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VIA ELECTRONIC SUBMISSION
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Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

The Medicare Rights Center (Medicare Rights) is pleased to submit feedback on the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. Medicare Rights is a national, nonprofit consumer service 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. Medicare Rights serves over 1.5 million Medicare beneficiaries, family caregivers, and professionals through its national helpline and educational programming annually.

If you have question about these comments or require additional information, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961 and Casey Schwarz, Policy and Client Services Counsel, at cschwarz@medicarerights.org or 212-204-6271. Thank you for the opportunity to provide feedback.

Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2016

Attachment II. Changes in the Part C Payment Methodology for CY 2016

The call letter's proposed Part C payment methodologies are consistent with applicable law, particularly the Affordable Care Act (ACA)'s changes to bring Medicare Advantage (MA) plan payments in line with costs under the Traditional Medicare program. We continue to support these policies, which are critical to stabilizing the fiscal health of the Medicare program, and to ensuring efficient spending of taxpayer dollars. CMS' proposed payment rates are reflective of these policies, and we support their implementation.

The law requires that MA payment rates be revisited on an annual basis to account for estimated per beneficiary spending by Traditional Medicare. The cost to provide the same benefits under the fee-for-service program is the legally required

and appropriate starting point for calculating MA payment rates. Both Medicare cost growth and national health expenditures have grown at historically low rates over the last several years.

It is appropriate that this slower growth is reflected in the MA payment methodology. These slowed rates translate into an improved financial outlook for the Medicare program as well as lower costs and stable premiums for beneficiaries. The 2016 MA payment rates proposed by CMS appropriately reflect this slower growth. We continue to observe that Medicare beneficiaries have ample choice and benefit from continued stability within the MA plan landscape.[1] Still, we urge CMS to continue to closely monitor the MA market to ensure that plans are optimally serving people with Medicare.

Attachment VI: 2016 Draft Call Letter

Incomplete and Inaccurate Bid Submissions/Formulary Submissions: The draft 2016 call letter includes a reminder that all plan bid submissions are timely and accurate. We support CMS' increased scrutiny of bid submissions. At the same time, we encourage CMS to more regularly and thoroughly review plan sponsors' bids for compliance with minimum provider access standards, formulary adequacy, and benefit parameters. Ensuring that plan sponsors meet these minimum standards—at the outset—is critical to ensuring that Medicare beneficiaries have access to appropriate and adequate coverage. Notably, we support the increased specificity of information about quantity limits which CMS proposes to require plan sponsors to submit.

We also support CMS' reminders to plans about the limitations on and reporting obligations related to mid-year formulary changes. While we appreciate that current enrollees who are protected from certain mid-year formulary changes are not "affected" due to their grandfathered status, we are concerned about CMS reducing reporting requirements for this type of change. A beneficiary who is protected from a mid-year change may nonetheless be surprised by the changed status in the next plan year. We encourage CMS to require plans to notify individuals who took a medication and whose status changes mid-year, even if that change will not affect them during the current plan year.

As an option to achieve this end, we strongly encourage CMS to consider adding personalized content to the Annual Notice of Change (ANOC). At best, this would be required of MA organizations and Part D plan sponsors. At a minimum, we encourage CMS to solicit and release best practices among MA and Part D plans on how to communicate this information in a specific and individualized manner to their enrollees through the ANOC.

Revisions to Good Cause Processes: Beginning January 2016, CMS proposes to transfer the review of good cause reinstatement requests to MA and Part D plans. While current regulation allows for this, we believe the transfer of this responsibility from CMS to plans represents a significant change. While we understand the rationale offered in the draft 2016 call letter—suggesting that beneficiaries frequently reach out to their plans when disenrolled, rather than to Medicare—we have some concerns about this transition.

First, it is essential that the 1-800-MEDICARE call center receives adequate training about this change, namely to ensure that beneficiaries are not mistakenly misdirected or delayed in seeking good cause reinstatement. Second, CMS should ensure that plans handle these requests appropriately, not only by evaluating plan systems, but also by auditing plan performance in this arena. Finally, we are concerned that plan billing errors will not be adequately captured in the Complaint Tracking Module (CTM) if plans are responsible for investigating the error and effectuating the reinstatement. We urge CMS to address this concern in the final 2016 call letter by requiring plans to report on the number of good cause reinstatements related to improper or incorrect plan billing practices.

Enrollment Eligibility for Individuals Not Lawfully Present in the United States: As noted in the final FY2016 Part C and Part D rule, CMS will not require additional notice to beneficiaries who are disenrolled from MA or Part D plans

[1] Baker, J., "Testimony Prepared for the U.S. House Committee on Ways & Means, Subcommittee on Health: Hearing on the Future of Medicare Advantage Health Plans," (July 24, 2014), available at: http://waysandmeans.house.gov/uploadedfiles/072414_baker_testimony_final_hl.pdf

because of a lack of appropriate immigration status.[2] The rationale for not requiring this notice is that the notice provided to individuals as part of "existing processes" at the Social Security Administration (SSA) regarding potential changes to lawful presence status is adequate. We are disappointed that CMS is encouraging, rather than requiring, plans to notify individuals who are disenrolled for this reason. Yet, we support CMS' intent to establish a Special Enrollment Period (SEP) to accommodate individuals who regain lawful presence status, and therefore eligibility for MA and/or Part D.

