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Submitted Via Email: AdvanceNotice2013@cms.hhs.gov

To Whom It May Concern,

The Medicare Rights Center (Medicare Rights) and the Center for Medicare Advocacy (CMA) submit the attached comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter.

Thank you for the opportunity to submit comments on the CY 2013 Advance Notice and Call Letter. We look forward to working with you to improve the Medicare Part C and Part D programs and ensure plans provide high quality care and services to older Americans and people with disabilities.

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General Comments

2012 Program Audit Findings and Best Practices

On January 20, 2012, CMS released an HPMS Memo that addressed systematic findings of non-compliance with Part D formulary administration, Part D coverage determinations, appeals and grievance procedures as well as agent and broker oversight and compliance program effectiveness. As CMS acknowledged in the memo, non-compliance can lead to serious harm to the beneficiary if procedures, for example, concerning transition fills and coverage determination requests, are not appropriately followed.

We appreciate that CMS released best practices to plans that provide guidance on procedures that plans should take to improve these aspects of their programs and think it is an important first step. However, transition fill requirements, inappropriate point of sale edits, formulary errors, misclassifications of requests for coverage determinations, improper tracking of appeals requests, failure to resolve coverage requests, improper agent and broker oversight and other compliance failures are serious violations of plans' obligations to beneficiaries and contracts with CMS. If plans are non-compliant, appropriate disciplinary action should be taken. We believe the audit results provide support for better and more stringent beneficiary protections and rules in the program. As a result, we encourage CMS to build on this initial effort by institutionalizing best practices included in the HPMS memo by, where possible, making them requirements rather than optional through regulatory or sub-regulatory guidance.

Office of Inspector General (OIG) Report, Medicare Advantage Organizations' Identification of Potential Fraud and Abuse

Due to the date of release of the OIG report, we understand that the recommendations could not be included in regulations and guidance for the 2013 plan year. However, we encourage CMS to examine the report's findings and consider implementing OIG's recommendations either through regulations or sub-regulatory guidance. These recommendations include CMS issuance of more complete guidance to plans about fraud and abuse detection, reporting and corrective action requirements as well as requiring plans to report potential fraud and abuse incidents to CMS rather than making such reporting optional.

Cost-Sharing, Tiering and Utilization Management

Though not specifically addressed in the Call Letter, we would like to express our continued concern over certain cost-sharing, tiering and drug utilization management issues.

a) Some non-preferred drugs that are placed on higher tiers may cost less than the copay assigned to the tier. We ask CMS to scrutinize plan structures closely to ensure that no drug is placed on a cost-sharing tier that exceeds the actual cost of the drug. The Part D benefit is still very complicated for beneficiaries to analyze. Beneficiaries become confused when they see that their expected cost-sharing exceeds the cost of the drug. It is difficult for them to understand the implications of a drug being on the formulary when they pay the full price of the drug. This creates a lot of dissatisfaction with both the drug plan and the Part D drug program.

b) We are very concerned that CMS once again has not increased the dollar amount for drugs that qualify as specialty tier drugs. The price variation of drugs eligible for placement on a

specialty tier is very wide, ranging from the $600 threshold to tens of thousands of dollars. Yet, utilization data indicate that most specialty-tier claims are for drugs at the lower end of this price range. According to the Government Accountability Office (GAO), the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 was $1,100.[1] This raises questions as to why CMS continues to utilize such a low threshold. Placement on a drug specialty tier can create significant barriers to drug access for beneficiaries. They may be asked to pay more out-of-pocket for the drug than they would if it was placed on a different cost-sharing tier and they cannot seek a tiering exception for such drugs. We, therefore, ask (1) for an increase in the specialty tier threshold amount and (2) for rulemaking to allow plan enrollees to seek an exception for specialty tier cost-sharing.

