patient access to care in the sponsor's plan contracts. We appreciate and support this recognition of the importance of explicit and enforceable metrics for judging plan performance.

Strengthening Beneficiary Notices. CMS proposes several changes to improve beneficiary notification pertaining to Part C and Part D plans. Specifically, in Part III, A, Section 11, CMS will codify existing requirements that Part D plan sponsors make an Annual Notice of Change (ANOC) available to beneficiaries 15 days prior to the Medicare annual election period, thus aligning Part D requirements with MA rules. While many Part D plans already provide this notice, as required through CMS guidance, we believe it is important that this requirement is made explicit through the rulemaking process.

Requiring an ANOC on Part D plans ahead of open enrollment serves the dual purpose of reminding beneficiaries to revisit their prescription drug coverage options annually, while also providing a summary of changes to a plan's coverage and cost sharing for the following year. Access to this information ahead of open enrollment is critical given that annual changes to premiums, cost sharing, utilization tools, and benefits are

commonplace. Additionally, CMS appropriately emphasizes that PDPs must clearly communicate cost sharing changes, in addition to formulary changes, through the ANOC.

In Part III, A, Section 12, CMS proposes to require that MA plans send the ANOC separate from the Evidence of Coverage (EOC), a detailed list of plan benefits and cost sharing. The EOC is a long and detailed document, and we often observe that beneficiaries find reviewing the EOC a daunting experience. In fact, we find that many beneficiaries require assistance from a trained counselor to decipher the EOC's content. By contrast, the ANOC is a streamlined tool designed to help beneficiaries determine whether or not switching to another MA plan or to Original Medicare during the open enrollment period would be a beneficial choice. As such, we support CMS' recommendation to separate the delivery of the ANOC and the EOC.

We continue to believe that individually tailored ANOCs would be most helpful to beneficiaries as a decision-making tool, and encourage CMS to consider opportunities to further tailor these notices to individual needs. Along these lines, we applaud improvements to the ANOC for MA plans in the "Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," which specifically strengthens requirements regarding plan notification on the potential for provider network changes.⁸

Strengthening MA plan requirements for Part D denials otherwise covered under Part A or Part B. CMS cites cases where a Medicare Advantage Prescription Drug (MA-PD) plan enrollee experiences delays accessing a needed medication, either at the pharmacy counter or through the coverage determination process, that should be covered under Part A or Part B of their plan benefit as opposed to Part D. Like CMS, Medicare Rights agrees that these cases represent a failure on the part of the MA plan to adequately coordinate patient care, and we have assisted helpline callers in these exact circumstances.

One of our callers, Ms. P, a 59-year old woman from Ohio who lives with Chronic Obstructive Pulmonary Disease was turned away at the pharmacy when an anti-asthmatic medication that she uses with a nebulizer was denied under her MA-PD plan's Part D benefit. Only after her physician sent an unsuccessful request for a coverage determination and a subsequent request for a tiering exception was it made clear to Ms. P that payment should have been made under the plan's Part B benefit. Her plan's inability to adequately coordinate care and communicate coverage rules caused a multi-day delay in access to her anti-asthmatic medication, increasing the risk of costly and life-threatening emergency intervention.

To rectify this behavior and help more beneficiaries like Ms. P, in Part III, C, Section 2, CMS proposes requiring that MA-PD plans take steps to appropriately address Part D denials of coverage for medicines that should be covered under Part A or Part B. CMS suggests that MA-PD plans should more effectively coordinate with network pharmacies and providers and ensure that coverage determinations are processed correctly and only once.

We strongly support these proposals, but suggest that CMS extend these requirements to both non-network as well as network pharmacies. Additionally, we continue to urge CMS to make needed improvements to the Part D appeals process, both by improving beneficiary notification and by streamlining the process, most importantly

⁸ CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," (February 2014), available at: <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Advance2015.pdf>

by requiring plans to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination.

Proposed Policies We Support with Changes:

Addressing improper prescriber practices. In Part III, A, Section 31, CMS acknowledges multiple instances of improper prescribing of medications in the Medicare program and notes that these prescribing practices result in unnecessary Medicare spending. Medicare Rights supports CMS' efforts to reduce this waste, fraud, and abuse by targeting those most likely to be acting inappropriately. We applaud efforts that target problematic providers and suppliers in a narrow and focused way, and that do not impose burdensome, expensive, and ineffective restrictions on beneficiary access to needed care.

