NSCLC
National Senior Citizens Law Center

PROTECTING THE RIGHTS OF LOW-INCOME OLDER ADULTS

March 7, 2014

Via www.regulations.gov

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Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Re: **NPRM CMS-4159-P Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs**

The National Senior Citizens Law Center (NSCLC) is pleased to submit these comments in response to the above-referenced Notice of Proposed Rulemaking (NPRM).

The National Senior Citizens Law Center is a non-profit organization whose principal mission is to protect the rights of low-income older adults, especially women, people of color and other disadvantaged minorities. Ensuring access to Medicare programs and improvements in delivery of Medicare services, particularly to low income seniors, have been priority issues for our organization for decades.

We begin by expressing our support for the efforts of the Centers for Medicare and Medicaid Services (CMS) to improve the regulation of Medicare Part C and D plans. The agency throughout the NPRM has provided specific data and examples supporting the need for more precise regulations and enhanced oversight in order to protect both beneficiaries and Medicare program integrity. We strongly support many provisions that enhance plan oversight and accountability and improve beneficiary access to affordable prescription drugs and other services. We have carefully reviewed the proposals and include a number of suggestions and comments about those proposals that we support.

There are some provisions with which we take issue, either in whole or in part, and express our concerns below. We have very serious concerns, however, about proposed changes to redefine protected drug classes, and urge CMS not to implement this proposal.

Our detailed comments are set forth below and are numbered to correspond to the numbering in the outline in the NPRM.

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III. Provisions of the Proposed Regulations

A. Clarifying Various Program Participation Requirements

2. Two-Year Limitation on Submitting a New Bid in an Area Where an MA has been Required to Terminate a Low-Enrollment MA Plan

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.

3. Authority to Impose Intermediate Sanctions and Civil Money Penalties

We support new proposed sanction authority for marketing and enrollment violations.

4. Contract Termination Notification Requirements and Contract Termination Basis

We support the increased authority of CMS to terminate non-performing contracts and to shorten the notice period given the other procedural protections available to plans.

6. Changes to Audit and Inspection Authority

In this section, 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 percent of plan sponsors, or 30 of 300 Part D and MA sponsors. We strongly agree that more regular auditing of plan sponsors is needed, and we support efforts to increase oversight of plan sponsors and the ability of CMS to conduct audits. While we generally support CMS's goal to require plans to hire an independent auditor, we are concerned about replacing CMS directed audits. The delegation of audits requires assurance that independent auditors will provide meaningful, truly independent, analysis. In the alternative, we urge members of Congress to make the resources available to allow CMS to perform its own independent audits on an appropriate scale.

7. Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties Under Parts C and D

We support the expansion of the "test period" requirement to all intermediate sanctions, and support the proposal that previously sanctioned benchmark Part D plans not be allowed to receive or process auto-enrollments for reassignments if so determined by CMS.

8. Timely Access to Mail Order Services (§423.120)

We appreciate that CMS is proposing to set minimum fulfillment requirements for mail order pharmacies and believe the parameters CMS proposes are appropriate. We also strongly endorse setting requirements for beneficiary materials to make requirements and beneficiary options and redress more transparent. With respect to beneficiary options if a prescription delivery is delayed or lost, we ask CMS to explore requiring that plans have systems in place so that individuals will be able to have their prescription filled at a participating plan retail pharmacy.

9. Collections of Premiums and Cost Sharing (§ 423.294)

Cost Sharing: While we appreciate the need to enforce anti-kickback requirements, we have concerns about the proposal to impose an absolute prohibition on waiving cost sharing when a pharmacy is related to a Part D plan sponsor. CMS has stated that the current proposal is a response to reports of sponsors reducing or waiving cost sharing. To the extent that those reports raise concerns about unfair practices, we urge CMS to more actively oversee compliance with current rules rather than remove a valuable safety valve.

The current exception that allows a pharmacy to waive cost sharing in the face of evidence of financial need of the beneficiary is already narrowly drawn. The exception requires that the waiver is not advertised (through media outlets, telemarketing or otherwise) and is not routine, and the cost sharing is waived after a good faith determination that the individual is in financial need or reasonable efforts to collect the cost sharing have failed.

Having this modest safety valve in situations where an individual urgently needs a medication and clearly is unable to pay at the time of need is an important beneficiary protection. Without timely access to needed medications, a desperate individual can easily end up in an emergency room with consequences both for the individual's health and for costs to Medicare. The urgency in those rare situations does not change depending on the ownership of the pharmacy.

Further we note that CMS would permit a pharmacy affiliated with a plan sponsor to continue non-routine waivers of cost sharing for individuals in plans with sponsors other than the sponsor with whom the pharmacy is affiliated. In theory, this policy would

narrow the number of instances where beneficiaries would be harmed because large chain pharmacies serve members of many Part D plans and the absolute prohibition would only apply to one of those sponsors. We have serious concerns, however, that in practice all beneficiaries in all plans using such pharmacies will be denied important emergency protections. We fear that the most likely outcome of the new rule will be that pharmacies affiliated with a plan sponsor will give employees a blanket direction that they may not waive cost sharing under any circumstances. This fear is reinforced because the anti-kickback provisions at issue trigger criminal penalties. The risks if a pharmacist makes an error in determining whether an individual is in an affiliated plan are likely too serious for sponsor-affiliated pharmacies to give any discretion to their employees.

