MEDICARE RIGHTS CENTER

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Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Re: CMS-4157-P

Filed electronically: http://www.cms.hhs.gov/eRulemaking.

Dear Ms. Tavenner:

The Medicare Rights Center (Medicare Rights) submits these comments to the above-referenced proposed regulatory changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program. See 76 Federal Register 63018 (October 11, 2011). The Medicare Rights is a national, nonprofit consumer service organization that works to ensure access to affordable, high-quality health care for older adults and people with disabilities through counseling and advocacy, educational programs and public policy initiatives. We have 22 years of experience providing education and counseling to Medicare consumers.

Overall, we believe that the proposed changes will improve and strengthen the Part C and Part D programs by implementing changes made by the Affordable Care Act and by addressing concerns raised by advocacy organizations on behalf of Medicare beneficiaries. We address many of the proposed changes in more detail below.

Thank you for the opportunity to submit comments on these proposed regulations. We look forward to working with you so that the Medicare Part C and Part D programs provide high quality care and services to older people and people with disabilities. If you have any questions or require additional information, please contact Casey Schwarz at cschwarz@medicarerights.org or 212-204-6271 or Ilene Stein at istein@medicarerights.org or 202-637-0961 ext. 5.

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DETAILED COMMENTS ON PROPOSED CHANGES

II. Provisions of the Proposed Regulation
A. Implementing Statutory Provisions

A.1. Coverage Gap Discount Program
(§ 423.100, § 423.505, § 423.1000, § 423.1002, and Subpart W (§ 423.2300–423.2410))

Overall, we support CMS's proposal to consolidate and codify certain requirements of the Coverage Gap Discount Program to be in line with the statutory requirements set forth in the Affordable Care Act (ACA). The gradual closing of the Part D coverage gap is an important improvement to Part D, and must be implemented in a manner that provides beneficiaries with seamless and uninterrupted access to the discounts to which they are entitled. We agree that codifying most existing Discount Program requirements through full notice and comment rulemaking provides additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

a. Scope (§ 423.2300)
b. Definitions (§ 423.2305)
(1) Applicable Beneficiary
(2) Applicable Drug
(3) Incurred Costs
(4) Manufacturer
(5) Medicare Part D Discount Information

II.A.1.b.6 Negotiated Price for Discount Program and Notice to Beneficiary

During the gradual closure of the coverage gap, the definition of the negotiated price should be the same as in the other stages of the Medicare drug benefit. In 2012, CMS changed the definition of negotiated price during the coverage gap to exclude the dispensing and vaccine administration fees. However, CMS provided in guidance that for straddle claims, both the dispensing and vaccine administration fees must be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold.

Beginning in 2013, plans will cover a small percentage of both brand and generic drugs during the coverage gap stage. Consequently, the negotiated price should include the dispensing and vaccination administration fees as it does during the other stages (and straddle claims) of the benefit.

Should CMS not change the definition of negotiated price, CMS should ensure that beneficiaries are provided notice that the negotiated price for the discount does not include the dispensing fee or vaccine administration fee for the applicable drug. Notice should be provided at the point of sale so that beneficiaries understand their costs associated with the prescription or vaccine. In addition, the model Part D EOB should be revised to include a statement that the discount program does not include the cost of the dispensing or vaccine administration fees.

(7) Other Health or Prescription Drug Coverage

II A 1 c. Conditions for Coverage of Drugs under Part D (§423.2305)

We agree with the narrower interpretation of section 1860-43(a) that is in the program guidance. We support this interpretation because it allows beneficiaries access to non-applicable drugs covered by Part D. If the statute were read plainly to exclude all the drugs of a manufacturer who declines to sign the Discount Program Agreement, CMS would have to exercise its authority based on section 1860D-43(c)(1), assuming many drugs that would be excluded are essential to the health of beneficiaries. This would place an administrative burden on CMS, not to mention the confusion for beneficiaries and advocates to identify drugs for which CMS allows coverage even though the manufacturer did not sign the Discount Program Agreement.

We also agree to treat manufacturers the same, whether they manufacture applicable drugs, non-applicable drugs or both. If manufacturers were treated differently based on what drugs they manufacture, beneficiaries would have to find out or be provided that information as well as why it matters and how it affects their drug coverage.