c) Beneficiary advocates have long asked CMS to move towards simplification and standardization of Part D plans. For this reason, we would like to voice our opposition against allowing benefit packages with up to six drug tiers. The greater the number of tiers, the more confusion there will be for beneficiaries. It is difficult to distinguish among a preferred generic, a non-preferred generic, a preferred brand drug, a non-preferred brand drug, a specialty tier, and an optional category (even if the optional category is limited to excluded drugs). It is virtually impossible to compare drug plans if some have a two tier system, some a 3 tier system, and some a 6 tier system.

d) Each year, the number of drugs that have utilization management restriction requirements increases. While we understand that these restrictions serve an important public policy purpose to ensure appropriate and safe use of drugs, we ask that CMS continue to study the use of restrictions on formularies to guarantee that such requirements are not being used in a discriminatory fashion.

Quality Bonus Payment Demonstration/ Applicable Percentage Quality Increase p. 8-9

We agree that CMS should emphasize plan quality. However, we still have concerns about providing bonuses to plans that receive three stars, which is considered "average" according to CMS' own terminology. Moreover, because CMS is proposing elsewhere in the call letter to terminate contracts with consistently poor performers with 1- and 2-stars (a proposal we support), we hope that in coming years the vast majority of MA plans will be rated at 3 stars or higher, which would undermine the purpose of quality bonus payments to three star plans. If CMS continues to move forward with this demonstration as we anticipate, we encourage CMS to make this demonstration time limited. If quality improvement policies are successful, over time the QBP demonstration would be unnecessary to encourage low-quality plans to improve their performance, and payment formulas for quality should revert to those created by the Affordable Care Act (ACA). A longer-term demonstration policy could encourage plans to become complacent once they obtain a 3-star, or average, quality rating – something that would not serve beneficiaries' interests.

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[1] The GAO's information was based on prescription drug event (PDE) claims data. See, GAO, *Medicare Part D: Spending, Beneficiary Cost-Sharing, and Cost Containment Efforts for High Cost Drugs Eligible for a Specialty Tier* (Jan.2010) http://www.gao.gov/new.items/d10242.pdf.

Risk Adjustment p. 13

CMS should further examine the General Accountability Office's (GAO's) findings in GAO's report, "CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practice" published in January 2012. Though the ACA requires some initial modifications, we believe CMS must adopt GAO's recommendation that CMS further account for coding differences between Fee-for-Service Medicare and Medicare Advantage that may result inaccurate risk score adjustments and billions of dollars in overpayments to plans.

Section B. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap p. 20

We support CMS's policy to define plan sponsor liability to include the dispensing fees for coverage gap claims, as it does during the other stages (and straddle claims) of the benefit. Also, the example on page 20 seems overly complex, however, we understand that the Call Letter is for plan use and anticipate that CMS and plans will develop a more beneficiary friendly example. As calculations for TROOP and beneficiary liability are complex, we hope that CMS, plans and advocates work together on developing appropriate consumer materials that clearly explain beneficiary liability.

Program Updates p. 52 - 59

We have concerns about CMS's revised dates for sending Medicare and You. Medicare and You is due to be mailed to beneficiaries a full month later than in the previous year. These new dates will mean that some beneficiaries will not receive the handbook until after Fall Open Enrollment period begins. CMS should make every effort to ensure that individuals receive the handbook before the start of Fall Open Enrollment.

We appreciate and fully support CMS's inclusion of the October 15 deadline for plans to list prior authorization and step therapy restrictions on plan websites.

Enhancements to the Plan Ratings, 2013 Plan Ratings and 2014 Plan Ratings pp. 68-71

We support CMS's effort to improve the accuracy and meaning of CMS plan ratings and improve quality measurement. As the Call Letter suggests, we encourage CMS to add measures that incorporate care coordination into star ratings as care coordination is an essential element of all MA plans' benefit structures. We also support CMS's consideration of measures that will better reflect plans' compliance with appeals, grievance and transition processes. The HPMS memo released on January 30, 2012 demonstrates that many plans are significantly non-compliant with appeals, grievance and transition requirements, which are essential beneficiary protections. We ask that CMS make continued efforts to improve compliance and believe that plan quality ratings should appropriately reflect the findings of the audit. Such non-compliance is of great concern to the beneficiary community and their advocates.

