January 11, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Re: CMS-4144-P

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

Dear Dr. Berwick:

The undersigned organizations submit these comments to the above-referenced proposed regulatory changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program. See 75 Federal Register 71190 (Nov. 22, 2010). Our organizations represent and advocate on behalf of older people and people with disabilities who rely on Medicare for their health coverage. We appreciate the opportunity to comment on the proposed changes.

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 most of the proposed changes in more detail below. However, we would like to highlight and summarize our comments on the following sections:

- Cost Sharing for Specified Services at Original Medicare Levels (§§ 417.101 and 422.100): We thank CMS for proposing to preclude Medicare Advantage organizations from charging more in cost-sharing for home health services than under Original Medicare, and we ask CMS to include durable medical equipment among the services that are protected. We disagree, however, with CMS's interpretation of the limitation on cost-sharing for skilled nursing facility services and ask that MA plans be prohibited from imposing cost-sharing during the first 20 days of skilled nursing facility care.

- SNPs (§§ 422.2, 422.4, 422.101, 422.107, 422.152): We are a bit confused about CMS's intentions for implementing the new requirements for NCQA approval of SNPs. We ask for clarification as to how those requirements relate to requirements for D-SNPs to contract with states and to CMS's

own approval process for SNPs. We are concerned about proposed plan approvals for more than one year and are uncertain about the reach of that proposal: would it apply only to Models of Care (MOC) and Quality Improvement (QI) requirements or to all SNP requirements? We ask for a fully transparent process to develop the NCQA standards on which CMS will rely for "the foundation" of SNP approval.

- Uniform Exceptions and Appeals Processes (§§ 423.128 and 423.562): We thank CMS for the improvements that it proposes to the exceptions and appeals processes. We believe that the creation of standardized coverage and redetermination request forms and the issuance of point-of-sale notices address some of the problems that beneficiaries encounter in attempting to use these systems. However, we believe that more needs to be done. We urge CMS to require that notices provided at the point of sale be beneficiary-specific, not generalized. We also ask that CMS provide access to the drug compendia as they are prohibitively expensive, not publicly available, and required to support certain exception.

- Translated marketing materials (§§ 423.2262 and 423.2264): While we appreciate the intent of CMS to clarify the requirements that plans translate vital documents, we believe that the proposed regulation does not go far enough and is inconsistent with Department of Health and Human Services and Department of Justice guidance. We include recommendations that are more consistent with guidance.

DETAILED COMMENTS ON PROPOSED CHANGES

B. Changes To Implement The Provisions Of The Affordable Care Act Of 2010

1. Cost Sharing for Specified Services at Original Medicare Levels (§§ 417.101 and 422.100)

a. Cost-sharing for SNF care: The provisions of the Affordable Care Act limiting cost sharing to the level required in original Medicare for at least chemotherapy administration services, renal dialysis services and skilled nursing care as well as for such other services as the Secretary determines appropriate, including services that the Secretary determines require a high level of predictability and transparency for beneficiaries, were welcome news for beneficiaries who often found themselves exposed to substantially higher cost sharing for similar services in managed care, than in original Medicare. This has historically been a particular problem for beneficiaries in need of skilled nursing care. According to MedPAC, the average number of covered days per

SNF admission in 2008 was 27, many fewer than the statutory cap of 100-days.[1] Thus, allowing MA plans to frontload their skilled nursing care cost-sharing requirements to the first 20 days basically undoes the protection that these provisions were designed to establish. MA plans should not be permitted to rely on the provision allowing for MA cost sharing for services for which there is no Original Medicare cost-sharing, as long as the overall cost sharing is the actuarially equivalent to the cost imposed under Original Medicare, to subvert the statutory intent of the Affordable Care Act. Specific examples from MA plans offered in Massachusetts include cost sharing of between $15 and $65/day for days 1-20. While this may comply with the letter of the law, it is clearly contrary to its spirit. We therefore strongly oppose your proposal to allow MA cost sharing for the first 20 days of skilled nursing facility care. We ask CMS instead to require MA plans to apply Original Medicare's $0 cost-sharing for the first 20 days of skilled nursing care.

b. Cost-sharing for other services: We applaud and support, however, your proposal to not allow cost-sharing for MA plan home health services, as there is no cost sharing for home health services in Original Medicare, and as we encourage you to do for skilled nursing facility care. Not allowing beneficiary cost sharing for MA home health services is an important positive move in increasing predictability and transparency for Medicare beneficiaries enrolled in Medicare Advantage plans.

We also urge you, in the interest of increasing predictability and transparency for Medicare beneficiaries, to add durable medical equipment to the list of MA services for which cost sharing should not exceed that required in Original Medicare.

With respect to "value based" rates, we believe that CMS has taken the right approach in drafting the proposed regulations. We do not share concerns that plans will lose the flexibility to institute value-based rates for seeing providers with better outcomes or incentives to ensure that enrollees comply with prescribed care. While value-based rates and incentives might appear to be attractive economic policies, they can create barriers for vulnerable populations. Transportation, access, and finances affect health care for many vulnerable Medicare beneficiaries. For example, individuals with low incomes should not be penalized by having to pay higher cost-sharing if the only provider to whom they have access does not have the best outcomes. Similarly, individuals should not be penalized for non-compliance if they cannot afford the cost-sharing for the prescribed service or do not have the transportation to get to the service. Rather than allowing variations in cost-sharing to encourage good consumer participation, we suggest that CMS use the new quality bonuses to create incentives for and to reward plans that use innovations to promote compliance, like contracting with providers who make house calls or offering transportation services to get to doctor visits.

[1] MedPAC, *Report to Congress -March 2010*, at pg. 179; available at http://www.medpac.gov/documents/Mar10_EntireReport.pdf.

2. Simplification of Beneficiary Election Periods (§§ 422.62, 422.68, 422.38, and 423.40)

We support the simplification of the Medicare enrollment periods, including changing the annual coordinated election period (AEP), in compliance with the ACA. We are concerned, however, that for the first year some beneficiaries may miss the opportunity to make important health care decisions because they were unaware of the change to the AEP. This would result in beneficiaries being locked into health coverage that does not meet their needs. Although the Medicare Advantage Disenrollment Period (MADP) provides an opportunity for some beneficiaries to make changes in health coverage, the MADP alone is inadequate. We ask that for the plan year 2012 CMS establish an exception for those beneficiaries who miss the December 7th close of the AEP. This exception should be available to any beneficiary who calls 1-800-MEDICARE between December 8th and the 31st and indicates that he or she was unaware the election period had ended. The representative at 1-800-MEDICARE should automatically grant the exception and allow the beneficiary to make any change that is available during the AEP. At the conclusion of the call the representative should explain that the AEP now ends on the 7th rather than the 31st.