We have serious concerns, however, that CMS's interpretation of the statute does not go far enough to protect the access of beneficiaries to new drugs. The proposed regulation would continue to prevent coverage for up to two years for an applicable drug in cases where a manufacturer has not entered into a Discount Program Agreement during the prior year because the manufacturer had not previously offered any applicable drug. This interpretation is inconsistent with the broader purpose of the statute to provide beneficiaries with coverage for all medically necessary prescription drugs. The purpose of the deadlines for entering into agreements was to incentivize manufacturers to participate, not to penalize beneficiaries who need drugs newly approved by FDA. It is not reasonable to conclude that Congress meant to delay beneficiary access to some new drugs solely because the manufacturer had not previously manufactured applicable drugs but allow and encourage immediate access to drugs of other manufacturers. See *Layzer v. Leavitt*, No. 1:07-cv-11339-HB, Slip Op. at 8 (S.D.N.Y. Mar. 7, 2011)(rejecting as "arbitrarily fine and unreasonable" statutory interpretation that would preclude "coverage of effective yet newly discovered prescription drug treatments.") The interpretation is also inconsistent with the CMS policy of allowing Part D plans to add new drugs to their formularies, Prescription Drug Benefit Manual, Ch. 6 at 30.3.3.1 and, in fact, requiring that plan P&T committees review new FDA approved drug products within 90 days to determine whether to add the drug to the plan's formulary. PDBM, Ch. 6 at 30.1.5. CMS's interpretation of the Discount Program Agreement provisions of the statute creates an unreasoned distinction that burdens beneficiaries and deprives them of needed drugs.

We ask that CMS consider and develop procedures that avoid this result. One possibility, given the long lead times for FDA drug approvals, might be for the agency to allow manufacturers to enter into provisional agreements to join the Discount Program pending FDA approval of a new drug so that there would not be a waiting period before the drug could be covered. Another option may be for CMS to routinely use its authority under Section 1860D-43(c)(1) of the Act to

treat as "covered" those drugs where a manufacturer has entered into but not yet effectuated a Discount Program Agreement.

We also want to point out the regulation does not address the rare but still important case of a drug that may have been believed to not be a covered Part D drug but is found through the exceptions and appeals process to be a covered drug. An example of such a drug is tincture of opium which, on appeal, the Medicare Appeals Council found to be a "grandfathered" drug that is a "covered Part D drug." The manufacturer of such a drug would be in the same position as a manufacturer of a newly approved drug, not having entered into an agreement because of a belief that the drug was not an applicable drug. If a beneficiary, using the exceptions process succeeded in obtaining coverage of a drug in a similar situation, the beneficiary would still not have access to the drug if the manufacturer did not produce other applicable drugs and did not already have a Discount Program Agreement in place. At best, the beneficiary would then have to start again to seek a determination that the drug is "essential" and should be immediately available. This puts an unacceptable burden on beneficiaries.

Finally, we are concerned that CMS has not indicated what process, if any, the agency will put in place for rendering a determination that a drug outside the Discount Program is "essential to the health of beneficiaries." There needs to be a procedure in place whereby beneficiaries can make the case for access. We urge the agency to interpret its authority under the statute to allow a determination that a drug is essential to the health of an individual beneficiary, through a showing of medical necessity in the exceptions process. Although the agency had predicted that it is "highly unlikely" that it will need to exercise its authority, we have concerns that the need will arise, particularly for individuals' serious or rare conditions. As discussed above, in the context of drugs newly introduced or newly acquired by a manufacturer without a previous Discount Program Agreement, there may be individuals whose condition cannot wait for the clock to run on the effectuation of the agreement. The issue may arise in other situations as well.

While we fully support strong incentives for manufacturers to join the Discount Program, CMS has a variety of mechanisms available to ensure manufacturer participation. We urge the agency to implement incentives in a manner that avoids harming beneficiaries, especially low-income beneficiaries who need access to medically necessary drugs and cannot get that access without Part D coverage of their needed medication.

d. Medicare Coverage Gap Discount Program Agreement (§ 423.2315)
(1) Obligations of the Manufacturer
(2) Length of Agreement
e. Payment Processes for Part D Sponsors (§ 423.2320)
(1) Interim Payments
(2) Coverage Gap Discount Reconciliation
f. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries (§ 423.2325)
(1) Obligations of Part D Sponsors; Point-of-Sale Discounts
(2) Collection of Data
(3) Other Health or Prescription Drug Coverage