Finally, especially because a criminal statute is involved, we question whether CMS has the authority to remove a statutory protection for pharmacies and their parent companies through this proposed regulation. Congress intended that pharmacies have the option of a humanitarian response to unusual and urgent situations without fear of criminal charges. The proposed regulation unnecessarily undermines that purpose. CMS already has adequate weapons in its arsenal to address abuses if they occur.

Premiums: Our concerns about waiving premiums are different. Over the course of implementation of Part D, we have seen repeated instances where plan sponsors, because of poor computer programming, bad records or other administrative errors, have failed to bill individuals for premiums due. These have not been instances of plans trying to lure enrollees with discounts; rather, they have been simple acts of mismanagement, with the errors extending over long periods of time, frequently more than a year. When the errors were discovered, CMS has permitted-- and in fact required --plans to send large bills for past due amounts to beneficiaries. As a result, many beneficiaries with limited incomes and very tight budgets found themselves facing large and unexpected payment demands.

In reality, if beneficiaries called to claim financial hardship or simply failed to respond to the notices, CMS required plans to write off some or all of the past due amounts. Beneficiary notices approved by CMS, however, did not tell beneficiaries that they had any option other than to pay the full amount. As a result many beneficiaries, worried about bill collectors or fearing loss of benefits, simply paid despite severe financial hardship.

This policy is unfair to beneficiaries. The purpose of the anti-kickback provisions is to prevent plans from getting unfair market advantage. It is not to protect plan sponsors from the consequences of their own mismanagement, particularly on the backs of beneficiaries, many with limited incomes, who are unprepared to handle large unexpected bills. We ask that CMS in the future set clear limits on how far back plans can go to collect premiums that

they failed to bill through mismanagement.[1] Further, we ask that notices to beneficiaries in such cases always include clear instructions on how to seek relief if payment of back premiums creates financial hardship.

10. Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§ 417.2, § 417.420, § 417.422, § 417.460, § 422.1, § 422.50, § 422.74, § 423.1, § 423.30, and § 423.44)

Sections 417.420, 417.422, 422.50, and 423.30. We wish to clarify the NPRM language at 71931 regarding Medicare eligibility for qualified aliens, which improperly states that "aliens who are not qualified aliens are ineligible for federal public benefits." Although this is generally true, this is not the rule for Medicare. Individuals who earn sufficient work history to qualify for Social Security benefits may be eligible for Medicare as well, if they are lawfully present in the U.S. The broader term "lawfully present" for this purpose includes "qualified" immigrants as well as several other categories of non-citizens. 8 C.F.R. § 1.3.

Lawful presence for the purposes of Medicare eligibility is defined at 8 U.S.C. §1641(b) and 8 C.F.R § 1.3. A qualified alien is but one category of lawfully present individuals, and Medicare eligibility including eligibility for the Medicare Advantage program, Part D and Cost Plans cannot be restricted to only qualified aliens.

Sections 417.460, 422.74, and 423.44. We suggest that CMS codify in regulation required notice and appeal rights for individuals disenrolled from their Part D or Medicare Advantage Plan based on absence of lawful presence. Notice should include clear information on why the individual is being disenrolled as well as what disenrollment into FFS Medicare will mean. In particular, CMS should make clear that an individual may remain enrolled in FFS Medicare if she pays premiums, but will not be eligible to have claims paid on her behalf for as long as she lacks lawfully present status. Furthermore, beneficiaries should be entitled to appeal their disenrollment through the process set out in 42 U.S.C § § 1395ff *et seq.* and 42 C.F.R. §§ 405.904 *et seq.*

Additionally, CMS should put in place a Special Enrollment Period for individuals who are disenrolled from their MA or Part D plan based on lack of lawful presence, but who later regain lawful presence status and wish to re-enroll in Part D or MA. Individuals who are disenrolled from Part D based on lawful presence requirements but remain eligible for Medicare should also be exempt from a Part D premium penalty should they later regain lawful presence status and choose to enroll in a Part D plan.

[1] We note that CMS is proposing to require that plans send out deficiency notices within 45 days of discovery of an underpayment. While we appreciate the addition of that requirement, it does not address the broader issue of the look-back period permitted or required for a collection effort.

Further, under no circumstances should a Medicare Advantage or Part D plan sponsor be empowered or permitted to request proof of lawful presence from an enrollee. Information on lawful presence should only be transmitted from SSA and CMS to Part D plans, and MA and Part D plans should be prohibited from seeking this information from enrollees.

11. Part D Notice of Changes

CMS proposes to 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 from 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.

12. Separating the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC)

CMS proposes to require that MA plans send the ANOC separate from the Evidence of Coverage (EOC), which is a detailed description 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's 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 strengthen requirements regarding plan notification on the potential for provider network changes.[2]

[2] 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," (Feb.

13. Agent/Broker Compensation Requirements (§ 422.2274 and § 423.2274).

While we appreciate efforts by CMS to simplify the calculation of agent compensation and reduce incentives for agents to move their customers to plans with greater compensation, we are skeptical that the proposed changes will accomplish that goal.