Making the Exceptions and Appeals Processes More Accessible for Beneficiaries: We applaud CMS for its commitment to improving the Medicare Advantage (MA) and Part D appeals processes for Medicare beneficiaries, family caregivers, and health care providers. Like CMS, we are deeply concerned by the findings of the agency's recent audits of plan sponsors, which revealed significant challenges related to organization/coverage determinations, appeals and, grievances as well as formulary and benefits administration. [3]

We are also deeply troubled by the high incidence of CMS sanctions involving plan sponsors' failure to comply with MA and Part D requirements concerning organization/coverage determinations, appeals, and grievances. In 2013, CMS notes that nearly all enforcement actions (89%) stemmed from non-compliance resulting in "…inappropriate delays or denials of access to health services and medications for enrollees."[4]

Similarly, we continue to be alarmed by CMS' annual data on Part D reconsiderations—the third level of decision and the first level of review conducted by an Independent Review Entity (IRE). Among reconsiderations, CMS found that an IRE reversed 32% of plan-level decisions in 2013. Importantly, IRE reversal rates for cases involving utilization management controls are also unreasonably high—47% in 2013. [5] These reversal rates, in concert with CMS' audit findings, underscore the need to strengthen the Part D appeals process.

It is essential to ensure that accurate decisions are made at the earliest possible stage to eliminate unnecessary delays in access to needed medications. A growing body of evidence suggests that medication compliance is critical to improving overall clinical care and to producing overall cost savings. Promoting medication adherence, including through a well-functioning appeals process, can serve to prevent breakdowns in the healthcare system that ultimately generate more costly care, such as unnecessary emergency room visits and hospital readmissions.

CMS' findings are generally reflective of what we continue to observe among Medicare beneficiaries who are denied access to a medication or for whom a specific medication's cost sharing proves overly burdensome. Beneficiaries struggle to navigate an overly onerous Part D appeals process—resulting in delays in access to needed prescription drugs, abandonment of prescribed medications, reduced adherence to treatment protocols, and higher than appropriate out-of-pocket health care costs for older adults, people with disabilities, and their families.[6]

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[2] Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" 80 Federal Register 7912 (February 12, 2015), available at http://www.gpo.gov/fdsys/pkg/FR-2015-02-12/pdf/2015-02671.pdf.

[3] CMS, "Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews," (Memo from G. Mulcahy to All Medicare Advantage Organizations and Prescription Drug Plans; August 27, 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

[4] CMS, "The 2013 Part C and Part D Program Annual Audit and Enforcement Report," (Issued by the Medicare Parts C & D Oversight and Enforcement Group; October 16, 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

[5] CMS, "Fact Sheet: Part D Reconsideration Appeals Data – 2013" (2013), available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html; These data points exclude cases that were dismissed, withdrawn or remanded as well as cases involving non-Part D drugs. In 2013, IRE reversals rates for non-Part D drugs amounted to 24%. Coverage determinations for non-Part D drugs are based on bright-line coverage rules. As such, we would expect plan-level coverage determinations to be fairly straightforward, leading to an IRE reversal rate nearer to zero than is currently reflected in the data. Appeals cases involving non-Part D drugs also warrant additional scrutiny.

[6] Letter to MedPAC from 30+ consumer advocates and health care providers (October 10, 2014), available at: http://www.medicarerights.org/pdf/101014-medpac-part-d-appeals.pdf; Letter to MedPAC from the Medicare Rights Center (September 20, 2013), available at: http://www.medicarerights.org/pdf/092013-part-d-appeals-medpac.pdf

Along these same lines, upon review of the available qualitative and quantitative research on Part D appeals, the Medicare Payment Advisory Commission (MedPAC) recently determined that, "…these findings suggest a need for increased transparency and streamlining of the processes involved so that beneficiaries and physicians are not discouraged from seeking exceptions for medications."[7] We concur with MedPAC's conclusions, and we support CMS' interest in pursuing multiple avenues to achieve this end.

In keeping with CMS' stated goals in the draft 2016 call letter, we urge CMS to establish a multi-stakeholder workgroup (including, but not limited to, Part D plan enrollees, Medicare beneficiary advocates, pharmacists, plan sponsors, pharmacy benefit managers, and pharmaceutical manufacturers) to work on developing a streamlined Part D appeals process that is initiated when a request for coverage of a prescription drug is denied in whole (or in part) at the pharmacy counter. We also encourage CMS to engage in a similar dialogue with multiple stakeholders on potential improvements to the MA appeals process.

We strongly encourage CMS to engage in these discussions as quickly as possible to ensure that the future improvements named by CMS in the draft 2016 call letter can be adequately assessed by all affected stakeholders. We appreciate that there are important technical considerations that must be weighed in order to implement some of the suggested improvements, and we believe a multi-stakeholder dialogue would be best suited to engage on these issues. Again, we applaud the agency's willingness to consider reforms to the MA and Part D appeals system with the aim of improving the accessibility of these processes for beneficiaries. Below we provide more detailed comments on the provisions included in the draft 2016 call letter.