In particular, we strongly endorse the requirement that prescribing providers have a Drug Enforcement Administration (DEA) certificate in addition to state prescribing authority to participate in the Medicare program. We also support the standards for continued participation in the Medicare program, and the ability of CMS to revoke participation for abusive behavior that threatens the health and safety of Medicare beneficiaries, though we would like to see enhanced beneficiary protections included. And, although we appreciate the increased oversight and credentialing that the provider enrollment requirement affords, we encourage CMS to amend the rule to avoid unintended adverse affects as follows:

- Hold beneficiaries harmless from the consequences of non-coverage for a non-compliant provider for at least one prescription fill;
- Require MA and Part D plans to reach out to the beneficiary and provider to explain the issue, allowing sufficient time for the beneficiary to see another provider or for the provider to correct their enrollment status;
- Make exceptions for those providers who do not normally see Medicare beneficiaries or receive Medicare payment, including dentists, psychiatrists, and Veteran's Administration doctors.
- Allow these excepted providers to, within a grace period, register with Medicare in a limited capacity to enable them to write prescriptions for Medicare beneficiaries;
- Reach out to policymakers in states that permit foreign prescriptions to determine what kind of alternate provider credential checking might be available to ensure that beneficiaries who spend portions of the year in other countries can access their medications without interruption; and
- Make easily searchable lists of provider status available to Medicare beneficiaries, consumer advocates, and counselors, as well as to MA and Part D plans.

Increasing access to the Medication Therapy Management (MTM) programs. CMS proposes expanding the population to which MTM programs must be offered in Part III, A, Section 15. It is generally acknowledged that Medicare's MTM programs are not living up to desired expectations, and it remains difficult to gauge the relative success of MTM programs, given lower than expected enrollment and limited evidence on the program's efficacy.⁹

⁹ Rucker, L.N., "Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive," (AARP Public Policy Institute: June 2012), available at: <http://www.aarp.org/health/medicare-insurance/info-06-2012/medicare-part-d-mtm-AARP-ppi-health.html>

Many callers to Medicare Rights' helpline, even those enrolled in MTM programs, are unclear about what the programs are and how they will benefit from enrollment. Common questions from our callers include: How will MTM help me save money on prescription drugs? Is it even "worth it" to enroll in MTM? These questions reflect a general lack of understanding about how MTM programs can assist beneficiaries in managing multiple medications.

We share CMS' concern that plans have not been effective in reaching the beneficiaries who would most benefit from MTM services, and we find evidence cited in the proposed rule on racial and ethnic disparities in access to MTM programs particularly alarming. Based on the research detailed in the proposed rule, we believe CMS' proposal to require that plans offer MTM services to individuals with two chronic conditions who are using at least two Part D prescription drugs a reasonable one and we endorse its adoption.

Although we question whether broad expansion is the best way to enhance the effectiveness of MTM programs, we appreciate that uniformity across plans is needed to facilitate research on program efficacy, best practices, and potential enhancements. We believe that the proposal for expansion would be strengthened with additional monitoring by CMS on MTM participation among the following populations: communities of color, beneficiaries with limited English proficiency, and other hard-to-reach subgroups. MA and Part D plans should be held responsible for their outreach to these groups and for their effectiveness in delivering MTM benefits.

Proposed Policies We Oppose and Areas of Concern:

Scaling back the protected drug classes. In Part III, A, Section 14, CMS proposes replacing the requirement that all Part D plans cover all available medications in six designated protected classes with a two-step test to determine which categories of medications are of sufficient clinical concern to merit continued protected access. Upon application of this test, CMS determines that antidepressants, immunosuppressants, and antipsychotics no longer meet the requirement for enhanced protections.

CMS' proposed rule relies on the appropriate functioning of beneficiary protections, including formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes, to justify easing robust formulary requirements for protected drug classes. Medicare Rights' experience serving Medicare beneficiaries suggests, however, that these protections are insufficient. In particular, we have continuously suggested that CMS critically examine and streamline the Part D appeals process, and we believe increased transparency about how well the appeals system operates is needed.