We also would like to take this opportunity to encourage CMS to ensure that all other important dates, such as when plan information is made available to State Health Insurance Assistance Programs (SHIPs), are adjusted as necessary to ensure that all stakeholders have the information they need in time to begin a smooth, seamless enrollment period. For example, if plan information is not made available in the Plan Finder until October 1, this will provide very little time for SHIPs to prepare for the enrollment period. Currently, SHIPs have some lead time between when plan information is made available and when the enrollment period begins to run test searches to ensure that the information included is accessible and accurate

3. Special Needs Plan (SNP) Provisions (§§ 422.2, 422.4, 422.101, 422.107, 422.152):

a. Adding a Definition of Fully Integrated Dual Eligible SNP (§ 422.2): The proposed regulatory definition fails to include statutory language that requires that a D-SNP receiving a frailty adjuster must have average levels of frailty (as determined by the Secretary) similar to those used by the PACE program. The statutory definition of fully integrated dual eligible SNPs includes reference to PACE frailty levels and we believe this reference should be included in the definition section of the regulation as well as where it now appears, in the payment section.

We ask CMS to clarify what it means by "aligned care management and specialty care network methods for high-risk beneficiaries." We hope that "aligned care management" would include managing care that is covered by Medicare or Medicaid in such a way that the individual beneficiary gets full access to all services covered by both programs. An example of such aligned management might be assistance to provide access to a full range of home health services such that the individual receives full benefits under Medicare to skilled and related home health services and additional benefits under

Medicaid home health and home and community-based service waivers, if any. We applaud the specific reference to "specialty care networks" as being required of fully integrated D-SNPs as we believe that access to specialists is critically important to dually eligible individuals who often have multiple co-morbidities and chronic conditions.

CMS is requiring fully integrated D-SNPs to have procedures to "coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance." We remind CMS of the many complaints we have received (and notified CMS of) from dual eligibles in D-SNPs who receive generic notices designed for non-dual beneficiaries that do not correctly identify their rights and obligations. Such notices include incorrect information about cost-sharing and enrollment obligations. A plan designated for additional payment due to the frailty of its enrollees must provide notices specific to the population it is serving.

As we understand the definition CMS is proposing, it applies only to those D-SNPs that wish to receive a frailty adjuster. That is to say, this is not a new definition of a D-SNP, but refers to a sub-group of D-SNPs offering comprehensive Medicaid services. Moreover, our understanding is that under this definition, a D-SNP eligible for the frailty adjuster must provide *all* long-term supports and services available under the State's Medicaid plan, or those provided under § 1115 and §§ 1915(c) and (d) waivers if available where the plan operates, as well as under State Plan Amendment options included in the Deficit Reduction Act and the Affordable Care Act. We believe that any SNP purporting to offer long-term supports and services must offer the full range available in a given state.

Having said that, we urge extreme caution in approving plans for the frailty adjuster. We do have some concern that requiring such ambitious integration to qualify for the adjuster will motivate plans that are not ready to take on that difficult task to do so in pursuit of a higher reimbursement. Comprehensive integration efforts need to be developed slowly and carefully and not solely for the purpose of qualifying for a frailty adjuster.

b. Extending SNP Authority: While the preamble discusses the statutory extension, through 2013, of SNP authority to restrict enrollment to those who meet the definition of special needs individual, the actual regulatory language is not changed. The regulation makes no mention of expiration of SNP authority. The reference to postponing the effective date to 60 days after publication of the final rule does not seem to have any real effect and thus does not seem relevant.

c. Dual-Eligible SNP Contracts with State Medicaid Agencies (§ 422.107): The proposed change to the regulations merely restates the statutory requirement that D-SNPs without contracts with their state agencies may operate through 2012 but may not expand their service area. Its effective date should not be postponed to 60 days after publication of the final regulations.

We believe the regulations need to address additional issues that have arisen with respect to state contract requirements. First, as to the population to be served by a D-SNP, we

believe the law intends that a SNP can only serve subpopulations that are being served as specific subpopulations of the State Medicaid program. For example, a D-SNP was approved in PA last year to serve an age 60+ population, even though the state Medicaid program had no specific program for an age 60+ population. Advocates objected to the fact that this plan had been approved; ultimately the plan withdrew from the market. We believe the main reason to serve a subpopulation in a D-SNP would be to fully coordinate with a program – such as a home and community based waiver program – being operated by the State. We ask that the regulations clarify this limitation.

Second, we ask that the regulations address the issue of CMS's oversight or review of state contracts with D-SNPs. We believe that states may not always be sufficiently engaged in the process of contracting with D-SNPs to ensure that adequate protections are included for beneficiaries. In Maine, for example, one contract with a D-SNP included, in its description of certain benefits covered by the contract, a reference to benefits under the Texas State Plan, suggesting that Maine had lifted nearly whole cloth a Texas-made contract. The possibility that this had occurred was strengthened by advocates' failure to find anyone at the state Medicaid agency with substantial knowledge about the contract. CMS has greater familiarity with SNPs than states do; it should provide states assistance with and exercise oversight of the contracting process.

Third, CMS should clarify in regulations that annual contracts with the state are required in order for the SNP to continue operating in the state. Thus, a SNP could not end its contract with a state in, say, 2011, but try to continue to operate without expansion in 2012. And, states and SNPs should be required to renew contracts each year through a transparent process that allows public input including the opportunity to raise issues that have occurred with the SNPs' services during the previous contract year and including the possibility of terminating the contract.