CMS proposes to tie the renewal compensation structure to a maximum of 35% of the FMV in the current year and eliminate the distinction between different types of plans for the purposes of renewal compensation payment. To accomplish this CMS proposes to make changes at §§ 422.2274 and 423.2274 and create a new (b)(1)(ii) that would allow plans to base initial and renewal compensation on a maximum of 35 percent of the current fair market value, and eliminate any limit on the number of years renewal compensation can be paid. While we are not opposed to the simplification of calculating agent compensation, variations in the amounts organization are willing to pay are likely to continue and be a factor in replacement decisions by agents and brokers. As CMS points out, even small differences in compensation can become significant when applied to numerous enrollees.

To neutralize the incentives created through compensation and reduce the likelihood of inappropriate replacement, we think a mandatory suitability form should be required. We suggest CMS develop a replacement document that requires an agent to make a simple comparison of the differences between an existing plan and a replacement plan, identify the reasons for replacement, and attest to the accuracy of that comparison to ensure the suitability of replacement coverage. Such a suitability form should be required as part of the application. The parent organization should be required to retain it and make it available to CMS for audit purposes, to departments of insurance during a market conduct exam, or for examination in the case of a disputed replacement. We think this kind of documentation would be effective tool to ensure that appropriate coverage is sold and that the replacement coverage is in fact the best coverage to meet the health care needs of the applicants.

In addition, we have become aware of other actions affecting compensation that lead to replacement. Parent organizations that slow down, artificially delay, or dispute payment of compensation encourages agents and brokers to take their business to another parent organization. We think this is an issue that deserves attention from CMS in their review and audit procedures of MA and PDP organizations.

2014), available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2015.pdf

We are concerned about referral or "finder" fees. We think this is an area that leads to abuse. Marketers and lead generation companies data mine every conceivable source to "inform" Medicare beneficiaries about their choices. The frenzy to find beneficiaries and sell them coverage should not be rewarded separately from the compensation for taking and submitting an application for coverage. We encourage CMS to ban this practice, or in the alternative to set a low dollar limit on this debatable practice.

14. Drug Categories or Classes of Clinical Concern and Exceptions (§ 423.120(b)(2)(v) and (vi)) (p.1936)

In this portion of the proposed rule, CMS replaces the requirement that all Part D plans must 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. We are deeply concerned about this change and urge CMS to revisit this analysis.

Existing beneficiary protections are not sufficiently strong to allow a relaxation of protected class rules. The proposed rule relies heavily 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. Advocate experience serving Medicare beneficiaries suggests, however, that these protections are wholly insufficient. Further, we find that multiple statements in the proposed rule are not reflective of the beneficiary experience as advocates observe through service to Medicare beneficiaries and their families.

Although the proposed rule asserts that plans "are required to issue a coverage determination . . . in accordance with strict regulatory timeframes," that requirement is *only* triggered by a request for a coverage determination, accompanied by a letter of physician support if the request is for a formulary exception. As the commentary notes, "plans are not required to treat every claim transaction as [a request for a] coverage determination." NPRM at 1940. As such, beneficiaries who present a written or e-prescription and are refused access at the point-of-sale receive only a generic notice about appeal rights, not an individualized decision. Beneficiaries must then 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. Beneficiaries often face long call wait times and inconsistent customer service when trying to obtain this information. The multi-step Part D exceptions and appeals process proves onerous and time-consuming for beneficiaries and prescribing physicians.

Given these on the ground realities, reliance on the Part D appeals system as a backstop to protect beneficiaries who might otherwise be harmed by relaxation of the current rules around protected classes is misplaced. CMS should first undertake a reform of the Part D appeals process before instituting any changes to the six protected classes.[3]

Adding to the need for caution about loosening standards for protected classes is the fact that transition fills are not always provided, do not help all in need. In 2013, CMS initiated a transition fill monitoring program in response to widespread failure to provide appropriate transition refills to those entitled to them.[4] The creation of this program suggests that the failure of plans to process transition fills is a persistent problem. CMS has attempted to address failures to properly effectuate transition fill by drug plans in the past, without improvement.[5] These systematic failures underscore the need for on-formulary access to a wide range of medications for certain classes of drugs. Uninterrupted treatment on specific medication is particularly essential for anti-depressants, anti-psychotics and immunosuppressants, the very same drugs for which CMS suggests protected status should be relaxed.

In addition to these known shortcomings, transition fills are only available to a narrow band of beneficiaries. Individuals previously stabilized on a particular anti-depressant, for example, but who are untreated for a period of time, are not eligible for a transition fill if they must return to treatment. These individuals are neither eligible for transition fills, nor are they new to treatment and so the rational that there is a lack of unique effect for distinguishing between different medications when initiating treatment does not apply. NPRM at 1945. The test for classes of clinical concern should reflect the needs of patients like these, or, at minimum, CMS should require Part D plans to provide "transition fills" or

[3] One step in that reform should be publication and review of plan level appeals data so that both CMS and stakeholders can better understand how well the appeals process is working at the first stages. The fact that over half of plan decisions that are appealed to the IRE get reversed suggests that serious problems exist. MedPac also reports that plans struggle to handle coverage determinations appropriately. Sokolovsky, J., Shinobu, S. and L. Metayer, "Part D exceptions and appeals," (Presentation to MedPAC: Sept. 2013), available at http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf.