As criteria are added to the plan rating evaluations, it will be essential to present this information to beneficiaries in clear, concise language that enables them to better identify plans scoring highest on critical points and, in conjunction with other key factors such as formulary design and cost-sharing requirements, deserve consideration in determining enrollment. As stated in our

comments submitted on the October 2011 proposed regulatory changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program, "We ask that CMS work with plans to develop beneficiary communication strategies that will help plan enrollees understand new activities related to quality improvement. Beneficiaries may shy away from participating in quality improvement programs if the purpose and nature of the program is not clearly explained. We ask that CMS and plan sponsors work closely with beneficiaries and consumer advocates to better help them understand the meaning of stars and quality measurement as well as programs aimed at improving quality."

Contracting Organizations with Ratings of Less than Tree Stars in Three Consecutive Years p. 72

We fully support CMS's position that plans that receive below three stars are non-compliant with the requirements of the Part C and D program. We also agree with CMS's determination that beneficiaries should be provided with a Special Enrollment Period (SEP) to switch to higher quality plans if their current plan has less than three stars. However, we suggest the following clarifications and modifications to the policy. First, we ask CMS clarify the language concerning the initiation of the SEP. Individuals subject to the SEP should not be limited to accessing the SEP by contacting CMS alone. We believe that beneficiaries should automatically be able to receive the SEP, for example, by contacting CMS or by enrolling in a new higher quality plan. Second, we believe these individuals should also have the option of switching back to Original Medicare and choosing a stand alone Part D plan if they so choose. Lastly, to further incentivize low-performing plans to take corrective actions as quickly as possible, we believe that individuals in low-performing plans should be able to access this SEP regardless of the number of years a plan has received a below three star rating. This means that individuals would have an SEP any time they are enrolled in a plan with less than three stars.

CY 2013 Bid Review pp. 72 – 76

We continue to believe that CMS is misinterpreting the provision of the ACA that limits cost sharing to the level required in Original Medicare for skilled nursing care. MA plans should not be permitted to allow cost-sharing for the first 20 days of a SNF stay, as long as the overall cost sharing is actuarially equivalent to the cost imposed under Original Medicare for the complete SNF benefit. The average stay in a skilled nursing facility is well under the 100 day benefit. The current CMS policy allowing MA plans to frontload their skilled nursing care cost-sharing requirements to the first 20 days undermines the protection that these provisions were designed to establish including preventing discrimination against beneficiaries who require more care. While this may comply with the letter of the law, it is clearly contrary to its spirit. We ask CMS to require MA plans to apply Original Medicare's $0 cost-sharing for the first 20 days of skilled nursing care.

Limits on Coverage of DME Based on Brand/Manufacturer p. 77

We reiterate our comments made on the October 2011 proposed regulatory changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program and hope the Call Letter's reference to beneficiary protections included in the final rule and Call Letter incorporate our recommendations. Specifically, we stated, "We appreciate the opportunity to comment on the beneficiary protections that are necessary as CMS allows MA organizations to create "preferred"

and "non-preferred" classes of DME suppliers and manufacturers, and to limit coverage to particular manufacturers. The listed beneficiary protections: requiring that MA organizations ensure access to all preferred products at network suppliers, requiring coverage of any medically necessary supply made by a non-preferred manufacturer, requiring adequate transition periods, disclosure requirements and the prohibition on "negative changes" are the minimum requirements essential to protecting beneficiaries' rights and ensuring access to needed supplies.

Although "there is evidence that beneficiary appeals of DME coverage decisions based on products or brands are not a significant problem in the MA program," with the implementation of these rules codifying the procedure, it is likely that more MA programs will implement these kinds of controls. Therefore, the notice provisions should be strengthened to require a separate notice of any new DME controls in addition to the required inclusion in the annual notice of change/evidence of coverage. CMS should incorporate plans' DME restrictions into Plan Finder in the same manner that information on Part D plans' formulary, preferred pharmacy networks, and utilization management tools are available through the tool. In addition, CMS should require plans, if the agency does not already do so, to provide clear explanations of DME restrictions and display information in a prominent manner on plans' websites.