Given the shortcomings of the appeals process and other beneficiary protections, namely formulary transparency and transition supplies, we cannot support the proposed changes to the protected classes at this time. Our specific concerns include the following:

The Part D appeals process needs significant repair. In 2012, over one third (33%) of calls to the Medicare Rights helpline concerned denials of coverage and appeals, making up the largest proportion of inquiries to the helpline. Recent findings by MedPAC confirm that many beneficiaries are unaware of their right

to appeal and do not know how to go about initiating the appeals process.¹⁰ We observe the following trends with respect to Part D appeals:

First, we find that people with Medicare are not provided individualized information or adequate education when refused a medication at the pharmacy counter. As such, beneficiaries must embark on a tedious, fact-finding search to learn the reason for the refusal and to determine the best path forward. Pharmacists may have limited or incomplete information and can only direct a beneficiary to call the drug plan for the denial reason. Beneficiaries often face long call wait times and inconsistent customer service when trying to obtain this information.

Next, we observe that the multi-step Part D exceptions and appeals process proves onerous and time-consuming for beneficiaries, pharmacists, and prescribing physicians. Although denied coverage at the pharmacy counter, this refusal does not constitute a formal denial by the plan, which would entitle the person to an appeal. Instead, with the support of the prescribing physician, a beneficiary must formally make an exception request. Only upon receipt of a written denial in response to this request, known as the coverage determination, is the beneficiary permitted to request a formal appeal, termed a redetermination.

While this multi-step process is described clearly here, it is important to note that this course of action may involve multiple phone calls and long wait times, often up to many days, for beneficiaries seeking access to a needed medication. A person must correspond with both their plan and their prescribing doctor on multiple occasions to see the coverage determination and redetermination phases through.

The current system is constructed in such a way that Part D drug plans are effectively granted three chances to make a correct determination about covering a prescribed medication: at the pharmacy counter, in the coverage determination, and in the redetermination. It is worth noting that this three-step process is distinct from Medicare Advantage (MA), Original Medicare, and Medicaid appeal frameworks. In these health programs, a beneficiary receives a notice of non-coverage after a service is received or prior to the service because it is not authorized. Unlike Part D, beneficiaries are not expected to formally request notice of non-payment after refusal of a service.

To date, there is no data or analyses available to the public or reflected in the proposed rule to suggest how often improper denials are corrected at the plan level. Further, what appeals data exists is not reassuring. CMS's 2012 audit suggests that Part D plans struggle most with managing coverage determinations, appeals, and grievances. Additionally, 2011 data released by the agency finds that over half (54%) of plan-level denials are overturned by the Independent Review Entity (IRE), which conducts the first post-plan level—and truly independent—review.

This alarming rate of reversals by the IRE, coupled with CMS' own audit data on plans, raises serious questions about how well the redetermination and appeals process is working, and demands greater transparency. We urge members of Congress to request that CMS make plan-level appeals data accessible in easy-to-comprehend formats so that targets for improvement can be identified.

¹⁰ Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, "Part D exceptions and appeals" (September 2013), available at: http://www.medpac.gov/transcripts/part_d_exceptions_&_appeals.pdf; CMS, "Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011" (2011), available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html>

More importantly, we strongly believe that the Part D appeals process must be streamlined and tested ahead of any changes that would relax the protected classes. A straightforward approach to improving the appeals process would combine a point-of-sale refusal with a formal request for a coverage determination, as suggested in a recent letter to CMS signed by members of the Senate Finance Committee.¹¹ Allowing the pharmacy counter refusal to serve as the coverage determination serves the dual purpose of removing a burdensome step for beneficiaries and their doctors while also expediting the appeals process for those who need it.

Formulary review and transparency need improvement. We believe that CMS sets an unreasonably low bar for evaluating beneficiaries' formulary needs. In the proposed rule, CMS writes, "...with our more than 7 years of experience with the Part D program, we are not aware of any Part D drug that is not included on at least one Part D formulary. Thus, beneficiaries who review plan formularies [on Plan Finder] can select plans that cover all of their current medications."¹² This statement is highly problematic as justification for reducing formulary protections for two key reasons:

First, it is inconsistent with Medicare Rights' experience helping tens of thousands of beneficiaries review their coverage options. While it may be accurate that there is no Part D drug that is not on at least one formulary, the same plan options are not available in all areas of the country, and beneficiaries must select a Part D plan within their geographic area. Furthermore, many beneficiaries, particularly those with complicated health status, take more than one prescription. The fact that drug A is on the formulary of Plan X and drug B is on the formulary of Plan Y is not sufficient for a person who must take both A and B.