[4] See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/ContractYear2013PartDTransitionMonitoringProgramAnalysis.pdf .

[5] See, e.g., http://www.ncpanet.org/pdf/leg/feb12/2011_program_audit_findings_best_practices.pdf.

some period of coverage, for all medications in the formerly protected classes, regardless of whether the other requirements for transition fills are met.

Finally, the stated justifications for the narrowing of these protections—financial savings and patient welfare-- are not well supported. There is no evidence presented that the inclusion of all drugs in these classes results in widespread overutilization of these medications, except for the over prescription of anti-psychotic medications in nursing home settings, which is best addressed by targeted interventions (see discussion below). Additional research, including analysis of the potentially increased costs related to doctor's services, emergency room visits, and hospitalizations that might result from decreased access to appropriate medications is needed before CMS relaxes the protected drug classes.

The proposed test is too narrow, and insufficiently accounts for complicated medical situation of beneficiaries taking these medications. The first prong of the test proposed by CMS is, as noted above, unrealistic in its use of seven days as an accurate measure for the time that an expedited appeal will be resolved. Beneficiary confusion, prescriber schedules and plan delays all create situations in which a person is without their needed medication for longer than seven days, and this should be reflected in the test. Furthermore, the standard of harm contemplated is too high, and these classes should be assessed based on whether a realistic delay caused by non-formulary status or utilization management tools would harm the health and well-being of the beneficiary.

The second prong of the test is that "a class is of clinical concern if CMS cannot establish that a formulary that includes fewer than all Part D drugs from within that category of class would include sufficient drugs needed to treat the diseases or conditions generally treated by such drugs" and that "more specific CMS formulary requirements will not be sufficient to meet the universe of clinical drug and disease specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations." NPRM at 1942. To evaluate whether "more specific CMS formulary requirements" will be sufficient it is essential that CMS release the more specific formulary requirements that it contemplates.

We support certain exceptions to remaining classes of clinical concern. We are supportive of the exception to allow point-of-sale utilization management safety edits based on maximum daily doses and black box warnings, drug interactions or duplications outlined in the NPRM at 1942, and think that this exception, if effectively utilized, can serve, in part, to address the stated need for plans to impose utilization management edits on inappropriately prescribed antipsychotics, as these medications carry a black box warning against use in individuals with dementia.

We do not, however, support the exception for drugs almost always covered by Part A or Part B, as noted in this proposed rule. NPRM at 2008. MA-PD plans do not handle these appeals efficiently or in a way that promotes access to needed medication in a timely manner. Furthermore, as CMS acknowledges in the discussion, delays in accessing medications, such as injectable anti-cancer medications, potentially subject to prior-authorization requirements under the proposed rule can lead to rapid and life-threatening medical consequences for beneficiaries.

While we appreciate desire to control costs, we are concerned that encouraging Part D sponsors to use prior-authorization edits for Part A/Part B versus Part D drugs could seriously delay access to needed medication and cause increased confusion. We encourage CMS to eliminate this exception, or to require Part D sponsors (and MA-PDs) to treat any pharmacy refusal resulting from these restrictions as an exception request.

CMS has requested comments on an exception that was "considered" for addition to the proposed rule—to allow Part D sponsors to implement prior authorization or step therapy controls on new prescriptions in the categories of clinical concern. We oppose this exception. In light of the extremely narrow criteria for the categories of clinical concern outlined in this proposed rule, delays in access due to these requirements are unacceptable. Furthermore, as noted above, treatment histories for particularly vulnerable beneficiaries, including those with mental health issues, are often inconsistent and incomplete, and beneficiaries might end and resume treatment without the continuity required to avoid this exception.

CMS Should Use Part D Rules to Establish Protections for Nursing Home Residents from the Pervasive and Inappropriate Prescribing of Antipsychotic Drugs.

Whether or not antipsychotic drugs remain a protected class for Medicare beneficiaries who have a medical need for such drugs is a separate issue from the need to protect nursing home residents from the inappropriate prescribing of antipsychotic drugs. Establishing long overdue protections for residents does not depend on changing the rules for antipsychotic drugs for people for whom they are medically necessary, as CMS implies in the proposed rules.

There is no question that antipsychotic drugs are medically inappropriate for the vast majority of nursing home residents who receive them. The Inspector General conclusively documented in 2011 that hundreds of thousands of residents received antipsychotic drugs and that 83 percent of the claims were for off-label conditions, including 88 percent for

conditions specified in the black-box warning given to antipsychotic drugs by the Food and Drug Administration (FDA).[6]

CMS is aware of the problem of the pervasive misuse of antipsychotic drugs in nursing homes and already has the tools to address it. CMS expresses concern in the proposed rules that the use of antipsychotic drugs for nursing home residents "is, in many cases, unwarranted and in others, possibly dangerous." NPRM at 1945. CMS also recognizes in the proposed rules that "Coverage under Part D is not available for drugs that are not used for a medically-accepted indication" and that "prior authorization requirements to determine medically-accepted indications should be limited to those drugs for which it is reasonably foreseeable that use for non-medically-accepted indications are likely to occur." NPRM at 1943. CMS must apply its knowledge and these principles to protect residents.