(4) Supplemental Benefits
(5) Pharmacy Prompt Payment
g. Manufacturer Discount Payment Audit and Dispute Resolution (§ 423.2330)
(1) Third Party Administrator Audits
(2) Manufacturer Audits
(3) Dispute Resolution
h. Beneficiary Dispute Resolution (423.2335)
i. Compliance Monitoring and Civil Money Penalties (§ 423.2340)
j. Termination of Agreement (§ 423.2345)

A.2. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs (§ 423.100)

We are glad that Part D coverage is expanding to include coverage of benzodiazepines and barbiturates. We believe that existing tools in the Part D program are sufficient to address misuse issues for these drugs, and agree that it is the plans' responsibility to use their tools (system edits, quality assurance checks, etc.) to ensure that the program rules are followed.

A.3. Pharmacy Benefit Manager's Transparency Requirements (§ 423.501 and § 423.514)

We strongly support CMS's efforts to promote transparency of financial transactions involving Part D sponsors and pharmacy benefit managers (PBMs) that manage prescription drug coverage under a contract with a Part D sponsor. We support CMS's proposed categories of information to be collected and reported by each Part D sponsor and PBM for a contract year, and also support the articulated exceptions allowing the Secretary to disclose information for the purposes outlined in the proposed rule.

Given that the Part D prescription drug benefit is available only through private Part D sponsors, we hope that CMS will continue to do everything within its authority to push for greater transparency in all aspects of the Part D program, from plan sponsors to PBMs to drug manufacturers. Concerns about access to information about financial transactions in the Part D arena are heightened, for example, by the planned merger of two of the nation's largest PBMs, Medco Health Solutions and Express Scripts.

B. Strengthening Beneficiary Protections

B.1. Good Cause and Reinstatement into a Cost Plan (§ 417.460)

We support CMS's proposal to amend §417.460(c) to allow for the reinstatement of enrollment of 1876 cost plan enrollees for good cause subsequent to an involuntary disenrollment associated with the failure to pay premiums or other cost-sharing amounts. We agree that requirements for reinstatement into cost plans should be in line with those established under Part C and D.

B.2. Requiring MA Plans to Issue ID Cards (§ 422.111)

We support this proposed requirement for all Medicare Advantage plans to issue member identification cards to all plan enrollees. We also support CMS's requirement that MA PPOs and PPFS plans indicate on the card that Medicare Limiting Charges apply, as we know that beneficiaries get confusing information about whether and at what level their physicians can bill them. The card should direct the holder to a source of information about Medicare Limiting Charges so the beneficiary can better understand the significance of this information.

We propose adding one more item to the card: an indicator of the beneficiary's status as a Medicaid enrollee and/or as a Qualified Medicare Beneficiary (QMB). Such individuals are protected by law from some or all Medicare cost-sharing (see 42 U.S.C. § 1396a(n) for QMBs; 42 U.S.C.§ 1320a-7b(d) and 42 C.F.R. § 447.15 for full Medicaid enrollees) but may be unable to establish their status with their providers. Medicare Advantage regulations already require that plans' contracts with providers include a requirement that the providers adhere to cost-sharing protections for those entitled to some form of Medicaid (42 C.F.R. 422.504(g)(1)(iii)), but providers may be unaware that their patients are, in fact, dually eligible. Such information on the identification card would go far to ensuring that the poorest Medicare beneficiaries receive the protections built into the law for them.

B.3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

We support CMS's proposal to modify the calculation of the actuarial value of defined standard Part D coverage as it relates to retiree drug subsidy (RDS) attestation to exclude discounts and cost-sharing reductions provided to applicable beneficiaries in the coverage gap. We also support aligning the calculation for the valuation of creditable coverage to exclude these expenses. These changes should ensure that more employer-sponsored plans are appropriately determined to be creditable, and therefore enrollees of those plans will not be subject to the Part D late-enrollment penalty should they later choose to enroll in a Part D plan.

B.4. Who May File Part D Appeals with the Independent Review Entity (§ 423.600 and § 423.602)

The proposed change to subsections 600 and 602 would allow a "prescribing physician or other prescriber (acting on behalf of the enrollee)" to request Independent Review Entity (IRE) review of a redetermination issued by a Part D plan sponsor, and require the IRE to notify the requesting prescriber of its decision.