The Medical Necessity requirement, requiring that MA organizations provide coverage of any medically necessary DME item and supply whether preferred or non-preferred, is essential. However, an exception should also exist to require plans to provide coverage of DME from a non-preferred supplier when DME from a non-preferred supplier is medically necessary for convenience and efficiency purposes. For example, in the case where an individual requires multiple DME supplies and one item they require is only available through a non-preferred supplier, the individual should be allowed to obtain all medically necessary equipment from the non-preferred supplier to promote efficiency and ease of obtaining equipment. We would like to prevent situations where individuals will be required to use multiple suppliers undermining coordination of that individual's care.

The transition period, while appropriate for medications, is unrealistic for long-use items like DME. We propose an extension of the transition period from 90 days to 120 days.

With regard to the provisions for appeals, we agree that a more streamlined, transparent and straightforward appeals process is preferable. CMS should also clarify that a plan's non-coverage of a manufacturer's product or brand of DME is an organization determination. Likewise, CMS should clarify that the placement of a product or brand into a non-preferred "tier" with higher cost-sharing than "preferred" products constitutes an organization determination. Although the additional steps of the Part D exceptions process need not be incorporated for DME and Part B drugs, the ability to appeal and request a "tiering exception" should be. Furthermore, we would ask that CMS promulgate guidance that illustrates, for the MA plan and the IRE, its medical necessity criteria for a particular DME product or brand. That guidance should mirror the guidance that is available for Part D drugs. For example physician's testimony that the "preferred" products are less effective for or would cause harm to the beneficiary should result in a favorable coverage determination or redetermination."

Supplemental Benefits pp. 77- 85

We appreciate CMS's clarification regarding what constitutes supplemental benefits under the MA program. We agree that plans who wish to offer supplemental benefits must be specific in their proposals and demonstrate how supplemental benefits offered exceed, in a meaningful way, those benefits and services already required under Part C. We also ask that CMS continue to review their definitions and interpretation of supplemental services and benefits annually as standards of care evolve and new benefits and services are incorporated into coverage under Original Medicare.

Special Needs Plans

Benefit Flexibility for FIDE SNPs pp. 85-91

While we appreciate that CMS is seeking to improve benefits for dual eligibles through the proposed flexibility, we have serious concerns that the call letter provisions do not adequately address the complexity of weaving long term supports and services into a D-SNP package. In our view the duals demonstration projects, which are being developed with significant stakeholder involvement, are the best places in which to experiment with this type of added benefits.

Our concerns are many. Deciding whether a particular service would be appropriate as a supplemental benefit would require a determination of what services already are available to dual eligibles in the plan service area. This would mean not only services available through the state's Medicaid program but also Administration on Aging funded services, county services, etc. For example, in some counties, a well-run Meals on Wheels service is available. A plan could simply refer its members to that service and offering it as a supplemental benefit would be redundant. In other counties, there may be no such services available. Transportation services would be similar. CMS, especially the Office of Medicare, is not in the best position to evaluate whether a particular benefit makes sense in a particular locality. Nor could CMS easily monitor the quality of and beneficiary access to such services. Further, quality measures and outcomes evaluation criteria should be developed in order to judge the value of supplemental benefits. The call letter does not discuss these.

We also have concerns about coverage limitations developed for supplemental benefits. For example, state Medicaid programs have developed very specific assessment tools for determining the amount and type of services needed by individual using in-home support services. Criteria for Adult Day Health Services also are well established but vary in different areas. Again we question whether the MA review process is designed to compare existing and proposed assessment criteria for LTSS, an area that is not within Medicare's traditional area of expertise.