Second, this statement ignores the well-documented shortcomings of the Plan Finder tool. As a recent GAO report found, despite CMS oversight and improvements, beneficiaries still encounter inaccurate and out-of-date information on Plan Finder.¹³ On an annual basis, Medicare Rights provides detailed recommendations to CMS about needed improvements to Plan Finder, drawing directly from our experience serving 2,500+ beneficiaries during the open enrollment period. Among our recommendations are to add appropriate MA plan content, most notably information concerning provider networks, ensure the clarity and accuracy of mail order information, improve the accuracy of cost sharing data, and more.¹⁴

We believe that CMS should take steps to improve both beneficiary education and Plan Finder before restricting access to some of the most urgently needed medications. Members of Congress should explore how to make the appropriate resources available to CMS to support making the Plan Finder a more robust and user-friendly tool.

Access to transition fills is inconsistent. Transition fills, coverage for one month for a continuing treatment when there has been a plan or formulary change, are an essential protection that we find many beneficiaries do not receive. In 2013, CMS continued a transition-fill monitoring program in response to widespread failure to provide appropriate transition refills to those entitled to them.¹⁵ CMS has attempted to

¹¹ Thomas, K. and R. Pear, (February 21, 2014) "Plans to Limit Some Drugs in Medicare is Criticized," *New York Times*, available at:

http://www.nytimes.com/2014/02/22/business/plan-to-alter-medicare-drug-coverage-draws-strong-opposition.html?_r=0

¹² Proposed rule at 1939

¹³ GAO, "CMS Has Implemented Processes to Oversee Plan Finder Pricing Accuracy and Improve Website Usability," (January 2014), available at:

<http://www.gao.gov/products/GAO-14-143>

¹⁴ Medicare Rights Center, "MEMO to the Centers for Medicare & Medicaid Services re: Plan Finder Observations during Fall Open Enrollment: October 15, 2012 – December 17, 2012," (March 2013)

¹⁵ CMS, "MEMO re: Contract Year 2013 Part D Transition Monitoring Program Analysis," (December 2012), available at:

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/ContractYear2013PartDTransitionMonitoringProgramAnalysis.pdf>

address failures to properly effectuate transition fill by drug plans in the past, without improvement. These systematic failures underscore the need for on-formulary access to a wide range of medications for certain classes of drugs.

Uninterrupted treatment on a specific medication is particularly essential for antidepressants, antipsychotics, and immunosuppressants, the very same drugs for which CMS suggests protected status should be relaxed. We applaud CMS for implementing the transition-fill monitoring program. Yet, we believe that CMS should wait for the full results, and publish those results, before relying on transition fills as an appropriate fail-safe for securing access to these essential medications.

In addition to these known shortcomings, transition fills are only available to a narrow band of beneficiaries. Individuals previously stabilized on a particular antidepressant, for example, but who are untreated for a period of time are not eligible for a transition fill if they must return to treatment. In these cases, a beneficiary's physician likely knows which specific medication is best suited to the person's health needs. In the absence of broad formulary protections, these beneficiaries may not be able to access the particular medicine essential to their health. In short, transition fills will not adequately protect these beneficiaries from diminished access to needed prescriptions if the protected classes are not preserved.

Targeted interventions are needed for overprescribing in long-term care settings. CMS presents no evidence to suggest that open access to protected classes of medications on Part D formularies results in widespread overutilization, with the exception of inappropriate prescribing of antipsychotic medications in nursing home settings. Like CMS, Medicare Rights is deeply concerned about this trend, and we encourage both CMS and members of Congress to explore targeted interventions in these settings to limit these egregious prescribing practices.

As such, we support CMS' proposed policy to target providers who prescribe antipsychotics for patients with dementia in direct violation of the drug's Food and Drug Administration (FDA) approved black box warning. Additionally, we urge CMS to explore partnerships with state boards that oversee prescriber and nursing facility practices, or to develop targeted, narrow exceptions to the protected class status to allow prior authorization requirements in certain prescription settings. These solutions would target abusive prescribing behaviors in specific settings, rather than jeopardize access for beneficiaries living in community settings who must access these medications.

Congress should seek Medicare drug savings that do no harm to beneficiaries. CMS cites increased drug prices as its primary reasoning behind scaling back the protected drug classes and requiring open drug coverage for specific classes of medications. CMS writes, "The principal disadvantage is that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes."¹⁶ CMS's concerns about Medicare's ability to secure the best possible prices on prescription medications are not unfounded. But we do not believe that CMS should pursue policies that may unduly restrict access to rectify this issue.