Coverage Denial Notices and Requests for Clinical Documentation:

Denial Notices: We strongly support and appreciate CMS' reminder to MA organizations and Part D plan sponsors about the information required in denial notices, specifically involving the reason for the denial, the applicable Medicare or plan coverage policy, and any specific coverage requirements that must be met to obtain coverage. The exact rationale for denials is critical to the ability of Medicare beneficiaries and health care providers to understand their situation, decide next steps, and advocate effectively. We urge CMS to include this language in the final 2016 call letter.

Requesting Clinical Documentation: We strongly support the requirements set forth in the draft 2016 call letter clarifying MA organization and Part D plan sponsor obligations to seek out clinical information when needed to process a coverage request. We also support CMS' requirement that plans adequately document attempts made to secure needed clinical information. Presently, Medicare beneficiaries must serve as a de-facto intermediary between their MA or Part D plan and their health care provider, even though many people with Medicare lack the aptitude to perform this role. The resulting breakdown in information-sharing likely contributes to fewer appeals and higher rates of denials, delays, and other inefficiencies. In the interest of efficiency and fairness, we urge CMS to finalize these requirements for MA and Part D plan sponsors in the final 2016 draft call letter.

Future Improvements: We strongly support CMS' suggested improvements to the Part D denial notice (Form CMS-10146) as well as CMS' strong encouragement that Part D plan sponsors begin implementing these improvements as quickly as possible. We expect that these enhancements to the Part D denial notices—namely the requirement that the denial reason cite to the CMS-approved plan formulary or other Medicare rule as a basis for the decision—will significantly ease the burden on beneficiaries and health care providers to provide adequate, actionable information when a beneficiary appeal is warranted. Additionally, we strongly encourage CMS to move forward with the agency's plans to include these same notice changes for MA denial notices.

[7] MedPAC, "Report to the Congress: Medicare Payment Policy" (March 2014; pgs. 368-369), available at: http://www.medpac.gov/documents/reports/mar14_entirereport.pdf?sfvrsn=0

Still, we believe these requirements would be further strengthened by a CMS review of the "enrollee-friendly" or "free text" portion of the Part D denial notice. We continue to observe that this "free text" section, largely intended for Medicare beneficiaries, causes significant confusion. In some cases, the content proves to be incomprehensible to the beneficiary. On this point, it is important to note that most Medicare beneficiaries may not be familiar with technical or legal language describing a plan denial.

To further build on the improvements recommended by CMS, we encourage the agency to make available best practices on communicating plain language reasons to explain denials (i.e., off-formulary, prior authorization, step therapy, quantity limits, etc.) in the "free text" section of the Part D denial notice. Given that the "free text" portion is directed to older adults and people with disabilities, it is critically important that this language is *both accurate*—meaning it matches the plan formulary, coverage rules, and the more detailed section described above—*and easy to understand*—meaning it is written in line with the education and health literacy levels of most beneficiaries.

Finally, as CMS looks at ways to strengthen appeal notices, we ask that the agency also consider imposing translation requirements on coverage determination notices. Because these notices directly affect meaningful access to services, they qualify as "vital documents" that should be subject to translation requirements.[8] Currently CMS rules around translation requirements are limited to certain marketing documents and do not cover any documents related to denial of services.

Improved Information at the Point of Sale: First, we commend CMS' willingness to explore improvements to the pharmacy counter notice (Form CMS-10147), and we urge the agency to explore this possibility as quickly as possible in consultation with multiple stakeholders. Medicare beneficiaries refused access to a medication at the pharmacy counter experience this "turning away" as a denial, and many struggle to understand why a formal request for coverage must be made to the plan with the support of the prescribing physician.

We strongly believe that access to information about the reason for a plan denial—provided at the pharmacy counter—will both eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the point of sale, Part D enrollees and their health care providers will be better equipped to determine the best course of action for the beneficiary's health—whether that involves securing a different prescription, waiting the appropriate time period for a refill, or filing an exception request with the health plan.

We appreciate that pursuing this option will involve working in collaboration with the National Council of Prescription Drug Programs (NCPDP). We encourage CMS to assess the potential of advancing this change for specific types of denials or other pharmacy edits, such as the application of any number of utilization management tools. We strongly encourage CMS to engage in a multi-stakeholder conversation on pursuing improvements to the current pharmacy counter notice.

Additionally, we encourage CMS to carefully explore a concern not addressed in the 2016 draft call letter related to the pharmacy counter notice. Specifically, we urge CMS to assess how frequently and consistently the pharmacy counter notice is delivered to Medicare beneficiaries denied access to prescription drugs as well as those who express concern with the coinsurance or copayment for a given medication. Only in recent years has the delivery of this notice been required by CMS of plan sponsors, and in turn required of plan sponsors' network pharmacies. We continue to hear from Medicare beneficiaries who claim they have not received this notice, meaning these individuals lack critical information about how to pursue a coverage determination and their appeal rights. Monitoring the delivery of the pharmacy counter notice is important, both to ensure beneficiary access to needed medicines and sponsor compliance with CMS rules.