We continue to support all CMS efforts to ensure that the Part D appeals process is accessible and useful to beneficiaries. This change will, as noted in the preamble, prevent some dismissals from the IRE for lack of a valid appointment of representation form and allow prescribers to assist beneficiaries in timely appeals for coverage of their needed Part D medications. We continue, however, to urge CMS to implement more automatic procedures for Part D appeals in

order to reduce administrative burdens and to better facilitate beneficiary access to needed medications including, but not limited to automatic IRE review of all adverse redeterminations.

Furthermore, although we agree that Part D prescribers are generally free from the conflict of interest problems that might apply in a Medicare Advantage appeal setting because they are generally not entitled to payment from the enrollee, plan or pharmacy, please clarify that prescribers who appeal to the IRE on behalf of their patients without obtaining an appointment of representation form are not permitted to charge the patient for appeals assistance. Currently, the appointment of representation form that is required for appeal to the IRE includes a section whereby a physician who did not "furnish the items or services" may, but is not required to, waive a fee for representing the beneficiary. A prescriber should not be permitted to charge the beneficiary a fee for representation in the appeals process unless the beneficiary agrees, in writing, to the fee.

In addition we urge CMS to reexamine the policy surrounding "allowable extra fees." Part D and MA appeals are rarely, if ever, successful without physician support, and to allow physicians to charge fees for providing letters of medical necessity or producing medical records creates an unnecessary and unwarranted tension in the doctor-patient relationship. These fees put the patient in a difficult situation because they require physician support for a successful appeal. CMS should prohibit providers, whose assistance is critical in the appeals process, from charging extra fees for the provision of medical expertise required for successful utilization of the Part D program, or, at a minimum, should create guidance illustrating a "reasonable" fee for physician assistance. However, to ensure that providers do not refuse to participate in the appeals process because they cannot be compensated, CMS should explore alternate means of compensating physicians for these tasks including, but not limited to, requiring plan sponsors to develop payment mechanisms for tasks associated with the Part D appeals process.

B.5. Independence of LTC Consultant Pharmacists (§ 483.60)

We strongly support the proposal to require long-term care consultant pharmacists to be independent of conflicts of interest. We concur with CMS that consultant pharmacists should make medication recommendations based solely on the best interests of residents, and that to do so, they must not have conflicting financial interests that can encourage over-prescribing, over-utilization, and inappropriate use of drugs. Therefore, we urge you to use your authority to publish regulations to require long-term care facilities to engage consultant pharmacists who are not employed by, under contract with, or affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any of their affiliates.

Recent federal and state lawsuits against large long-term care pharmacies, pharmaceutical manufacturers, and nursing home chains provide evidence that conflicts of interest and misaligned financial incentives in the payment system perpetuate overmedication and inappropriate care at least some of the time. A settlement agreement between the long-term care pharmacy giant Omnicare and the Justice Department in a False Claims Act *qui tam* case in 2009 stipulated that Omnicare submitted claims to Medicare and Medicaid that were fraudulent

because they resulted from remuneration in the form of consultant pharmacist services that Omnicare provided to nursing homes below its cost of providing the services.[1]

We concur with comments on this proposed rule submitted separately by the National Consumer Voice for Quality Long-Term Care (Consumer Voice, formerly NCCNHR) and other advocates. We urge CMS to:

- Require long-term care consultant pharmacists to be independent of any affiliations with long-term facilities or pharmaceutical manufacturers, distributors, or affiliates of these entities.
- Require long-term care facilities to use qualified professional pharmacists to conduct drug regimen reviews and make medication recommendations solely on the best interests of the resident.
- Define independent pharmacists as those who are not employed, under contract, or otherwise affiliated with the facility's pharmacy, pharmaceutical manufacturer or distributor, or any affiliate of these entities.
- Create strict enforcement mechanisms to ensure the independence of long-term care pharmacists, including lengthy exclusion from participation in Medicare and Medicaid for non-compliance.