We urge that Part D rules be amended to:

- Require plans to implement prior authorization rules for antipsychotic drugs for nursing home residents. Plans know which plan participants are in nursing homes.

- Require plans to implement medication therapy management for all nursing home residents who receive antipsychotic drugs.

15. Medication Therapy Management Program (MTM) under Part D (§ 423.153(d))

We share the concerns of CMS that Medicare MTM programs are not living up to desired expectations. It remains difficult to gauge the relative success of MTM programs, given the lower than expected enrollment and limited evidence of the program's efficacy.[7] 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

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[66] Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011), http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf.. _ednref3. See also Senate Special Committee on Aging hearing on the misuse of antipsychotic drugs in nursing homes, *Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes* (Nov. 30, 2011), http://www.aging.senate.gov/hearings/overprescribed-the-human-and-taxpayers-costs-of-antipsychotics-in-nursing-homes,

[7] 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.

program efficacy, best practices and potential enhancements and endorse the more precise rules being proposed by CMS. Further, we share the agency's concerns about the effectiveness of plans in reaching the individuals who could most benefit from MTM. The studies cited by CMS concerning racial and ethnic disparities in access to MTM are particularly concerning.

We believe that the proposal in the NPRM which requires offering MTM to individuals with two chronic conditions, who are using at least two Part D prescription drugs, and whose spending meets a cost threshold based on the cost of two generic drugs is reasonable and we endorse its adoption. The reasons enunciated by CMS are compelling and uniform requirements will help ensure that beneficiaries have similar access to MTM across plans.

We also strongly endorse CMS's proposal to require that plans "have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan." We agree that outreach through pharmacies where individuals fill their prescription is one good approach to finding and engaging hard-to-reach beneficiaries. Plans also have access to the identities of prescribing physicians and could use that information as well, particularly if a physician or group practice primarily serves an LEP population.

We further ask that CMS closely and specifically monitor MTM enrollment by minority populations, LEP beneficiaries and other hard-to-reach subgroups. Plans should be held responsible both for their outreach to these groups and for their effectiveness in delivering MTM benefits, including Comprehensive Medication Reviews (CMRs) to enrolled individuals.

Finally, we wish to respond to the invitation in the NPRM to suggest additional approaches for MTM outreach to hard-to-reach populations. We believe that one important piece of the puzzle is expansion of language access rules for plans, specifically an expansion of the categories of documents subject to the requirement for translation and for multi-language inserts.

The NPRM touches briefly on translation requirements, stating that "translators and multi-language inserts currently required may not be adequate to address the cumulative effects of race and ethnicity, lower levels of education, and poverty that are frequently associated with individuals with limited English proficiency." NPRM at 1952. We agree that a multi-faceted, culturally competent approach is required and that translation of documents is only one piece of that approach—but it is a very important and foundational piece. Translation also is a piece that is currently missing in connection with MTM notices and

many other notices (appeal notices, disenrollment notices, etc.) that are critical for beneficiaries to understand how to access services.

Currently, the Medicare language access regulations governing written communication, 42 CFR 423. 2264 for Part D and 422.2264 for Part C, only apply to a narrowly defined set of marketing documents. Plans are not required to translate any other important documents or notices into other languages or to include multilingual inserts with any non-marketing mailings.[8] CMS should expand its requirements for translations and inserts to encompass a much broader range of beneficiary communications, including communications about MTM enrollment. Since communications about MTM affect access to services that, as CMS has noted, are an important part of the Part D benefit, these communications should be treated as "vital" documents under Title VI of the Civil Rights Act of 1964 and should be subject to a requirement for written translation and inserts.[9] Plans can and should start with translated notices and inserts and build on this baseline to reach out to LEP beneficiaries.

16. Business Continuity for MA Organizations and PDP Sponsors

We support the proposed requirements that plans sponsor have plans for unavoidable interruptions, and to anticipate disruptions that could occur and reduce interference with beneficiary access. CMS highlights the experience of beneficiaries affected by Hurricane Sandy as the basis for new planning and service continuity requirements. We are aware that a number of beneficiaries were 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.

17. Requirements for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions

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

[8] The requirement for multi-language inserts is found in the Medicare marketing guidance at 30.5.1. As with written translations, inserts are only required in connection with marketing documents.
[9] See HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf for a discussion of how to determine whether a document is "vital." One element is "meaningful access" to services which includes as awareness of rights or services. Id.

experience delivering the Part D benefit in order to a 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.

18. Requirements for Applicants for Stand Alone Part D Sponsor Contracts to be Actively Engaged in the Business of the Administration of Health Insurance Benefits

We support the proposed minimum experience requirements – this provision would help ensure that plan sponsors entrusted with providing vital prescription drug coverage to enrollees are up to the task and would help minimize harm caused by either a fly-by-night entity or learning how to administer the benefit on the fly.

19. Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract Per PDP Region (§423.503)

We support the proposal to not approve a PDP sponsor application when the applicant is applying for qualification in a PDP region where another subsidiary of the applicant's parent organization already holds a PDP sponsor contract. We agree such a change would promote the effective administration of a Part D program by addressing the significant inefficiencies to the program of having duplicate contracts that do not provide more benefit plan options than could be offered under a single contract.

We strongly support CMS' efforts to prevent anti-competitive "gaming" by requestors of duplicate contracts by segregating low-income beneficiaries into their own contract or segregating low-performing plans into their own contracts so as not to taint the performance rating of better performing plan offerings. We recognize that, as noted by CMS, this proposed limitation is necessary to preserve the integrity and strengthen the transparency of CMS' star rating assigned at the contract level. If a parent organization artificially inflates the star ratings on one contract by excluding the poor performance under its other contract, we agree that some beneficiaries could make a plan election without complete information about the performance of the organization ultimately responsible for the quality of services they would receive by enrolling in that plan. We also agree that because there can be more than one plan per sponsor, the program does not need more than one sponsor per parent organization, and encourage CMS' s effort to further consolidate the sponsors it proposes to grandfather under this rule.

20. Limit Stand-Alone Prescription Drug Plan Sponsors to Offering No More Than Two Plans Per PDP Region

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.[10]

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 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.[11]

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 for enhanced plans. This means that the less robust enhanced plans will tend to attract a wealthier, healthier

[10] 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: Dec. 2013), available at http://kff.org/medicare/issue-brief/medicare-part-d-prescription-drug-plans-the-marketplace-in-2013-and-key-trends-2006-2013/.

[11] 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, Oct. 2013), available at http://kff.org/medicare/issue-brief/to-switch-or-not-to-switch-are-medicare-bneficiaries-switching-drug-plans-to-save-money/?special=footnotes - footnote-87213-9.

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. We agree with CMS that this kind of risk segmentation should be avoided.

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. These proposals increase price transparency and accuracy. As discussed in more detail below, we strongly support this series of proposals, and we believe these changes will benefit both taxpayers and Medicare beneficiaries.

25. Pharmacy Price Concessions in Negotiated Prices (§423.100)
26. Payments to PDP Plan Sponsors For Qualified Prescription Drug Coverage (§423.308) and Payments to Sponsors of Retiree Prescription Drug Plans (§423.882)

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.

27. Preferred Cost Sharing (§ 423.100 and § 423.120).

In Section 27, CMS seeks to address existing problems with "preferred pharmacy" arrangements. We strongly endorse the plan of CMS to codify requirements that preferred pharmacies actually save money for Medicare and beneficiaries. The cost statistics discussed in the NPRM are indeed troubling. As beneficiary advocates, we care deeply about the long-term viability of Medicare. The fact that some plan sponsors have concocted cost-sharing structures that drive consumers to mail order pharmacies costing Medicare more than non-preferred retail pharmacies is appalling. It demonstrates that the Part D marketplace—like every other marketplace—needs vigorous oversight to prevent market distortions.

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…" NPRM at 1975. 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." NPRM at 1976.

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.

We also support 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.

28. Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21))

We appreciate that CMS is proposing greater transparency in pricing between plans and pharmacies. While we expect that large pharmacy chains are able to use their considerable resources to ensure that they are treated correctly by plan sponsors, we expect that the burdens of an opaque system fall more heavily on smaller rural and community pharmacies on which many beneficiaries depend. The uncertainties of an opaque system may lead pharmacies to choose not to participate in a plan's network, thus limiting beneficiary access. The proposed changes should help alleviate the problem.

29. Any Willing Pharmacy Standard Terms and Conditions (§ 423.120(a)(8))

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. We agree that local pharmacies willing to match competitors' prices should be allowed to charge the applicable cost sharing.

We strongly endorse the proposed changes applying the "any willing pharmacy" standard to preferred networks as a way of increasing beneficiary access and reducing beneficiary costs.

We also strongly endorse the requirement that pharmacies in a preferred network must consistently charge preferred cost sharing and consistently bill no more than the ceiling price for all prescriptions. Beneficiaries have the right to a system that is predictable and understandable. Knowing that "preferred" means preferred across the board is necessary

for consumer confidence. Further, without this consistency, it is almost impossible to use the Plan Finder to make intelligent decisions about plan and pharmacy choices.

Finally, we agree that limiting the number of cost sharing levels to a maximum of three retail levels, two mail order levels and one nlong term care/specialty/infusion level helps with beneficiary understanding. Beneficiaries are easily overwhelmed by many variables in making their choices of pharmacies and plans. This limitation offers some relief.

31. Improper Prescribing Practices (§ 424.535)

We support CMS's efforts to curb improper prescribing practices and patterns, to reduce fraud, waste, 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 support the requirement that prescribing providers have a DEA certificate and 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.

We are encouraged by the requirement that CMS conducts a thorough review, and will limit action in those cases involving off label prescribing to only "cases where there is evidence of reckless disregard for the health and safety of the patient, not when the prescribing is based on peer reviewed literature or community standards of practice."