Second, we applaud CMS' willingness to explore allowing the presentation of a prescription to serve as the request for a coverage determination. As noted above, it is conceptually very difficult for a beneficiary to parse the difference between

[8] DHHS, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," 68 Fed. Reg. 47311 (Aug. 8, 2003).

a health plan's refusal at the pharmacy counter and a formal denial resulting from a request for a coverage determination. 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, first by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it. As such, we continue to believe this course of action is in the best interest of beneficiaries, their families, and their health care providers.

Again, we appreciate that potentially implementing this process, either for some or all claims not paid at the pharmacy, will involve technical considerations that should be explored among multiple parties. We ask CMS to fully explore how to implement this proposal for each reason that a prescription drug may be refused payment at the point of sale (i.e., non-formulary, prior authorization, step therapy, quantity limits, refill too soon, inadequate information from a prescriber, potential adverse interaction, etc.). As noted above, we strongly encourage CMS to engage in an open and ongoing dialogue with all stakeholders about this option, and others that might be pursued to streamline and simplify the Part D appeals process for Medicare beneficiaries, caregivers, and providers.

Although not directly addressed in the draft 2016 call letter, in addition to solutions related to payment refusals at the point of sale and denials of coverage, we encourage CMS to explore policy changes specific to beneficiary requests for tiering exceptions. We regularly hear from older adults and people with disabilities desperate to reduce the cost of medications who are altogether unaware of their right to request a tiering exception. We fear only those Medicare beneficiaries who are particularly savvy or who have the assistance of a trained counselor are positioned to successfully request a tiering exception. Increased beneficiary and health care provider education about when tiering exceptions are available and appropriate is sorely needed. At a minimum, we encourage CMS to require plan sponsors to provide such training to network providers, including pharmacists, physicians and other prescribers.

Expanded Data Collection for Part D Appeals: We strongly support CMS' openness to developing a more rigorous Part D appeals tracking system. Like CMS, we are concerned that the available data on Part D coverage determinations, redeterminations, and reconsiderations does not adequately reflect the full range of beneficiary experiences with the process. We strongly supported CMS' August 2014 release of plan-reported data on MA and Part D coverage determinations, appeals, and grievances through a public use file.[9] Yet, like CMS, we agree that this information is insufficient. In 2014, MedPAC also expressed concern about the transparency of plan-level decisions and the availability of concrete data on the Part D appeals process.[10]

We share CMS' alarm with the high reversal rates of plan decisions at the redetermination level (80%) in CY2013, coupled with an extremely low rate of beneficiary appeals (17%).[11] And, as noted above, we are equally concerned with the high rate of reversals of plan decisions by the IRE, at the reconsideration level. As described above, Medicare beneficiaries who leave the pharmacy counter empty-handed may never access the formal appeals process. This can result in a beneficiary paying for the full cost of the prescribed medication, purchasing one or two pills at a time to get by, seeking drug samples from the prescribing physician—which may or may not be readily available—or simply going without a prescribed medication altogether. Given this experience, we are very supportive of enhanced data collection on all steps of the Part D appeals process.

As such, we strongly encourage CMS to expand the scope of its proposed tracking system. For Medicare beneficiaries who experience difficulty securing a needed prescription drug, the process ultimately begins at the pharmacy counter—

[9] CMS, "Part C and Part D Data Validation," (July 2014), available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html

[10] MedPAC, "Report to the Congress: Medicare Payment Policy" (March 2014; pgs. 368-369), available at: http://www.medpac.gov/documents/reports/mar14_entirereport.pdf?sfvrsn=0

[11] CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter," (February 20, 2015; pg. 80), available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf

not with the request for a coverage determination. CMS currently requires plan sponsors to report on pharmacy transactions, including claims paid and rejected, and requires data collection on various utilization management tools and other reasons for nonpayment.[12] We strongly encourage CMS to develop tracking that begins with the refusal at the pharmacy counter and ends with the Administrative Law Judge (ALJ) or Medicare Appeals Council (MAC). We believe that tracking on this level would allow CMS to gauge how often beneficiaries are able to secure prescription drugs through informal mechanisms, such as through the assistance of a prescriber, as opposed to through the appeals process.

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years: We commend CMS for moving forward to terminate health plans that fail to achieve at least a Star Rating of 3 stars for three consecutive years. Failure to achieve this goal could be indicative of systemic problems within a plan and negative outcomes for enrollees. CMS should use the Star Ratings as an oversight tool to protect beneficiary interests. Thus, when CMS has evidence that a plan does not meet average quality expectations over a consecutive 3-year period, CMS should remove the plan from the program. This will enhance public confidence in the utility of the public reporting system, signal plans that CMS intends to use the Star Ratings system as an oversight mechanism, and drive quality improvement in the MA program. When terminating low performing plans, CMS should provide clear and timely notice to affected enrollees of their full range of options, and ensure that they receive the support necessary to make an informed decision.

Enhancements to Star Ratings and Beyond:

Integrated Star Rating System: We appreciate that CMS is exploring an integrated Star Rating system for Medicare-Medicaid Plans participating in the capitated Financial Alignment Initiative. Ongoing development of tools that effectively evaluate participating plans and also convey information to potential enrollees in a format that they can use to make informed choices is an important element of the demonstration.