C. Excluding Poor Performers

1. CMS Termination of Health Care Prepayment Plans (§ 417.801)

C.2. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§ 422.504,§ 422.510, § 423.505, and § 423.509)

We fully support CMS's position that plans which receive one or two stars for a consecutive number of years should be subject to termination. However, we think three years of low star ratings before plan termination is too long. Keeping a low quality plan in the market for three years seems inappropriate and dangerous for beneficiaries. We also suggest that, as we believe is implied in the proposed rules pre-amble, if plans have a one or two star rating in any one year that CMS use the existing sanctions process to strengthen incentives for plans to improve quality immediately and better protect beneficiaries. Furthermore, we recommend CMS consider the use of sanctions or other enforcement mechanisms if a plan's rating consistently fluctuates between one to three stars. Once a plan with one or two stars improves to three stars, the plan should demonstrate that it is able to consistently score three stars. For that reason we ask CMS to consider a probationary period of an appropriate number of years if a plan avoids termination because it improves its star rating to three stars in one year but has shown a prior history of poor performance. The proposed rules suggest "the clock" for plan termination should be begin using plan star ratings released for 2013 to put plans on proper notice about this policy, as this proposal was part of the Advance Notice of Methodological Changes for Calendar Year 2012, we believe

[1] *Settlement Agreement among (A) United States, (B) Omnicare, and (C) Adam Resnick, David Kammerer, Deborah Maguire, and Bernard Lisitza*, 2009.

plans were put on proper notice for the 2012 plan year and as a result, "the clock" should begin this year.

More generally, as star ratings and the quality measurements on which they are based become more meaningful as part of the quality bonus program, we ask that CMS continually evaluate the star ratings system and the underlying measures over time. If, for example, in reviewing plans' reporting on measures, there are certain trends whereby most plans make improvements on certain measures but not others, boosting their overall star ratings, it may mean that incentives and the weight given to certain measures must be reconsidered so that plans continue to improve, not simply those measurements that may seemingly be "low hanging fruit." This comment should not be read to suggest that quality measures achieved more simply, the "low hanging fruit", are unimportant. Rather we ask that CMS use its regulatory powers to ensure plans do not avoid or overlook improvements on measures that may be difficult or more expensive to tackle.

In addition, we ask that CMS engage in appropriate oversight of plan activities to improve star ratings to ensure that the activities do improve plan quality and are not attempts to "game the system." Activities that fall into the latter category would undermine the star rating system and the policy of rewarding high quality and high performance insurance plans.

Furthermore, 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.

C.3. Denial of Applications Submitted by Part C and D Sponsors with a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

We support providing CMS with the authority to deny applications submitted by MAOs and Part D sponsors that have performed poorly in the past, however we believe that CMS should have even greater authority than the scope proposed in this rule.

We agree that a 14-month look back is an inadequate amount of time to assess plan performance in the case of organizations whose performance was so poor as to have their contracts terminated or non-renewed by CMS. CMS proposes to modify the past performance review period to capture CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application. We agree that the time period should be extended, but 3 years is not long enough. CMS should have the maximum amount of flexibility to prevent poor performing plans from contracting with Medicare, and therefore CMS's look back period should either be greatly extended – for example, 10 years – or open-ended altogether. As CMS notes, plan sponsors that have been previously terminated or non-renewed "have broken faith with the program in a more significant way than in the case of a voluntary non-renewal."

With respect to CMS's current authority to review the performance of current plan sponsors, CMS notes that fourteen months "is a reasonable amount of time to review the performance of an organization with current and ongoing Medicare Part C and D contracts." Similar to the proposed extension to review previously terminated or non-renewed plans, we disagree that this short time period is adequate, and assert that CMS should have greater authority to review a longer period of performance. Plan performance if often best measured when plans are responsible for implementing changes in program rules, which might not occur with enough frequency to be measured by such short time periods. For example, if a plan performs poorly in implementing a new consumer protection required by statute, regulation or guidance, but there are no additional such changes to program requirements within the next 14 months through which to measure a plan's subsequent performance, this should factor into performance reviews that occur more than 14 months in the future.

We support the newly proposed language regarding "covered persons" stating that in implementing the new proposed 3 year look back provision, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract.

We agree that these proposals, particularly if expanded as discussed above, would directly enable CMS to protect beneficiaries from poor care. The Medicare program, including the Medicare trust fund, will be strengthened if consistently poor performers – particularly those who were previously terminated from the program or did not have their contracts renewed – are not rewarded with contracts.

D. Improving Program Efficiencies

1. Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal (§ 417.492)

D.2. New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

We are in favor of experimenting with flexibility for supplemental benefits along the general parameters that CMS proposes, but expect there will be many issues in implementation that need to be thought through and addressed. Thus, we propose moving slowly and paying close attention to the actual provision of such benefits by the plans involved and to the effect of the offering of such benefits on how Medicaid long term supports and services are provided in the relevant states.