Finally, we ask CMS to address the relationship between the requirement for D-SNPs to contract with the state, the CMS SNP approval and contracting requirements generally, and the new requirement that SNPs be approved by NCQA to operate. Since most D-SNPs are now required to have a state contract (and, beginning in 2013, all will be so required) and SNPs must be NCQA-approved, we assume that CMS would not contract with a D-SNP that does not meet those requirements. We also assume, but wish to see clarified, that if a D-SNP were approved by NCQA for longer than one year (we have reservations about this, addressed below) but lost its state contract, CMS would not approve it or contract with it.

d. Approval of Special Needs Plans by the National Committee for Quality Assurance (§§ 422.4, 422.101, 422.152): The preamble language related to this requirement states that new SNPs and SNPs that are expanding their service areas are already required to submit a Quality Improvement Program Plan (QI) and a model of care (MOC). We are confused and disturbed to see this narrowing of pre-existing statutory and regulatory mandates that *all* SNPs operating in 2010 and beyond must have models of care and that *all* Medicare Advantage plans must have Quality Improvement plans. (42 C.F.R. § 422.101(f); § 422.152)

While the statutory language merely states that for 2012 and subsequent years, SNPs must be approved by NCQA, the proposed regulation goes much farther. CMS proposes to delegate full authority to NCQA to certify the appropriateness of SNPs' Models of Care and Quality Improvement programs. CMS states that this certification will provide "the foundation" for selecting Medicare Advantage Organizations that understand the special needs of the populations served by SNPs. We do not favor giving so much authority to a private entity whose processes and activities are not as subject to public scrutiny as those of the government. In any case, we believe CMS must undertake periodic audits of NCQA's work in this regard to assure that its approval process is serving the beneficiaries' interest. We assume, but would like to have clarified, that CMS will continue its own review of SNP applications rather than allowing the NCQA approvals of two elements to serve as "deemed compliance" with all regulatory requirements.

CMS invites comment as to the appropriate frequency for the SNP approval process. Again, we are slightly confused as to whether this refers only to NCQA approval of the QI and MOC or also includes overall acceptance of the plan. We believe that SNPs must submit bids and be reviewed/approved or denied annually like other MA plans. If CMS is asking about approval of the QI and MOC, we believe that any plan whose QI or MOC is not reviewed annually must be required to certify that it has not changed either one in the intervening period and does not intend to change it during the remainder of the approval period. We also note that some standards for NCQA review might be structural and thus better suited to multi-year approval, while others may measure performance and should be subject to annual review.

Beyond this, we urge CMS to have a fully transparent and public process for developing the standards to be used by NCQA to review plans' QIs and MOCs.

e. Models of Care: Beneficiary advocates have repeatedly requested that SNPs be required to provide prospective enrollees with a copy of their Model of Care. We request again that the final regulations require SNPs to make their Model of Care available. Given how much the plans cost, and given that some SNPs do not really provide a benefit package that is "special," potential enrollees should have this information so they know what special services the plans say they will provide and the plans can be held accountable.

5. Making Senior Housing Facility Demonstration Plans Permanent (§§ 422.2 and 422.53)

The regulations should make clear that persons enrolled in such plans who leave the relevant facility are eligible for a special enrollment period for their prescription drug and medical coverage.

6. Authority to deny bids (§§ 422.254; 422.256; 423.265; 423.272)

The authority to deny bids is a crucial beneficiary protection. CMS should use this authority to ensure that plan benefit options are distinguishable from each other in a way that is understood by beneficiaries, and that plans are offered by MA organizations and Part D sponsors that comply with Medicare rules and regulations to provide high-quality offerings to Medicare beneficiaries.

We therefore believe that the proposed regulations, which authorize CMS "to decline to accept *any or every otherwise qualified bid*" submitted by an MA organization (MAO), by a potential MA organization, by a Part D sponsor, or by a potential Part D sponsor, properly implement Section 3209 of the Affordable Care Act. We also agree that the new statutory section allows CMS to decline to approve a Part C or a Part D bid that proposes significant increases in cost sharing or decreases in benefits offered under the plan, as the proposed regulations would allow.

CMS asks in the proposed regulations whether the criteria outlined in the April 16, 2010 guidance issued via HPMS are the appropriate criteria to use in limiting plan offerings in a service area. We would add to the criteria, for Part D plans, the number of tiers used by a plan, whether the highest level tier includes drugs other than "specialty tier drugs," and whether the cost sharing for any covered drugs exceeds 25% of the cost of the drug. We would also have CMS look at the number of drugs subject to utilization management criteria. For Part C plans, we would ask CMS to consider the extent to which the use of actuarially equivalent cost-sharing still results in beneficiaries paying more than traditional Medicare for high-cost services and items.

Finally, the authority to deny bids should be used as a vehicle to ensure that only high quality plans are offered to beneficiaries. CMS should deny bids from MAOs and Part D sponsors that consistently are sanctioned for failing to comply with Part C and Part D regulations and guidance. We suggest that the regulatory language be modified to clarify that CMS will use its authority to deny bids from organizations that have been repeatedly sanctioned for failing to comply with these rules.

The proposed regulations should be implemented so as to be in place for the 2012 bidding cycle, raising concerns for us about the delay of implementation until 60 days after the final rule is published. We believe that the ACA statutory language gives CMS authority to deny bids for the reasons outlined above; delaying implementation will hurt beneficiaries who are confused by unclear choices or who enroll in plans that do not operate to provide the highest quality services to them.

7. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

We thank CMS for making this positive change.

8. Voluntary *De Minimis* Policy for Subsidy Eligible Individuals (§§ 423.34 and 423.780)

Changes to paragraph (c). The addition of paragraph (c)(2) requires amendments to paragraph (c)(1) to clarify exactly what the general rule of reassignment is. The current regulation simply states that CMS may reassign some LIS recipients if warranted. It does not explain that reassignment occurs when a Part D plan's premium rises above the benchmark amount and it does not specify which individuals are subject to reassignment. This general language has been sufficient up to this point. The addition of the new paragraph (c)(2), however, which provides much more detail about which plans are not eligible for reassignment requires that more detail be added to (c)(1). Without that detail, there is no context for interpreting (c)(1) or (c)(2). Paragraph (c)(1) reads as if reassignment can occur for any reason the Secretary determines to be warranted. Paragraph (c)(2) reads as if no reassignment from these plans could ever occur for any reason. It is clear that the statute intended these plans to be exempted from the reassignment 'based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark amount.' This should be made more explicit. We recommend that a simple sentence that describes the annual reassignment process be added to (c)(1).