Exploring whether an integrated Star Rating system would work and what it would look like is important work. We ask that stakeholders, including consumer advocates, be included in the process from an early stage. There will be particular challenges because of the differing design of the demonstrations across states. It also is important that any Star Rating development be in addition to, and not in place of, real time data and longer term evaluations of the demonstration. Transparency and timeliness of data reporting are both critically important so that all stakeholders, including advocates, policy makers, and regulators can evaluate the demonstration both for long-term analysis and for mid-course corrections.

New Medication Therapy Management (MTM) Measure: CMS proposes to add a new measure that evaluates the number of individuals eligible for MTM who receive the required Comprehensive Medication Review (CMR) and written summary in a CMS-approved format. We support this additional measure. It is important to note that while we are strongly supportive of medication therapy management in principle, we continue to share CMS' concerns that MTM programs are not adequately serving Medicare beneficiaries.[13] While 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, we support CMS' efforts to acknowledge and reward effective—as opposed to merely existent—MTM programs.[14]

Duals/LIS: CMS has identified seven measures (six MA measures and one Part D measure) for which it has determined that differences in outcome exist for dually eligible beneficiaries. CMS is currently conducting analyses to determine the cause of these differential outcomes. The draft 2016 call letter proposes reducing the weights of these measures by half when calculating a plan's Star Rating.

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[12] CMS, "Medicare Part D Reporting Requirements," (Effective January 1, 2014), available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2014PartDReporting_Requirements_V022514.pdf

[13] 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) p. 1947.

[14] 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

While we support CMS' ongoing inquiry on these issues and its efforts to improve care for dually eligible beneficiaries, we are concerned by the approach outlined in the draft 2016 call letter. Decreasing the weight of measures that CMS has found to disproportionately affect dually eligible beneficiaries will increase Star Ratings for plans without actually improving care for those beneficiaries. For example, because the measure for breast cancer screenings will receive less weight in the Star Rating determination, plans may see improvements in their Star Rating while having unacceptably low breast cancer screening rates among dually eligible enrollees.

It also concerns us that the identified measures generally relate to preventive services. Preventive services, like screenings and fall prevention, are essential benefits that improve long-term patient outcomes and reduce long-term costs associated with treating advanced conditions. We are concerned that down weighting these measures will disincentivize plans to develop programs and methods to encourage the use of this essential preventive care among low-income populations.

Audit & Oversight: Like CMS, and as noted above, we are concerned by MA organization and Part D plan sponsor performance, as reflected in audit findings, particularly related to coverage determinations, appeals, and grievances. We believe CMS' best practices memos are an important tool—both to encourage plan improvement and also to strengthen accountability and transparency. As such, we would urge CMS to consider additional ways to spotlight these findings, such as requiring a public statement by MA organizations and Part D plan sponsors when a plan audit results in enforcement action. Such statements should be displayed prominently on plan websites.

We strongly support CMS' intention to pilot additional audit modules on Medication Therapy Management (MTM) and provider network adequacy. We hear directly from beneficiaries on both of these issues. As noted above, we share CMS' historical concern that the MTM program is not fulfilling its promise and Medicare beneficiaries are not benefiting fully from the availability of these services.

It is also important to note that we were disappointed that CMS, as announced in the final CY2016 Part C and Part D rule, opted not to require plans to hire outside auditors, except in limited cases.[15] We remain concerned about the agency's limited internal capacity to regularly audit MA organizations and Part D plan sponsors. As such, we hope that CMS will revisit this determination if audit results do not significantly improve.

Integrated Dual Special Needs Plans: CMS expresses its ongoing commitment to promoting integrated care for beneficiaries who are enrolled in both Medicare and Medicaid, and describes current and proposed policies to improve coverage and care for this population. CMS expresses a desire to grant increased flexibility and other benefits to Dual-Special Needs Plans (D-SNPs) with high levels of integration outside of the Financial Alignment Initiative led by the Medicare and Medicaid Coordination Office (MMCO).

CMS seeks comment on areas, other than supplemental benefits, where administrative flexibility could promote alignment, looking particularly at beneficiary communications, coordination of regulatory oversight, and integration of state quality-of-care priorities. We believe that there is much room for innovation in these areas, including:

- *Language access:* A particular concern is communications in languages other than English. Many D-SNP beneficiaries receive a wide range of notices in their preferred language for their Medicaid benefit because the state Medicaid agency requires it. Yet, in Medicare, these same individuals often receive notices in English without even a multi-lingual insert because Medicare rules are much more limited.

  To the extent that administrative flexibility is needed to allow more translated materials, we fully support such flexibility. Moreover, we believe that D-SNP plans should be required to comply with Medicare or Medicaid

[15] Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" 80 Federal Register 7912 (February 12, 2015), available at http://www.gpo.gov/fdsys/pkg/FR-2015-02-12/pdf/2015-02671.pdf

language access and alternative format rules—whichever are more favorable to the beneficiary—so that beneficiaries receive consistent notifications is one language.

- *Models notices and consumer testing:* We encourage CMS to develop model notices, which are then tested among consumers. Plans should be allowed and encouraged to test notices developed by, or in consultation with, CMS. In our experience, notices developed with stakeholder participation, including consumer advocates, are much stronger.