We support, with some reservation, the requirement that prescribing physicians have appropriate enrollment or opt-out status with Traditional Medicare. Although we appreciate the increased oversight and credentialing that this requirement affords, we encourage CMS to include beneficiary protections to avoid unintended adverse affects. First, CMS should require plans to hold beneficiaries harmless from the consequences of non-coverage for a non-compliant provider for at least one fill of the prescription. Additionally, plans should be required 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.

Second, exceptions should be made for those providers who do not normally see Medicare beneficiaries or receive Medicare payment, including dentists, psychiatrists, and Veteran's Administration doctors. These providers should be able to, after a grace period, register with Medicare in a limited capacity to enable them to write prescriptions for Medicare

beneficiaries. We also encourage CMS to reach out to policy makers in the 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 or the unneeded expense of additional physician visits.

35. Eligibility of Enrollment for Incarcerated Individuals (§ 417.1, § 417.460, § 422.74, and § 423.44)

We appreciate the CMS clarification that individuals released from incarceration can use the special enrollment period for changes in residence in order to enroll in a plan. Continuity of medical care is an important need for these individuals as they return to the community.

Although beyond the scope of this rulemaking, we ask CMS to also revisit other Medicare provisions affecting incarcerated beneficiaries. As CMS is aware, most Medicare-eligible prison inmates are destitute and unable to pay their Part B premiums during their incarceration. Upon release, they do not have any special enrollment period to join Part B, which can result in significant gaps in coverage. Moreover, they are subject to late enrollment penalties. With the number of elderly prisoners soaring, many states are considering release programs targeting this high cost low-risk group.[12] We ask that CMS undertake a comprehensive review of changes that could be undertaken in order to ease the transition as these beneficiaries leave incarceration and to ensure their access to benefits as they seek to reenter the community.

36. Reward and Incentive Program Regulations for Part C Enrollees (§422.152)

We suggest that CMS move cautiously in exploring how to expand wellness programs and are firmly opposed to any wellness program that "incentivizes" participants through a penalty such as higher cost-sharing. As CMS moves forward with this initiative, it should be noted that while rewards and incentives have been shown to increase *participation* in wellness programs, there is less evidence showing that rewards or penalties actually lead to meaningful changes in health behaviors and outcomes.[13] Furthermore, there is currently

[12] See, e.g., ACLU, Report: At America's Expense: The Mass Incarceration of the Elderly, available at https://www.aclu.org/criminal-law-reform/report-americas-expense-mass-incarceration-elderly , which reports that the elderly inmate population has soared 1,300 percent since the 1980's.
[13] R. Adams Dudley, Chien-Wen Tseng, Kevin Bozic, William A. Smith, and Harold S. Luft, *Consumer Financial Incentives: A Decision Guide for Purchasers* (Rockville, MD: Agency for Healthcare Research and Quality, November 2007).

no scholarly research that has examined the effectiveness of wellness rewards or incentives that specifically raise or lower individuals' health care costs.

Additionally, outcomes-based reward/penalty programs can disproportionately penalize groups like the elderly and people with disabilities who often already face additional barriers to maintaining their health and obtaining health care services. Furthermore, racial and ethnic minorities are more likely to suffer from hypertension, obesity, and other health problems for which they may be penalized under wellness programs that use outcomes-based rewards or penalties. Low-income individuals who struggle to afford health care may also face greater barriers to many of the other resources that are necessary to improve health and achieve wellness goals. Even if a wellness program provides participants with wellness activities, rewards or penalties can unfairly harm lower-income individuals who may face unique barriers to participation in those activities.[14]

We share CMS' concern that health-driven rewards and incentives programs may be targeted only to healthy enrollees and that sicker enrollees could be discouraged from participating. If MA plans are allowed to offer such programs, we strongly agree with CMS that reward-eligible activities be designed so that all enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status or other impairments. We also agree with CMS that if such programs are offered, MA organizations must provide information about the effectiveness of such program to CMS (instead of "on request", though, such information should be regularly reported by plans.)

38. Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D-SNPs) to Another D-SNP to Support Alignment Procedures (§ 422.60)

We do not believe that the proposal in the NPRM to passively enroll members of a non-renewing D-SNP into another D-SNP is in the best interest of the beneficiary. Instead we support the current process of returning the individual into Fee For Service Medicare. FFS Medicare guarantees access to any Medicare provider and does not require the beneficiary to make any changes, something that cannot be guaranteed even with another D-SNP with a "similar" network. The beneficiary continues to have the choice of enrolling in another D-SNP, including a D-SNP aligned with the individual's Medicaid MCO.

[14] Families USA, Wellness Programs: Evaluating the Promises and Pitfalls (June, 2012) http://familiesusa2.org/assets/pdfs/health-reform/Wellness-Programs.pdf.

We also note that demonstrations in several states are testing passive enrollment of dual eligibles into managed care. Those demonstrations are expected to provide valuable information on how passive enrollment impacts beneficiaries. We urge CMS to wait for those results before deciding on any further expansion.

If, however, CMS allows passive enrollment as proposed, it is important that it place strong continuity of care requirements on the D-SNP into which individuals are passively enrolled. There should be at least a six month transition period in which beneficiaries can use non-network providers that were part of their non-renewing D-SNP network.