We also ask that CMS examine the impact on enrollment stability if the agency were to apply the *de minimis* policy to partial premium subsidy recipients.

Addition of paragraph (d)(4). As currently drafted paragraph (d)(4) would permit for the first time the auto-enrollment of low-income subsidy recipients into MA-PDs. While we support the idea of selectively treating *de minimis* PDPs the same as other benchmark PDPs for purposes of reassignment (for example, to keep an individual in a plan offered by the same sponsor) we do not support extending this treatment to MA-PDs. Enrolling in a MA plan is fundamentally different from enrolling in a PDP and involves complicated decisions about provider networks, benefit structure and more. Even in the limited exception noted in the preamble, it would not be appropriate for CMS to reassign an individual enrolled in a PDP losing benchmark status into a MA-PD offered by the same plan as such a change could have drastic consequences on how the individual accesses Part A and B benefits. CMS should not diverge from its long standing policy to only auto-enroll LIS recipients into PDPs per 423.34(d)(1).

We understand that CMS is attempting to effectuate statutory language that includes a reference to MA-PD plans. That language does not make sense in the current regulatory scheme. Paragraph (d)(1) makes explicit that reassignment will only be to PDPs. The new paragraph would extend the option to include MA-PDs, but only those that have Part D premiums in the *de minimis* amount. This would leave out MA-PDs that have Part D premiums below the benchmark amount. The result does not make sense. In addition, nothing in the statute or the proposed regulation addresses a situation where a MA-PD has a Part D premium within the *de minimis* range and a Part C premium that would leave the LIS recipient with a liability. Since the statutory language creates an option, not a

requirement, to assign LIS recipients to *de minimis* plans, we recommend that CMS not exercise this option or only do so with respect to PDPs.

We also understand that the agency does not have immediate plans to exercise the option created in the new paragraph. We are concerned, however, that the language in the regulation could, in the future, be used as a basis for broad auto-assignments of dual eligibles into Special Needs Plans, a policy which we have generally opposed and which conflicts with Medicare's freedom of choice provision.

9. Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (Part D IRMAA) (§§ 423.44 and 423.293)

We thank CMS for proposing a longer grace period to pay the additional Part D IRMAA premium. We appreciate CMS' concern about a beneficiary's prescription drug coverage in proposing an opportunity to be reinstated without interruption if the enrollee, within three calendar months after the termination date, demonstrates "good cause" for failure to pay the Part D IRMAA during the initial grace period. We ask CMS to provide guidance on what is "good cause," include examples of "good cause" and make clear that "good cause" is not limited to the examples.

We recognize that the new Part D IRMAA requires coordination among CMS, Part D sponsors, and SSA, with SSA having primary responsibility for determination whether a particular beneficiary must pay the higher premium. In order to facilitate this coordination, we ask that the final regulations address the need for the timely exchange of beneficiary information and any updates. For example, if a higher income beneficiary is no longer enrolled in a Part D plan, the Part D sponsor should send this information immediately to CMS and SSA so that the Part D IRMAA is no longer deducted from this beneficiary's Social Security check or billed to this beneficiary.

10. Elimination of Medicare Part D cost-sharing for individuals receiving home and community-based services (§§ 423.772; 423.782)

We appreciate that CMS has proposed that this regulation take effect on January 1, 2012. We also look forward to the planned guidance on Best Available Evidence for the new zero co-payment amount. In implementing this important protection for individuals receiving long-term care services in the community, we propose that CMS use the same procedures it uses for individuals who qualify for the Low Income Subsidy based on Medicaid enrollment. Specifically, if an individual appears on state files as eligible under this regulation at any point during the year, that individual will qualify for the zero co-payment for the remainder of the year. If an individual shows as eligible in July or any later month in the year, the zero co-pays will continue through the next plan year as well.

CMS indicates (Federal Register at pg 71204) that it will rely on data from State Medicaid agencies to identify eligible individuals, and that the data is submitted to CMS no less frequently than monthly. We ask CMS to issue a letter to State Medicaid Directors to remind states that data may be submitted daily, and to encourage them to do

so. Additionally, we urge CMS to work early with states to develop data transfer protocols that allow for daily transfers and processing of state information that will capture all eligible individuals and to fully test these systems prior to January 2012.

With respect to Best Available Evidence for this population, our understanding is that waiver participants and state plan participants under Sec. 1915(i) generally receive letters telling them they have qualified and, for many waiver recipients, telling the individuals the maintenance allowance they are permitted under the waiver. We expect that the form of this letter will vary significantly among states and programs and suggest that CMS work with plans to help them (and pharmacists) understand what such letters might look like.

We have particular concerns about beneficiaries who are receiving HCBS services through Medicaid managed care plans. We are concerned both about how the use of HCBS services by these individuals will be captured in state data exchanges and about BAE. If the plan sponsor of the Medicaid managed care plan is also operating a Dual Eligible Special Needs Plan in which the beneficiary is enrolled, then the plan sponsor should have an obligation to ensure appropriate co-pay status. In other cases, however, it may be necessary to develop a form for managed care plans to provide attesting to the beneficiary's use of HCBS services.

Advocates look forward to working with CMS as the agency develops guidance and procedures around this new provision. We expect that a number of technical issues will need to be resolved so that all eligible beneficiaries, most of whom will have no idea that they qualify for elimination of their co-pays, will get access to this important benefit.

11. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA-PD Plans (§ 423.154)

CMS notes in the preamble to the proposed rule that the copayment methodology will change for people receiving prescription drugs in a long-term care facility because of the implementation of the policy that certain prescription drugs be filled in seven-day doses, rather than 30-day or more doses. This policy is intended to reduce waste of prescription drugs. While we support this change in dispensing policy as a move towards reducing waste of prescription drugs, we believe that whatever co-payment methodology is implemented, it should be to the benefit of the beneficiary.

a. Different co-payments depending on the long-term care facility: The preamble (page 71208) suggests that co-payment methodologies for beneficiaries could differ within a plan, depending on the long-term care facility in which the beneficiaries reside. The proposed regulatory language at §423.154 is silent on this point.