- *Integrated appeals process:* We strongly recommend a fully integrated appeals process that includes Medicare, Medicaid and Part D appeals. A fully integrated appeals process requires integrated coverage determination notices for Medicare and Medicaid services as well as Part D coverage.

Seamless Conversion Enrollment Option: While we support CMS' interest in enhancing care integration, we have concerns about the proposed and existing mechanisms related to D-SNP administrative flexibility. Most importantly, we urge CMS to exercise extreme caution in approving requests for seamless conversion. We know firsthand that the transition to Medicare from existing insurance coverage causes confusion and creates challenges for many newly eligible Medicare beneficiaries. Yet, this transition also represents an essential decision point, during which individuals must be adequately educated about all available coverage options.[16] Under the law, Medicare enrollees are guaranteed freedom of choice with regard to MA and Part D enrollment, and we believe CMS has an obligation to protect this right.[17]

We understand that various seamless conversion programs are permissible under the current manual language. Yet, given our concerns, we encourage CMS to allow seamless conversion only by D-SNPs with a Star Ratings score of 4 stars or higher. In addition, we encourage CMS to publically report on the frequency with which these schemes are approved, and to carefully review mailings and other materials to ensure that enrollees are aware of their right to opt out and know how to exercise their right. Additionally, mailings should include clear encouragement for the beneficiary to contact their State Health Insurance Assistance Program (SHIP) for assistance.

In short, we urge CMS to stringently evaluate and closely monitor all seamless conversion applications and programs to ensure that beneficiaries are made fully aware of their rights and options with respect to these plans. This is particularly important in states that lack additional Medigap protections. In these states, automatic enrollment into an MA/D-SNP plan may put some individuals at a serious disadvantage at a later date or cause individuals to lose their Medicaid if the Medigap is used to spend-down to the Medicaid income limit.

Benefit Flexibility for Highly Integrated, High Performing D-SNPs: We also urge increased oversight and monitoring of the enhanced benefits that highly integrated, high-performing D-SNPs are permitted to offer enrollees. First, we have concerns that the definition of a "high performing plan" is a plan in a contract with at least three stars.[18] We do not believe that a three-star plan—which is merely adequate—should be treated as high performing. Second, we are particularly concerned about plans that "offer" enhanced benefits to dually eligible beneficiaries where accessing these benefits proves difficult or even impossible. In addition to reviewing the offered benefits, we strongly suggest that CMS track the rate at which these services are actually provided to plan enrollees.

Value-Based Contracting to Reduce Costs and Improve Health Outcomes: CMS expresses its intent to begin a dialogue with MA organizations and health care providers with respect to incentive payments (e.g. payments based on care quality, patient satisfaction, etc.), innovative payment designs, and value-based contracting. We share CMS' interest in promoting a high-value health care system, both within Traditional Medicare and through health plan innovations. As

[16] Sanders, S. "Medicare Part B Enrollment: Pitfalls Problems and Penalties" (Medicare Rights Center: November 2014), available at http://www.medicarerights.org/part-b-enrollment-nov-2014/
[17] Social Security Act, 42 U.S.C. §1802 & §1902(a)(23).
[18] *See* Chapter 16b, Section 40.4.4 of the Medicare Managed Care Manual.

such, we support CMS' intent to evaluate ongoing demonstration projects in Traditional Medicare and experiences in other markets to support payment reforms that reward the delivery of value-based, as opposed to volume-based, care.

We commend the careful process reflected in the draft 2016 call letter, focused on transparent information gathering and the involvement of multiple stakeholders. Yet, we believe a critical component is missing from this discussion. In addition to involving health plans and health care providers, we urge CMS to include beneficiaries and consumer advocates in these conversations, specifically to assess needed messaging, education, and tools to help beneficiaries navigate and maximize a continuously evolving Medicare delivery system.

Meaningful Difference (Substantially Duplicative Plan Offerings): Starting in 2017, CMS proposes to evaluate meaningful differences between various plans offered by a legal entity/parent company. We support this proposal. We find that beneficiaries are better able to evaluate plan choices and determine their best match when they are able to clearly discern differences between plan offerings. Allowing multiple plans to be offered by the same parent company that do not meaningfully differ in terms of costs or benefits simply adds noise to the market, increases confusion, and potentially allows companies to improperly steer certain types of beneficiaries to one or another of their otherwise identical products.

Tiered Cost Sharing of Medical Benefits: CMS notes that MA organizations are allowed to use tiered cost sharing designs for contracted, network health care providers, "…as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data," and describes mechanisms to allow plans to more clearly define this tiering during the bid submission process. The network design described in the draft 2016 call letter appears to adopt Value-Based Insurance Design (VBID) principles, which were the subject of a Center for Medicare and Medicaid Innovation (CMMI) Request for Information (RFI) in late 2014.