We support limiting this flexibility to high quality FIDE-SNPs that have been in operation, as FIDE SNPs, for at least one year. We favor this approach both because FIDE SNP members would likely benefit most from flexibility and because a smaller pilot makes sense, allowing careful review of plan proposals and of issues that may arise in implementation. That said, we also recognize that FIDE SNPs, by definition, are either providing or coordinating delivery of state Medicaid long-term supports and services and that the supplemental benefits proposed to be offered may duplicate those already provided by the State Medicaid program.

We also agree with CMS that limiting the flexibility to FIDE-SNPs serving only full benefit dual eligibles also makes the most sense.

We appreciate the concept of supplemental benefits that would *coordinate* with or enhance Medicaid benefits but share the concerns of CMS that they could be used to inappropriately substitute Medicaid benefits. Of the benefits CMS has offered as examples of what might be permitted, some are required Medicaid benefits (non-skilled nursing activities in the home), some are optional (personal care services in the home) and some may be available only under a home-and-community-based services waiver (in-home food delivery and possibly custodial care, although we are unclear what is meant be custodial care). Thus, a state must offer the required benefits, may offer the optional benefits and, if it offers the "wavier" benefits, they might be capped as to numbers of people to whom they are offered and numbers of hours of service available. Though the variety of possibilities, with respect to the individual beneficiary's rights under Medicaid, could make CMS's monitoring of implementation to assure that the benefits offered do not supplant Medicaid benefits more challenging, CMS must engage in appropriate oversight.

In a related vein, because Medicaid benefits are entitlements with strong beneficiary protections while supplemental Medicare benefits are not, there is a real danger of erosion of beneficiary rights to needed services. (For this reason, while we believe we understand the underlying motivation for the comment, we are somewhat alarmed by CMS's noting that the supplemental benefits would be good in situations where a state reduces coverage of a Medicaid benefit. States are circumscribed by law in how, if at all, they can "reduce" coverage of a benefit, while Medicare Advantage plans are under no obligation at all to offer these particular benefits.) Also, if supplemental benefits are for services also covered by Medicaid, then the criteria for coverage should be at least as good as Medicaid criteria. For all benefits, whether or not they are also Medicaid-covered services, there need to be criteria so that beneficiaries can exercise their appeal rights if they believe they meet the criteria and have been denied the supplemental benefits. Lastly, the benefits need to be meaningful: a week's worth of personal care services is of little value to a person needing *long-term* supports and services.

To assist it in monitoring State behavior to reduce the likelihood of shifting cost, CMS could require a FIDE SNP that wishes to offer supplemental benefits to include in its submission a full description of long-term supports and services covered by the State Medicaid program, including what waivers are available, what the eligibility criteria are and the typical length of wait for waiver services. (We must note that, because Medicare is the primary payer for all services where dual coverage exists, supplemental Medicare benefits that have traditionally been only Medicaid benefits *will* result in some cost-shifting to Medicare. The outcome we are seeking to prevent is the State reducing access to Medicaid services that are also included in the FIDESNP's supplemental package.) The description would also include a statement of how the plan's supplemental services will work together with available Medicaid services, recognizing that Medicare is the primary payer. Because the plan is a FIDE SNP and by definition is knowledgeable of the Medicaid services, this should not prove burdensome to the plan.

With respect to this proposal, the lack of transparency regarding FIDE SNPs current models of care, contracts with states, and benefit structures creates difficulty in understanding how these provisions fit into the overall Medicare Advantage and Medicaid landscape. For example, it is unclear how FIDE SNPs work with the various long-term supports and services provided by the states in which they operate and how the FIDE SNPs work with waiver programs. In addition, these rules must not be promulgated in a vacuum but rather coordinated to reflect ongoing work by the Medicare-Medicaid Coordination Office. It is yet unclear if FIDE SNPs offering these benefits will be part of states' integration projects and in the case that they are it seems it would be important for the supplemental benefits to fill in gaps in the services the State is already providing. In addition, CMS must develop the proper tools to evaluate such initiatives.