We do not support CMS's analysis of this issue. Beneficiaries' co-payment obligations should not depend on their facility and the particular dispensing methodology it chooses. All beneficiaries in a Part D plan should have the same co-payment obligations. Beneficiaries use many factors, including co-payments, to choose Part D plans. Co-

payments will no longer be a meaningful factor for beneficiaries if the amount of the co-payment depends on the particular nursing facility where the beneficiary lives.

b. Calculation of co-payments: We also observe that the proposed regulations do not address whether the change from 30-day dispensing of drugs to seven-day dispensing will result in beneficiaries' being charged additional co-payments. We strongly oppose allowing beneficiaries to be charged additional co-payments as a result of seven-day dispensing rules. We recommend instead that CMS require a copayment methodology that is prorated based on the number of days a Part D drug was dispensed in a month. This would mean that any copayment would have to be charged at the end of the dispensing month. Beneficiaries should not be required to pay a copayment for a 30-day supply if they are not going to take a full 30-day dose of the medication. Just as Part D and long-term care facilities benefit from a reduction in wasted prescription drugs, so too should beneficiaries.

12. Complaint System for Medicare Advantage Organizations and PDPs (§§ 422.504 and 423.505)

The proposed regulations do not, and should, make clear what constitutes a "complaint." The regulations should also make clear that the filing of a complaint does not relieve a CMS caseworker of the obligation of simultaneously working to resolve the complaint; a beneficiary should not be left waiting for a medically necessary service until the complaint resolution process runs its course.

In addition to a model electronic complaint form on *Medicare.gov* and Medicare Beneficiary Ombudsman web sites, a paper form should be available in *Medicare & You*. And for complaints to be useful there should be specific information about how a beneficiary learns of the response to his or her complaint. Ideally, the beneficiary should see the resolution data or summary note.

In your proposals, you suggest and solicit comments on using a drop down checklist to document closure of complaints in lieu of free text descriptions. We oppose the use of a drop down checklist, unless it is used in conjunction with a mandatory free text description. A drop down checklist by itself encourages superficial and uninformative responses. There should also be a transparent procedure for documenting and addressing complaints that have been resolved but which result from a problem that should not have occurred.

13: Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans(§§ 423.128 and 423.562)

We thank CMS for its decision to utilize Section 3312 of the ACA, which requires each PDP to use a single, uniform exceptions and appeals process, to make improvements to that process. Beneficiaries must rely on exceptions and appeals to get access to medically necessary prescribed drugs, and, as CMS indicates, the current process has not worked well. We therefore include a number of comments in response to the questions

posed in the notice of proposed rulemaking and additional suggestions to make the process more user-friendly.

a. Creation of a standardized coverage and redetermination request form: We applaud CMS's amendment to § 423.128(b)7, which requires a uniform, standard request form for coverage determinations and redeterminations. CMS asks whether a standard request form is feasible. It is our experience that variation in plan forms, including drug-specific forms, is unnecessary and only makes accessing the exception and appeals process more difficult.

Regardless of the reason for the request, a beneficiary needs to provide the same information: Beneficiary's name and contact information, identification number (which should be available on the beneficiary's card), and name of the drug in question. We suggest that the form also ask for the name and phone number of the prescriber and provide the beneficiary with the opportunity to submit additional information.

Moreover, because coverage determinations are critical to obtaining access to needed medications, we urge CMS to translate these standard forms into many languages (we recommend the 15 languages used by the Social Security Administration) and require that plans make all such translated forms available on their websites. Since CMS is proposing to develop a non-plan specific form, it is appropriate that the agency, rather than plans, assume translation responsibilities for this relatively brief but absolutely essential document.

We propose 15 languages because CMS, unlike plans, is serving all 46 million Medicare beneficiaries. Because an appeals form is so important to the ability of beneficiaries to access their benefits, it is appropriate that CMS make this form available to all. We note that SSA translated the instructions for applications for the Low Income Subsidy into these 15 languages. The uniform appeals form is at least as important a document.

In order to ensure that beneficiaries have access to the standard form, a copy should be included in the Evidence of Coverage (EOC). The EOC should also inform beneficiaries how to access the form from the plan's web site.

Finally, we urge CMS to retain in the regulations the requirement that plans use a standard, rather than a model, request form, to ensure that the form is utilized by all plans and that the process is uniform. We ask that CMS provide an opportunity for all stake-holders to comment on the form at the earliest point possible in its development, as well as through the Paperwork Reduction Act process.

b. Electronic and telephonic coverage determination requests: We appreciate efforts to provide beneficiaries with an electronic option for coverage requests for those beneficiaries who are able to use such an option. We suggest that §423.128(b)(ii) be modified to require access to a *secure* Internet Web site. We also suggest that the regulation should clarify that plans must continue to provide paper-based options for

beneficiaries and not disadvantage beneficiaries who use the paper-based appeals process.

Given that formulary and tiering exceptions must include support from the prescriber, it is essential that the interface provides the prescriber with the ability to provide support electronically, including filing attachments. Allowing the beneficiary to make an electronic request but requiring hard-copy support from the prescriber would add confusion and delay to the appeals process, and would negate the benefit of filing an electronic request. In some instances, however, beneficiaries may file a request before the prescriber has the opportunity to put together the supporting documentation. Beneficiaries who file electronically should receive an identification number that the prescriber can use when submitting medical and other information at a later date.

Additionally, beneficiaries and prescribers should be provided with an email receipt documenting that the appeal was submitted. Moreover, at the conclusion of any submission to the plan through the interface beneficiaries and prescribers should be directed to a submission webpage that outlines the information submitted and is time stamped. The page should note that it is printable and that the beneficiary or doctor should print this information. Both the email and the submissions page should serve as evidence the plan received the coverage determination or redetermination request. Based on our experience with plans claiming they did not receive a coverage determination or redetermination request, we think the ability to print a receipt from the web site is a necessary beneficiary protection.

The proposed revision to § 423.128(d)(1), which requires plans to provide a toll-free telephone line for requesting coverage determinations and appeals, is another necessary improvement. We appreciate that CMS will develop model scripts for customer service representatives (CSRs) and ask that the model scripts be made available for stakeholder review and input before they are distributed. It is our experience that beneficiaries have received incomplete and inaccurate information from CSRs. In addition to developing model scripts, CMS should also promulgate and/or approve training materials for CSRs as well as monitor hotlines to ensure complete and accurate information is provided to beneficiaries. Plans should develop mechanisms to track calls to ensure compliance with relevant deadlines. If a beneficiary provides an email address the plan should send an email outlining the information submitted and the time of submission.