CMMI sought comment on a potential demonstration program to grant added flexibility to MA organizations to implement tiered cost sharing for health care services, prescription drugs and health care providers. We encourage CMS to review our comments to the RFI, which detail specific questions and concerns about the potential program design and beneficiary education needs.[19] While we are generally supportive of CMS' desire to promote the delivery of high-quality, cost-effective care, we request that CMS clarify the following with respect to this section:

- To what extent is tiered cost sharing for contracted, network providers allowed and practiced?
- What metrics do MA organizations employ to evaluate health care provider quality and efficiency?
  - How transparent are these metrics? In particular, how are these metrics communicated to beneficiaries?
- How is CMS evaluating beneficiary-facing content on these tiers?
- How does the current practice differ from the potential demonstration under consideration by CMMI?
- What oversight is CMS employing to minimize the risk of adverse selection resulting from this practice?

We are particularly concerned about how these tiered networks are being presented to Medicare beneficiaries. Based on our experience with preferred- and non-preferred pharmacy networks in Medicare Part D, we know that people with Medicare often find it difficult to grasp the concept of networks within networks. In the absence of strict oversight, clear and transparent criteria for determining value, and robust beneficiary education, we would be hesitant to support attempts by CMS to further encourage tiered provider network designs among MA organizations.

We do not frequently hear from beneficiaries navigating tiered cost sharing for medical services, but given the demonstrated problems with access to preferred pharmacies discussed in the draft call 2016 letter, we are concerned about the potential for future problems, particularly if tiered provider networks become more common. We urge CMS to carefully evaluate 'preferred' networks based on size and availability, and to monitor for designs that discriminate or

[19] Medicare Rights Center, "Re: Request for Information on Health Plan Innovation Initiatives at CMS," (November 3, 2014), available at: http://www.medicarerights.org/pdf/110314-health-plan-innovations-rfi.pdf

discourage enrollment among beneficiaries with certain conditions. It is also critical that CMS monitor how tiered networks are used within specific geographic regions in a plan's coverage area, as we are concerned that providers who treat primarily lower-income or non-native English speakers may be categorized as non-preferred.

Part C Emergency/Urgently Needed Services Deductible Guidance: For MA plans, CMS proposes to eliminate the requirement that any cost sharing for Emergency/Urgently Needed Services apply toward the plan deductible. We oppose this proposal. Beneficiaries who pay cost sharing for any covered service have the expectation that this cost sharing will accrue towards their plan deductible. Most Medicare beneficiaries live on low and fixed incomes, and they are reliant on the plan deductible to gauge their expected annual health care costs. Exempting certain cost sharing from the deductible would harm beneficiaries and increase—not alleviate—confusion.

Guidance to Verify that Networks are Adequate and Provider Directories are Current: We strongly support CMS' efforts to provide additional guidance with respect to regulatory requirements and the proposed enhanced oversight of MA organization provider directories. We are particularly supportive of the requirement to "establish and maintain a proactive, structured process that enables them to assess, on a timely basis, the true availability of contracted providers which includes, as needed, an analysis to verify continued compliance with applicable network access requirements."

We support regular communications and contact with health care providers to ascertain their availability, but suggest CMS require more frequent updating than the quarterly requirement proposed. We also support CMS' proposed three-pronged approach to monitor compliance with the regulations, particularly the audit protocol to assess whether the lack of availability and accessibility of providers may impact a plan's ability to meet provider network adequacy standards. In short, we strongly encourage CMS to engage in a continuous process of assessing plan's network adequacy standards.

In addition, we strongly support CMS' proposal to institute a requirement for MA organizations to provide—and regularly update—network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. We applaud CMS' goal to "make provider network data readily available to beneficiaries, stakeholders, and the public and in a uniform format." We agree that such an approach will "enhance the transparency of provider networks, and enable beneficiaries to make informed decisions about their health care coverage." For example, making MA provider network directories accessible through the Medicare Plan Finder would greatly enhance beneficiaries' ability to choose plans based upon the criteria most important to them.

At the same time, we encourage CMS to revisit and strengthen the agency's policies concerning mid-year provider network terminations. We continue to believe that additional enhancements are needed to lessen the harmful impact of mid-year terminations on Medicare beneficiaries. At best, we would encourage CMS to prohibit mid-year terminations of network providers without cause. At a minimum, we encourage CMS to extend the timeframe required of MA plans to provide notice to beneficiaries about mid-year network changes from 30 days to at least 60 days. Additionally, we continue to encourage more proactive education on the availability of a Special Enrollment Period (SEP) for Medicare beneficiaries affected by significant mid-year provider network terminations.

Guidance for In-Home Enrollee Risk Assessments: We support CMS' effort to more carefully examine at-home risk assessments to ensure that the services provided to beneficiaries through these visits are meaningful and effective, and are not simply a means for collecting risk adjustment diagnoses without ensuring that meaningful follow-up care is delivered. We share CMS' concern that the at-home risk assessment is not being appropriately applied.

We agree that the purpose of risk adjustment is to measure health status that is related to plan liability. Where there is no treatment or care associated with these diagnoses, this practice contributes to increased risk scores ("upcoding") and inappropriate differences in coding practices between MA and Traditional Medicare. We support both the adoption of a standardized framework for performing health risk assessments, and CMS' proposal to encourage plans to adopt, as a best practice, a core set of components for the in-home assessments they perform.