Instead, Congress should act. To address concerns regarding drug pricing in Medicare, Congress should restore Medicare drug rebates, as reflected in the Medicare Drug Savings Act (H.R. 1588; S.740), and save taxpayers

¹⁶ Proposed rule at 1937

\$141.2 billion over ten years.¹⁷ Additionally, Congress should explore policy proposals included in the President’s recent budgets to accelerate manufacturer rebates to help close the Part D prescription drug coverage gap, prohibit pay-for-delay agreements, and reduce the exclusivity period for biologic drugs. These sensible and straightforward solutions would allow Medicare to save billions on prescription drug costs, without increasing beneficiary costs or restricting access.¹⁸

Expanding MA reward and incentive programs. In Part III, A, Section 36, CMS suggests allowing MA plans to offer reward and incentive programs to current enrollees to encourage participation in activities that promote improved health, prevent injuries and illness, and encourage efficient use of health care resources. Medicare Rights remains cautious about the expansion of wellness programs, and we are firmly opposed to any wellness program that “incentivizes” participants through penalties, such as higher costs. Research suggests that incentives may increase *participation* in wellness programs, but there is little evidence to suggest that rewards and penalties lead to meaningful changes in health behaviors and outcomes.¹⁹

Our primary concern is that outcome-driven rewards and incentives programs may disproportionately penalize individuals who already face persistent barriers to maintaining their health and obtaining health care services, including older adults, people with disabilities, communities of color, and low-income patients.²⁰ As such, we share CMS’ concern that rewards and incentives programs may be targeted only at healthy enrollees and that sicker enrollees could be discouraged from participating—and thus from enrolling in an MA plan that offers these programs.

Given these well-documented concerns, we appreciate that CMS proposes requiring that all MA plan enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status, or other impairments. We also appreciate CMS’ requirement that plans submit data on these plans at CMS’ request. However, we also believe that CMS should solicit data from these programs on a regular basis and should carefully monitor their implementation. In the absence of robust oversight to prevent discrimination based on race, disability, or economic status, and “cherry picking,” we are hesitant to support the expansion of these programs.

Other notable areas of concern in the proposed include the following:

Prohibiting the copayment waivers: In Part III, A, Section 9 CMS proposes prohibiting the waiver of cost sharing when a plan sponsor and pharmacy have common ownership. We appreciate the need to enforce anti-kickback and uniformity of benefit rules, but we believe that CMS should enforce compliance with current rules rather than to remove a valuable safety valve. The current narrow exception allows a pharmacy to waive cost sharing on a non-routine basis when a beneficiary urgently needs a medication and is clearly unable to pay. This is an important beneficiary protection that should not be eliminated or reduced.

¹⁷ Office of the Honorable Senator J. Rockefeller, “Rockefeller and 18 Other Senators Introduce Legislation to Protect Seniors & Reduce Deficit by \$141.2 Billion,” (April 2013), available at: <http://www.rockefeller.senate.gov/public/index.cfm/press-releases?ID=617fffeb-4c5a-4123-a5b3-1f8b790e5f8b>

¹⁸ Office of Management and Budget (OMB), “The President’s Budget for Fiscal Year 2014,” (April 2013), available at: <http://www.whitehouse.gov/omb/budget>

¹⁹ Adams Dudley, R., Tseng, C., Bozic, K., Smith, W.A., and H.S. Luft, “Consumer Financial Incentives: A Decision Guide for Purchasers, (AHRQ: November 2007), available at: http://www.healthcarevisions.snapmonkey.net/f/2008_AHRQ_Incentive_Report.pdf

²⁰ Families USA, “Wellness Programs: Evaluating the Promises and Pitfalls,” (June, 2012), available at: <http://familiesusa2.org/assets/pdfs/health-reform/Wellness-Programs.pdf>

Establishing time frames for retroactive premium collection: In the same section, CMS proposes a timeframe to require plans to refund or seek repayment if premium amounts were incorrectly collected. We frequently observe instances when a plan sponsor makes billing errors as a result of mismanagement or poorly designed systems. When errors are discovered, CMS requires plans to send large and unexpected payment demands to beneficiaries, and often low-income beneficiaries cannot afford this expense.