Finally, CMS should extend its authority and provide the same electronic and telephonic appeals options to those in MA-only plans.

c. Point of Sale (POS) plan-specific notices: We thank CMS for modifying §423.128(b) to require all plans to have a system that transmits codes to network pharmacies so that they can provide a written notice at the pharmacy counter explaining how to request a coverage determination.

One of the biggest problems for beneficiaries has been their failure to receive the information they need to understand that they have a right to request a coverage

determination and to understand the process for making such a request. Before encountering the coverage issue at the pharmacy, most beneficiaries are unaware of any restriction on their medication, including that a prescribed medicine is not on their plan's formulary. This confusion is compounded when the pharmacist is unable to explain adequately the reason coverage is not being provided and the steps the beneficiary must take to obtain coverage. Even if the pharmacist completely and fully explains the process the beneficiary leaves the pharmacy without a written reference.

The proposed change is a very important first step towards ensuring that beneficiaries get at least basic, generalized information about the coverage determination process. However, the information provided to the beneficiary will only be generic in nature, and really is not sufficient to protect the rights of beneficiaries, including those who are dually eligible for Medicare and Medicaid, to receipt of medically necessary prescriptions. To ensure that beneficiaries receive something more than generalized information about their right to request a coverage determination, we urge CMS to require that the notice provided at the point of sale include the beneficiary"s name, the plan name; the name of the drug; and the actual reason for denial – non-formulary, no prior authorization, the specific utilization requirement applicable to the drug – and alternative drugs where appropriate. The reason for the denial should be in clear, easy to understand terms, not simply an alpha-numeric or similar code. Having this information will allow beneficiaries to make informed decisions about whether to request a coverage determination. Moreover, if the beneficiary decides to request a coverage determination he or she can appropriately tailor the request.

Finally, any notice or form should provide culturally and linguistically appropriate notice. We ask also that CMS publish a draft POS notice for public comment.

d. Access to the drug compendia: We also ask that CMS extend its regulatory authority and make the drug compendia referenced in the Medicare Prescription Drug Benefit Manual, Chapter 6, § 10.6 publicly available. When coverage is denied because the plan asserts the medication is not prescribed for a medically accepted indication, beneficiaries face a challenge different from that of other appeals. To prevail in their effort to secure coverage, they must show that the usage for which they seek coverage, although "off label", is nonetheless approved in one or more of the drug compendia. These compendia are not publicly available, either through the Internet or through libraries, and subscriptions to obtain access are prohibitively expensive for Medicare beneficiaries, their families, their advocates, and often their providers.[2] Even where prescribers have access to the compendia, it is our experience that they do not have the time required to compile the information to provide to the beneficiary to pursue an appeal. Although the compendia are copyrighted material, *Veeck v. Southern Building Codes Congress*, 293 F.3d 791 (5th Cir, 2002) holds that copyrighted material can be made publicly available if incorporated into law, as the compendia have been incorporated.

[2] CMA Report: Medicare Coverage for Off-Label Drug Use (Sept. 19, 2010), available at: http://www.medicareadvocacy.org/InfoByTopic/PartDandPrescDrugs/10_09.16.OffLabelDrugCoverage.htm.

If CMS chooses not to make the compendia available, we ask CMS to include in the regulations a requirement that plans in their coverage determination and their redetermination decisions, and the Independent Review Entity in its reconsideration decisions, specifically state the compendia that they examined to determine whether the medication is included for the prescribed use and provide the beneficiary with copies of all relevant pages. Moreover, the relevant portions of the compendia should be made available to beneficiaries who make requests by calling 1-800-MEDICARE.

14. Including costs incurred by AIDS Drug Assistance Programs and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold (§§ 423.100; 423.464)

These proposed regulations implement ACA changes to treat individuals who receive assistance for AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service (IHS) similarly to individuals who receive assistance from State Pharmaceutical Assistance Programs (SPAPs), in that drugs paid for by ADAPs and HIS programs will count towards the incurred costs necessary to reach catastrophic drug coverage. We ask that the regulations be made effective on January 1, 2011 as the ACA requires. If the regulation becomes effective 60 days after publication of the final rule, as CMS proposes, beneficiaries who receive assistance from an ADAP or from the IHS will not benefit fully from the long-awaited statutory change.

15. Cost-sharing for Medicare-covered preventive services (§§ 417.101; 422.100)

We agree with CMS that the agency has authority to require all MA organizations to provide Medicare-covered preventive benefits at zero cost-sharing, consistent with ACA requirements for traditional Medicare, Medicaid, and private health insurance plans. Zero cost-sharing serves as an incentive for individuals to seek and obtain preventive care, thereby improving their health and the cost effectiveness of care provided under Medicare.

While we understand that some MA organizations may want to impose cost-sharing for preventive benefits obtained from non-network providers as an incentive to obtain such services in-network, we believe that MA organization should be required to eliminate cost-sharing for covered preventive services regardless of whether they are provided by an in-network or an out-of-network provider. In our opinion the incentive to obtain preventive care outweighs, in this situation, any incentive needed to utilize network providers.

17. Improvements to Medication Therapy Management Programs (§ 423.153)

New subsection 5 in §423.153 includes a new requirement for medication therapy management programs (MTMPs) to coordinate with nursing facilities' consultant pharmacists. This is an excellent proposal that we fully support.

Under the Nursing Home Reform Law, consultant pharmacists each month perform drug regimen review of all drugs taken by each resident. Drug regimen review is both more comprehensive than MTMP (because it covers all drugs, those covered by a resident's Part D plan as well as non-covered and over-the-counter drugs) and more frequent (because it occurs monthly, rather than quarterly).

Nevertheless, MTMP can play a critical role in reviewing residents' drug regimen. An area where MTMP could be most important is reviewing residents' use of antipsychotic drugs, a protected class of drugs under Part D.