Notices in these circumstances also need to be crafted to be very clear and specific. Beneficiaries should receive a notice that combines the ACA reassignment notice about their prescription drug coverage[15] with information on whether their PCP and other frequently used providers are covered by the new plan. They also need clear guidance about their continuity of care rights and how they can be exercised.

Finally, because the needs of D-SNP enrollees are high and their numbers usually relatively low, we ask that CMS work closely with SHIPs to provide individualized counseling to members of a non-renewing D-SNP. CMS should also impose specific outreach responsibilities on receiving D-SNPs so that beneficiaries understand their choices and, if they decide to accept passive enrollment, can transition smoothly. We also ask that CMS closely monitor this experiment to determine whether it works well for the beneficiary.

C. Strengthening Beneficiary Protections

1. Providing High Quality Health Care

We support the inclusion of the explicit requirement that plans take quantifiable steps to improve all five categories identified in CMS' Star Ratings Program into plan contracts. Moreover, we particularly agree that MA organizations and Part D sponsors should take steps to improve or maintain three of the five categories: process, patient experience, and patient access to care.

2. MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D

Advocate experience serving beneficiaries reflects the same concern raised here by CMS--that beneficiary access to needed drugs is impeded when an MA-PD does not properly adjudicate claims that may be covered under Part A or Part B, rather than Part D, at the

[15] Available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources/Downloads/11475.pdf.

point of sale. When this happens, serious and rapid medical consequences can result. We appreciate and support CMS' proposal to require MA-PDs to actively work with network pharmacies so that coverage an MA-PD denies under Part D can be authorized immediately at the point of sale under Part A or Part B.

Requiring MA-PDs to issue a coverage determination and authorize or provide benefits under Part A or Part B, or under Part D when a party requests a coverage determination, is superior to the current situation where beneficiaries often have to determine which part they ought to be appealing to. Beneficiaries should not have to be well versed in the admittedly complicated and unclear rules surrounding coverage of medications under various parts in order to access their needed and covered medicines.

The rule could be improved, however, by additionally streamlining the process for beneficiaries. As noted above, we have previously urged CMS to require MA organizations and Part D sponsors to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination, and the response from the plan as an initial coverage determination, giving the beneficiary access to the appeals process. While we continue to encourage CMS to adopt this policy for all pharmacy rejections, it is especially important for rejections for coverage under Part D when coverage may be available under Part A or Part B under the same Medicare Advantage entity to be treated as a request for a coverage determination to avoid delays in access.

Adopting proposed 422.122(b)(7) without the clause "when a party requests a coverage determination" would make the proposed regulation more effective by requiring MA-PDs to actively coordinate coverage under Part A or Part B with coverage under Part D, ensuring beneficiaries' timely receipt of needed drugs. This change is consistent with CMS' acknowledgement that coverage rejected under Part D, but available under Part A or Part B, should be made available to beneficiaries as expeditiously as the beneficiary's medical condition requires.

While we appreciate the statement in the discussion that CMS expects MA-PDs rejecting claims at the pharmacy to establish adequate messaging and processing requirements with network pharmacies to determine if the rejected medication may be authorized under Part A or Part B, or under Part D, we urge CMS to codify this requirement in proposed 422.122. Furthermore, CMS expand this requirement to non-network pharmacies.

3. Good Cause Processes (§§417.460, 422.74 and 423.44)

[NOTE: see also our discussion about Part A.9 above concerning plan mismanagement and failure to timely bill for premiums]

We appreciate that CMS is contemplating options to further improve and streamline the good cause review process relating to involuntary disenrollment from MA and Part D plans. As noted by advocates in comments to the draft 2014 Call Letter, however, we are concerned about expanding Part C and D plans' role in the process to evaluate good cause for delays in payment of premiums. We believe the regulations should not be revised to allow CMS to permit an entity acting on behalf of CMS – including the plans or an independent contractor – to complete portions or all of the good cause process, including effectuating reinstatements. Good cause review process should remain within the purview of CMS and outside the purview of a plan or independent contractor.

As beneficiary advocates we continue to hear from MA and Part D enrollees about their plans' failure to adequately distinguish between appeals and grievances, and to adhere to applicable appeal timeframes. Adding an additional type of review to be conducted or facilitated by a plan might diminish a plan's ability to perform its current obligations in the appeals and grievances processes. In addition, we are concerned that in a good cause review process, a plan's primary incentive would be to collect outstanding premium payment rather than ensuring an individual is provided with accurate information about the process, encouraged to gather supporting evidence substantiating a good cause argument, and shepherded through a timely review process. We agree with CMS that ensuring objectivity in the review of these cases and equity among beneficiaries is critically important

We also have concerns about designating independent contractors to complete the good cause process based upon our clients' experiences with current Medicare contractors tasked with processing claims and appeals. In short, Medicare beneficiaries often experience difficulty reaching or communicating with contractors, and initial denials by Medicare or MA or Part D plans are routinely rubber-stamped by such contractors despite available evidence in support of a beneficiary's given cause.

Thank you for the opportunity to submit these comments.

Sincerely,

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