We are confused by CMS's request for comments on ways to minimize this proposed provision's cost impact on dual eligible beneficiaries, while ensuring that States, SNPs, and providers can feasibly provide additional supplemental benefits to a full benefit dual eligible population. First, it is unclear what CMS means about states offering supplemental services. But more importantly, the rule seems to suggest that beneficiaries in FIDE SNPs are paying premiums. Because in most cases FIDE SNPs only serve dual eligibles, they should not be charging premiums. Even those duals in nursing homes, some of whom have higher incomes to start with than most of the Medicaid population, are protected from Part D and other kinds of cost-sharing on the understanding that they must pay nearly all of their income to the nursing facility before Medicaid will pay the rest. In addition, since many duals have incomes below 100% of the federal poverty level, they should be Qualified Medicare Beneficiaries (QMBs) and thus protected from all cost-sharing under Parts A and B. Though certain states Medicaid programs may charge certain individuals who are dually eligible nominal cost-sharing, the very fact that all these cost-sharing protections are in place supports the position that there should be no cost implications of these benefits on the population at hand. We urge CMS to prohibit FIDE SNPs from charging duals any co-payments for supplemental benefits.

There may be the potential for appeals complications if a Medicare supplemental benefit overlaps with a Medicaid benefit. But this is already true under current benefit structures. For example, an individual is entitled to only 100 days, maximum, of Medicare skilled nursing facility care but unlimited numbers of Medicaid skilled nursing facility days. Another example are cases where Medicare wheelchair coverage may be less generous than Medicaid wheelchair coverage. While these overlaps and occasional misalignments occur in other settings for duals, we expect that an entity that has qualified as a high quality fully integrated dual eligible special needs plan (FIDE SNP) is offering excellent coordination of benefits such that the beneficiary does not experience coverage complications.

3. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

D.4. Clarifying Coverage of Durable Medical Equipment (§ 422.100, .111, .112, .578, .592)

We appreciate the opportunity to comment on the beneficiary protections that are necessary as CMS allows MA organizations to create "preferred" and "nonpreferred" 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 Planfinder 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.

a. Access to Preferred DME Items and Supplies
b. Medical Necessity Requirements for DME Items and Supplies
c. Transition Period for Coverage of Non-Preferred DME Items and Supplies
d. Midyear Changes to Preferred DME Items and Supplies
e. Appeals
f. Disclosure of DME Coverage Limitations

II.D.5 Broker and Agent Requirements (§ 422.2274 and § 423.2274) – General Marketing Comment

Though not the subject of this rule, we ask that CMS begin to consider revisions to marketing rules in anticipation of 2014 and the implementation of ACA related coverage. It is important that appropriate firewalls be put in place between Navigators, exchanges, QHP plans, and Medicaid managed care plans to ensure that people transitioning to Medicare are not auto-enrolled into Medicare insurance products including MA plans or specific PDPs that may be inappropriate for them and that those new to Medicare base enrollment decisions on independent information. It is important that Medicare enrollment decisions are not based on incomplete information that result from conflicts of interest that are present if a plan sponsor offers products through an Exchange, Medicaid, and/or Medicare. CMS should provide for independent resources to ensure that people have a comprehensive review of their options and are not "steered" into the Medicare Advantage program rather than Original Medicare or any particular plan within the Medicare Advantage Program or the Medicare prescription drug benefit. We also ask CMS to review rules regarding appropriate and allowable contact with Medicare beneficiaries under the existing rules to better account for new products and scenarios that will exist in 2014.

6. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program (§ 423.104 and § 423.153)

E. Clarifying Program Requirements
1. Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)
2. Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans (§ 417.427)
3. Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement (§ 422.101)
4. Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements (§ 422.216)
5. Application Requirements for Special Needs Plans (§ 422.500, § 422.501, § 422.502, § 422.641, and § 422.660)
6. Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)
7. Clarification of Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)
8. Valid Prescriptions (§ 423.100 and § 423.104)

E.9. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

We agree that all targeted beneficiaries residing in a long term care setting, including those with cognitive impairment, must be offered the opportunity to participate in the annual comprehensive medication review. We recognize that some cognitively impaired beneficiaries may not have the capacity to participate in this review. In those circumstances, CMS should **require** that the pharmacist, or qualified provider, provide written notice to the appropriate health care proxy/legal representative and provide the opportunity for the health care proxy/legal representative to take part in the beneficiary's CMR, if so desired.

10. Employer Group Waiver Plans Requirement to Follow All Part D Rules Not Explicitly Waived (§ 423.458)
11. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

III. Collection of Information Requirements
IV. Response to Public Comments
V. Regulatory Impact Analysis