In 2005 and 2008, the Food and Drug Administration issued Black Box warnings for antipsychotic drugs, both atypical and conventional, informing physicians that these drugs are life-threatening for people who have dementia but no diagnosis of psychosis.[3] Despite these federal warnings, many nursing home residents receive antipsychotic drugs. The most recent federal data (second calendar quarter 2010) indicate that, nationwide, 18.4% of residents receive antipsychotic drugs in the absence of psychosis or a related condition.[4] With approximately 1,600,000 residents living in nursing facilities, the 18.4% figure means that 294,400 nursing residents without a qualifying diagnosis are receiving antipsychotic drugs. These drugs are typically paid for by Part D plans.

Drug regimen review has not been effective in reducing residents' life-threatening use of antipsychotic drugs. Use of antipsychotic drugs, as chemical restraints, has increased as use of physical restraints has declined since the federal Nursing Home Reform Law became effective in 1990. Antipsychotic drugs, when used as restraints, are less visible than physical restraints. A second cause of the increased use of antipsychotic drugs is their off-label marketing by drug companies. In November 2009, Omnicare settled a False Claims Act with the United States, based on its consultant pharmacists' off-label promotion of the antipsychotic drug Risperdal for nursing home residents.[5]

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[3] FDA, "Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances" (April 5, 2005), http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm (atypical antipsychotics); FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," FDA Alert (June 16, 2008), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm (conventional antipsychotics).

[4] CMS, MDS Quality Measure/Quality Indicator Report, Psychotropic Drug Use (April-June 2010), http://www.cms.gov/MDSPubQIandResRep/02_qmreport.asp?isSubmitted=qm3&group=10&qtr=22, For residents at "high risk" (defined as those "who exhibit both cognitive impairment and behavior problems on the most recent assessment"), 39.3% receive antipsychotic drugs.

[5] U.S. Department of Justice, "Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay $112 Million to Settle False Claims Act Cases; U.S. Also Files Complaint Against Two Atlanta-Based Nursing Home Chains and Their Principals" (News Release, Nov. 3, 2009). Complaint of the United States , http://www.phillipsandcohen.com/CM/NewsSettlements/United%20States%20v%20%20Omnicare%20Mariner%20et%20al%20%20complaint.pdf; Department of Justice News Release, http://www.justice.gov/opa/pr/2009/November/09-civ-1186.html; United States Attorney for Massachusetts News Release, http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Nov2009/OmnicarePR.html.

We suggest that CMS direct MTMPs to address the issue of antipsychotic drug use for nursing facility residents. CMS should amend §423.153(d)(5) by adding a new sentence at the end:

> MTMPs must develop programs with consultant pharmacists to ensure that nursing facility residents do not receive drugs with Black Box warnings, including, but not limited to, antipsychotic drugs, and other inappropriate drugs.

CMS should provide guidance in how to develop and implement such programs. They could begin by developing computer-based programs to flag antipsychotic drugs carrying a Black Box warning that are ordered for nursing facility residents. This recommendation is based on a computerized drug warning program that has been successfully used in a Boston hospital to flag drugs meeting Beers criteria.[6]

18. Changes to Close the Part D Coverage Gap (§§ 423.104 and 423.884)

We welcome the proposal to codify new requirements in §423.104(d)(4) to implement the closing of the Part D coverage gap. We thank CMS for proposing to add new definitions for "applicable drug," "applicable beneficiary," and "coverage gap" for the Coverage Gap Discount Program. We suggest adding definitions for other terms, such as "generic drug." The term "generic drug" used in the Coverage Gap Discount Program includes medical supplies associated with the delivery of insulin and Part D compounds, and thus has a different meaning from its use in other contexts. We request that CMS make clear in the regulatory language that the term "negotiated price" used in the Coverage Gap Discount Program has a different meaning from the term as defined in §423.100. In §423.100, "negotiated price" includes dispensing fees, whereas in the Coverage Gap Discount Program, the "negotiated price" does not include dispensing fees.

Furthermore, we ask that the regulatory language define what is counted toward True Out-of-Pocket (TrOOP) when the manufacturer's discount is applied and when the "generic" gap cost-sharing is applied. Helping beneficiaries understand what is and is not counted toward TrOOP is crucial to help them plan ahead and know when they will reach catastrophic coverage.

20. Medicare Advantage Benchmark, Quality Bonus Payments and Rebate: (§§ 422.252; 422.258; 422.266)

a. Quality Bonus Payment Program: A quality bonus payment (QBP) program should be used to reward true quality of care and to provide incentives for MAOs to do a better job in caring for Medicare beneficiaries than many plans currently do. The ideal program should consider improvements in beneficiary access to care, beneficiary health status and health outcomes, prevention, care coordination, and management of chronic

[6] Melissa L.P. Mattison, Kevin A. Afonso, Long H. Ngo, Kenneth J. Mukamal, "Preventing Potentially Inappropriate Medication Use in Hospitalized Older Patients With a Computerized Provider Order Entry Warning System," Arch Intern Med/Vol. 170 (No. 15), Aug 9/23, 2010.

conditions. It should also consider whether appeals systems, customer service mechanisms, and beneficiary information comply with statutory and regulatory requirements and are use-friendly. It should utilize patient-reported outcomes and experience. Finally, an ideal QBP program should take into consideration how an MAO works with CMS and, where appropriate, other state and federal agencies, including whether an MAO meets deadlines for submitting or sharing information and/or has been subject to corrective action plans or sanctions.

A true QBP program should not be used, however, as a back-door mechanism for increasing payments to MAOs. We ask CMS to ensure that the QBP system it develops does not reward mediocrity or complacency. The ACA requires that plans attain a rating of four or five stars to receive the increased payments; those ratings should not be awarded lightly. Nor should star ratings be adjusted to ensure that every region of the country has a four or five star plan. Very good plans should have to work to continue receiving a high rating.

We urge CMS to develop the QBP, including the current nationwide demonstration program, in a fully transparent manner. All aspects of the demonstration and the subsequent QBP, such as information on the measures used to assess performance, and the methods used to weight, score, determine cut points, identify benchmarks, and all other details, are fully disclosed to the public. We also ask that CMS continue to include beneficiaries and their representatives in the conversations about QBP.