Improving Drug Utilization Review Controls in Medicare Part D: CMS requests feedback on the potential implementation of a pharmacy edit threshold regarding overlapping opioid prescriptions, and seeks comment about whether to expand its overutilization policies to other prescription drugs or classes of drugs and clinical treatment issues. We appreciate CMS' efforts to address the challenge of opioid misuse in a responsible and restrained way, including requirements related to the involvement of treating physicians and common-sense exceptions to ensure limited impact on beneficiaries with a medical necessity for specific medications. We encourage CMS to continue to approach this issue carefully, and to ensure adequate beneficiary protections are implemented as part of any expansion in the use of additional pharmacy edits.

Before CMS considers expanding current policy to additional categories, we urge CMS to further study the existing opioid program. We continue to be concerned with the implementation of any additional point-of-sale edits or restrictions, as our experience—and CMS' own audit results—show that these restrictions are routinely mismanaged by Part D plan sponsors. Again, we appreciate the careful balance CMS brings to bear on addressing the problem of misuse, and we encourage CMS to continue to work with all stakeholders to develop effective and targeted strategies.

Part D Benefit Parameters for Non-Defined Standard Plans:

Tier Labeling and Composition: Starting in 2016, CMS proposes to alter labeling for generic tiers by merging the generic and non-preferred generic tiers into one "Generic" tier, largely in response to concerns expressed by multiple stakeholders, including consumer advocates. Should plans wish to have a lower cost-sharing tier for certain generic drugs, the tier would be labeled the "Preferred Generic" tier. In addition, CMS expresses concern over "a growing trend of generic drug products being shifted to non-preferred brand tiers," a shift that results in substantial increases in cost sharing.

We share CMS' concerns with respect to generic medications, and we support CMS' proposed nomenclature change. In addition, we strongly support the increased scrutiny of formulary design reflected in the draft call 2016 letter. In particular, we encourage CMS to review plan placement of first-line, clinically-preferred generics on higher tiers.

We are also concerned about the growing frequency with which plans utilize coinsurance (percentage rates) rather than copayments (fixed cost amounts). Recent analysis suggests the use of coinsurance is on the rise. In 2015, 66 percent of Part D plans used coinsurance on more than one tier, compared to only 32 percent in 2014. According to the same analysis, enrollment in Part D plans with more than one coinsurance tier increased from 6.4 million in 2014 to approximately 11.1 million in 2015.[20] Because non-specialty tiers can employ coinsurance rates as high as 50 percent, this can represent a significant increase in cost sharing to beneficiaries and less predictability about annual medication costs.

In short, we are concerned that formulary robustness and affordability are declining. According to a recent *Health Affairs* study, the affordability of prescription drugs has actually declined for some Part D enrollees. Specifically, the study found that older adults with four or more chronic conditions observed an *increase* in the prevalence of cost-related non-adherence from 2009 to 2011, reversing previous downward trends.[21] Given these trends, we request that CMS carefully review Part D formulary designs and explore opportunities to lessen the burden of cost sharing on Part D enrollees. In particular, we suggest that CMS closely examine the types of medications most commonly placed on Part D plans' non-preferred brand and specialty tiers.

We encourage CMS to consider ways that formulary design, such as through value-based insurance design (V-BID) principles, may be employed to increase the affordability of first-line, clinically-preferred medications. While we do not

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[20] Avalere Health. "Avalere Analysis: Medicare Beneficiaries Will Pay Higher Out-Of-Pocket Costs As PDPs Increase Use Of Coinsurance In 2015." November 13, 2014. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-medicare-beneficiaries-will-pay-higher-out-of-pocket-costs

[21] Naci, et al. "Medication Affordability Gains Following Medicare Part D Are Eroding Among Elderly With Multiple Chronic Conditions." *Health Affairs.* August 2014. http://content.healthaffairs.org/content/33/8/1435.abstract

expect that formulary design modifications will alleviate cost sharing concerns for all high-cost medications, we suspect these solutions may offer targeted relief to select beneficiaries. Additional oversight, monitoring, and research are needed to ensure that the Part D benefit remains an affordable choice for comprehensive prescription drug coverage.

Specialty Tiers & Deductible: CMS retains the $600 threshold for specialty tier medications in the draft 2016 call letter—now the ninth year that the threshold remains unchanged. CMS' 2015 release of the threshold methodology provided valuable insight into how CMS calculates the threshold, the percentage of beneficiaries who need medicines on the specialty tier (including both Low-Income Subsidy [LIS] and non-LIS enrollees), and how often prescription drugs that meet CMS' cost threshold are in fact placed on plan specialty tiers. As such, we commend CMS for its commitment to again releasing this methodology. In addition, we appreciate CMS' clarification to plan sponsors concerning the treatment of deductibles for specialty tier medications.

Still, we remain concerned about Part D plans' specialty tiers in two respects. First, we continue to urge that CMS allow tiering exceptions for prescription drugs placed on a plan's specialty tier, both as a matter of fairness and to promote affordable access to high-cost medications. We urge CMS to allow tiering exceptions for all specialty medications, or to consider limited cases where these exceptions would benefit a sizable share of Medicare beneficiaries. Second, we remain concerned that beneficiaries living on low, fixed incomes—though not low enough to qualify for LIS—are going without needed prescriptions due to high cost sharing on the specialty tier as well as the non-preferred brand tier (as noted above).

Thank you for the opportunity to provide comment.