Beneficiaries in these circumstances are often unaware of their right to seek financial hardship exceptions and many simply pay an exorbitant cost, despite the severe financial hardship that results. CMS should set clear limits on how far back plans can retroactively collect premiums that were not billed as a result of plan error, and provide notices to beneficiaries with clear instructions about how to seek relief if payment would cause financial hardship.

Automatic or passive enrollment for Duals Special Needs Plan (D-SNP) enrollees. CMS proposes to passively enroll members of a non-renewing D-SNP into another D-SNP in Part III, A, Section 38. Medicare Rights opposes this change, and prefers the current process of returning the individual into Original Medicare, guaranteeing access to any Medicare provider. Passive enrollment processes are not aligned with the values of choice and informed decision-making central to the success of the Medicare program.

Conclusion:

In conclusion, we hope that members of Congress will support CMS on the proposed policies outlined in this testimony that will improve the Medicare benefit and preserve access to needed health care. Many of the policy revisions suggested by CMS will advance these goals and should be adopted. Among these changes are Part D plan consolidation; increased transparency on drug pricing, fairness and accuracy; enhanced oversight regarding plan experience, terminations, and continuity planning; improved beneficiary notice; and strengthened coordination requirements for MA-PD plans concerning appeals.

At the same time, we hope Congress will raise questions in areas where well-meaning CMS proposals can be improved, most notably with respect to addressing improper prescribing practices and expanding the Medication Therapy Management (MTM) programs. Finally, we hope members of Congress will carefully scrutinize proposed policies that may harm vulnerable beneficiaries, particularly with respect to the proposed rule to scale back the protected drug classes.

We believe that the suggested need to secure better prices reflected in the CY2015 Part C and D rule presents an opportunity for Congress to act, most notably by restoring Medicare drug rebates, a proposal that will save over \$140 billion in the Medicare program. Additionally, Congress should use this opportunity to demand greater transparency and ask critical questions about existing beneficiary protections for those enrolled in MA and Part D plans, namely with respect to prescription drug appeals.

Thank you for the opportunity to testify.



Summary of Testimony by Joe Baker, Medicare Rights Center

The Medicare Rights Center is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

The Medicare Rights Center answers 15,000 questions on our national helpline (800-333-4114) each year, serving older adults, people with disabilities, and those who help them—family caregivers, social workers, attorneys, and other service providers. We believe that each of the proposed policies reflected in the “Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” rule should be evaluated on their own merits—as opposed to supporting or opposing the proposed rule as a whole.

Proposed Policies We Strongly Support:

- **Ensuring meaningful differences between Part D plans** by requiring that plan sponsors offer one basic plan and one enhanced plan in a given region. The proposed rule will facilitate more informed decision-making by beneficiaries by further streamlining available plan choices.
- **Increasing drug pricing transparency, fairness, and accuracy** through measures designed to ensure that “preferred” pharmacy network status translates to lower costs for consumers and for the Medicare program.
- **Enhancing plan oversight through** expanded contract termination authority, increased audit and inspection authority, new requirements for continuity planning, and enforced plan improvement via star rating metrics.
- **Improving beneficiary notices** through changes to delivery of the Annual Notice of Change (ANOC), which details annual plan changes, and the Evidence of Coverage, a more detailed summary of plan benefits.
- **Strengthening MA plan requirements for Part D denials** by requiring that MA-PD plans ensure coverage for medicines denied under Part D that should otherwise be paid for under Part A or B of the plan.

Proposed Policies We Support with Changes:

- **Addressing improper prescriber practices** by appropriately targeting providers not acting in the best interest or safety of beneficiaries. Additional consumer safeguards are needed to ensure continuity of care as CMS transitions to systems to more closely monitor Medicare providers.
- **Expanding Medication Therapy Management (MTM)** through revised eligibility guidelines. Adequate data collection and monitoring is needed to ensure that plans extend MTM services to diverse and at-risk populations.

Proposed Policies We Oppose and Areas of Concern:

- **Scaling back the protected drug classes** should not be adopted at this time, as existing beneficiary protections, especially the Part D appeals process, are not sufficient to preserve access to essential medicines.
- **Expanding Medicare Advantage (MA) reward and incentive programs** should only be pursued with rigorous oversight and monitoring given well-documented concerns about the potential risk for discriminatory impact and cherry picking.