These issues are all difficult. They can be worked out but, we believe, the planning process for the dual demonstrations, where stakeholders, state Medicaid offices and CMS are working together to fill in gaps and set criteria for additional services is the more appropriate path to developing meaningful benefit expansion. Negotiations between plans and CMS, done in isolation and without mechanisms for state and stakeholder input are less likely to optimize beneficiary impact.

We also expect that many of the FIDE-SNPs will be participating in the dual demonstrations, which also argues against launching a separate FIDE-SNP experiment simultaneously.

In addition to these larger issues, we also wish to raise more specific concerns, particularly if CMS decides to move forward with the FIDE-SNP experiment.

Qualifying Criteria for SNPs Participating in the Benefits Flexibility Initiative p. 86

If CMS does move forward with this proposal in CY 2013 against our recommendation, given the vulnerability of this population as well as the complications and risks associated with this experiment, we ask that only 4 and 5 star plans qualify for enhanced benefit flexibility.

Zero cost-sharing p. 88

The call letter states that CMS "would consider" requiring SNPs to offer supplemental benefits at zero cost. We urge CMS to firmly decide that all MA services, including supplemental services, be delivered at zero cost to the beneficiary. Dual eligibles are protected from Medicare cost-sharing and there should be no exceptions. In addition, if these services are being provided by a state Medicaid program there are likely being provided with no cost-sharing. Allowing the FIDESNP to charge cost-sharing when the service is being provided as part of the Medicare benefit package would create significant confusion and would potentially leave beneficiaries worse off.

QIP p. 88

We do not fully understand the reference to possible QIPs related to preventing partial dual eligibles from declining to full-dual status. The proposed regulations that have not yet been finalized had proposed that FIDE SNPs could only enroll full benefit dual eligibles. While we share CMS's concern that partial duals do not have adequate access to community services that would prevent unnecessary institutionalization, we do not understand how a FIDE-SNP would work for partial duals, since they only qualify for premium and, in the case of QMBs, cost-sharing, but not for Medicaid services.

Non skilled in-home support services p. 89

We have concerns about the requirement that services would be performed by individuals licensed by the State to provide personal care services, if applicable. A number of states, for their Medicaid personal care benefit, include the option of self-directed personal care services. Under this option, beneficiaries select, hire, fire and train those providing their personal care. If a FIDE SNP were to supplement such services by providing more hours, it would make sense that the individual be permitted to use a care worker she has already trained and with whom she has a good working relationship, whether or not that individual has any particular license. We recognize that the "if applicable" wording may have been meant to cover such circumstances but we request that CMS be more clear in its articulation.

Marketing Flexibility p. 91

We agree with CMS that marketing documents for FIDE-SNPs need to be tailored to dual eligibles and that standard MA model documents are inappropriate. We urge CMS to work with

plans to develop documents written in plain language that are tailored to the individual. We particularly urge purging documents of information that is irrelevant to dual eligibles. Further where documents describe what is not covered by Medicare, they should clearly explain whether and to what extend Medicaid coverage is available. We see these sorts of flexibilities as positive.

We note, however, that because FIDE SNPs serve the most vulnerable Medicare population and offer the most complex packages of services, they need more, not less scrutiny. If CMS moves forward with the benefit flexibility, despite our stated concerns, we ask that CMS pays special attention to materials marketing extra benefits. Misrepresentations or over generalizations about extra benefits could induce individuals to enroll in plans even if coverage limitations would not make such extra benefits available to certain individuals even if they meet the general SNP parameters. We urge thorough review of marketing materials and practices. Beneficiaries need streamlined documents but the review process should not be short-circuited.

Lastly, we would like to reiterate our past requests that SNP models of care (MOC) be made public. This is an important beneficiary protection and allows beneficiaries and their caregivers to better assess if a SNP is an appropriate choice for them. The public availability of the MOC becomes even more important if D-SNPs are able to offer new supplemental benefits and serve as added protection to monitor if benefits are meaningful or duplicative of benefits already available in an area through another program.

All Dual Eligible SNPs Required to Contract with State Medicaid Agencies p. 94

CMS requested comment for possible approaches for transitioning beneficiaries from D-SNPs that will no longer operate in 2013 as a result of state contracting requirements. We do not believe it is appropriate to transition these individuals into another MA plan, especially if those MA plans are not D-SNPs. While under law, those who are dual eligible are able to see all Medicare providers, in reality they are restricted to seeing only those that accept Medicaid for a variety of reasons. The restrictive nature of MA plan provider networks would not ensure that these individuals have access to physicians. In our experience, even some D-SNPs contract with physicians that do not except Medicaid. For this reason, we believe Original Medicare is the most appropriate option for these individuals. Original Medicare's open provider network will help to prevent unnecessary disruptions in care and allow individuals to continue to see more of the providers that they currently use. Those providers that accept Medicaid likely accept Medicare but would not necessarily be part of a MA provider network.

Preferred /Non-Preferred Network Pharmacies p. 97

We agree with CMS that tiering pharmacies has created confusion among beneficiaries. This is especially true in the case of mail-order pharmacies. We do not believe that plans should be allowed to have preferred and non-preferred mail order pharmacies. Such policies make the Part D benefit difficult for consumers to navigate and tiering does not seem appropriate in the mail-order context.

Integration with ACOs and Other CMS Innovation Models p. 98

While there may be future benefits to aligning incentives for ACOs and Part D plans, we do not believe at this time it would be appropriate to enable Part D plans to enter business arrangements with ACOs. ACOs are built in a manner in which providers, not beneficiaries, enroll. If ACOs

enter business arrangements with specific prescription drug plans, we fear that those beneficiaries assigned to an ACO would be required to enroll in a designated plan. This would undermine the ability of those Medicare beneficiaries assigned to an ACO to enjoy the same freedom of choice that exists for all other Medicare beneficiaries. We are also concerned about potential conflicts of interests that may result under such agreements, for example if ACOs or plans inappropriately steer a beneficiary into a specific plan as a result of an affiliation.

ACOs by nature are charged with coordinating care. As a result, ACOs and their staff can and should be required to provide the same services that a plan provides under a Medicare Therapy Management Program and to help their patients navigate Part D benefits and appeals processes. Furthermore, as formularies, utilization management restrictions and costs differ from plan to plan, ACOs would need to enter into business relationships with multiple plans as plans are not one size fits all.

Medicare Therapy Management (MTM) Programs pp. 105 -107

We appreciate CMS' commitment to increase beneficiary awareness about MTM programs. In addition, we support auto-enrollment of targeted beneficiaries, as long as beneficiaries understand their option to opt out of this voluntary program. We also support CMS' designation of 2 additional core chronic conditions, Alzheimer's disease and ESRD (requiring dialysis), as targeted conditions for 2013.

Improving Drug Utilization Review Controls in Part D p. 107

We agree that fraudulent, over utilization of opiods is of serious concern. As CMS implements and oversees these new policies, the agency must maintain a balanced approach that ensures beneficiaries have access to prescription drugs in accordance with their need. While heightened scrutiny of drug use may be warranted with respect to overutilizers of drugs, CMS should avoid drastic measures that severely restrict access to needed prescription drugs; general "rules of thumb" should not be used to restrict utilization. For example, we are concerned about a situation where a beneficiary who has side effects from one medication may be restricted from obtaining a medically appropriate alternative due to plan restrictions.

We believe that approaches that build on existing Part D systems put in place to prevent this type of fraudulent over utilization is the most appropriate way to proceed. We do not believe that policies used under other programs, such as restrictive recipient programs, are appropriate under Part D given the Part D and Medicare benefit structure and the characteristics and health needs of the Medicare population.

Appendix B-CMS Model Notice

We believe that the last sentence of the section entitled "Here's what to do next," requires clarification. The notice should articulate the ways that the benefits may be different by including examples and action steps. For example, a sentence should be added that instructs beneficiaries to check that their drugs are covered on the new plan's formulary and to also check any new rules or restrictions that may affect their ability to access the drugs they use.