In terms of the proposed regulatory language, we believe that the proposed changes to §422.266, Beneficiary rebates, implement the ACA requirement of tying beneficiary rebates to quality ratings. The monthly rebates are used to provide additional benefits that may make a plan attractive to beneficiaries. Plans that provide only average care should not be able to entice beneficiaries to enroll through a wide array of extras when they do not a good job of providing required Medicare services. Receiving a higher rebate amount for a higher rating, and therefore having more leeway to offer the optional benefits that attract enrollees, should serve as another incentive to MAOs to improve quality.

b. Quality Working Group Advisory Panel: CMS notes in the preamble on page 71220 that it has established the Quality Working Group Advisory Panel to create a Medicare Advantage quality agenda. We commend this step and support ongoing efforts to improve the quality of care that MA plans provide to Medicare beneficiaries. We would also encourage CMS to establish a stakeholder group with outside organizations, including beneficiaries and their advocates, to provide input into the process of developing the quality agenda.

C. Clarification of Various Program Participation Requirements

This section of the notice of proposed rulemaking contains a number of important clarifications that will ensure MAOs and Part D sponsors are qualified to provide health and prescription drug coverage to Medicare beneficiaries; that providers will be paid

adequately; that only qualified individuals serve in management positions; and that compliance officers will be trained to oversee the day-to-day operation of compliance program.

We are particularly pleased with the proposed amendments that ensure that appropriate licensed professionals make medical decisions that affect plan enrollees. These are the proposed amendment to §423.4, to codify that a pharmacist must have a current, valid license to practice pharmacy, and the proposed amendments to §§422.562, 422.566, 423.562, and 423.566, to require that medical necessity decisions be reviewed by a currently-licensed physician or other health professional. The proposed regulations also would require, appropriately, that an MAO employ a medical director to ensure the clinical accuracy of all organization determinations and reconsiderations that involve medical necessity determinations. We hope that the requirements concerning medical necessity decisions will result in the need for fewer appeals.

D. Strengthening Beneficiary Protections

1.a. Agent and Broker and Training Requirements (§ 422.2274 and § 423.2274)

We support the proposal to require all MA and Part D agents and brokers to receive training and testing via CMS-endorsed or approved training programs. It is our experience that many agents and brokers are still unaware of or deliberately ignore the complexity of Medicare-related products. As a result beneficiaries receive bad information and purchase products that are inappropriate for them. For example, some beneficiaries with creditable retiree coverage are convinced by agents to enroll in a Part D plan, jeopardizing their retiree coverage; others are steered towards Medicare Advantage coverage that unnecessarily duplicates coverage that they already have. During this last enrollment period, we heard multiple stories of agents claiming that the Medigap N plan is the "same as" a Medicare Advantage plan. Providing uniform, standardized CMS-approved training should improve this situation. Training materials should be uniform and be graded by an outside and independent entity. The scope of training should be more than "minimal," and CMS should specify the materials that will be used on the annual testing. Topics should include how Medicare Parts C and D coordinate with other coverage (if at all) including Medicaid, the dangers of losing or unnecessarily duplicating existing coverage due to enrollment in a Part C or D plan, and eligibility for the Part D low-income subsidy and state-specific Medicaid programs, including Medicare Savings Programs.

We are open to using an RFP process to develop the training curriculum. However, regardless of whatever process CMS ultimately adopts, we urge that the process for developing the training curriculum be transparent and that the beneficiary advocacy community have the opportunity to review and provide input into the training materials to ensure accuracy and appropriateness. The curriculum and its development should not be considered proprietary, even if it is developed by a private contractor. Because benefits issues can be very complicated, it is important to have experts with varying perspectives, including those outside CMS, review the training. Even those who consider themselves

expert in the field may not know every relevant situation addressed in the training; even CMS's own beneficiary materials have occasionally contained substantive errors. Furthermore, we urge that all elements of the trainings, including written materials and sessions, be open and available to the public for review. This will help improve the quality of the trainings and ensure that all stakeholders understand what is and is not expected of agents and brokers. Finally, we ask that the regulations include a requirement that the training materials be updated at least annually to ensure that they are current.

1b. Extending Annual Training Requirements to All Agents and Brokers

We support the proposal to correct the error in previous regulations that applied training requirements only to independent agents and brokers. We agree that all agents and brokers, including those employed by MA and Part D plans, should be subject to the same training requirements.

2. Call Center and Web Site Requirements (§ 422.111 and §423.128)

We appreciate the decision to extend formally call center and internet web site requirements to MA plans.

We also appreciate that CMS is proposing to codify its subregulatory guidance requiring that plans provide interpreter services to beneficiaries in all languages. Such a requirement is necessary to effectuate the purposes of Title VI of the Civil Rights Act and to ensure that plan participants understand their benefits and can get access to needed services and medications. Like CMS, advocates have tested plan telephone interpreter services and found them frequently inadequate.[7] Enforceable regulations are an important step in improving compliance.

In addition to putting the requirement in the regulations, we ask that CMS provide plan sponsors with more specific sub-regulatory guidance that spells out in detail requirements and best practices expected of plans covering such areas as prevention of excessive wait times for callers in non-English languages, competence of interpreters, training of CSRs in how to work with interpreters, etc. See, for example, the best practices document prepared by advocates[8] as a guide for plans.

Finally, we recommend that CMS add a similar section codifying the requirement that plans make available on their websites translated materials. A review of plan websites from this fall revealed that many plans in the Miami and Los Angeles areas did not have

[7] See *Please Hold: Medicare Plans Leave Limited English Proficient Beneficiaries Waiting For Access* (2008) and *Medicare Prescription Drug Plans Fail Limited English Proficient Beneficiaries* (2007), both available at www.nsclc.org .

[8] *Best Practices: Serving Limited-English Proficient Medicare Part D Beneficiaries* (2007), available at www.nsclc.org . In 2007, CMS distributed a memo to plans that summarized this document and included a reference to it. We propose, however, that, in addition to a one-time transmittal, CMS include language access best practices in its Prescription Drug Benefit Manual and Managed Care Manual and also continue its monitoring and enforcement of language access requirements.

Spanish versions of important documents (for example, Formulary, Summary of Benefits and Evidence of Coverage). See comments below regarding translation requirements.

3. Require Plan Sponsors to Contact Beneficiaries to Explain Enrollment by Agents and Brokers (§§ 422.2268, 422.2272, 422.2274, 422.2276, 423.2268, 423.2272, 423.2274, 423.2276)

We support the proposal to require plans to terminate agents upon discovery that they were unlicensed and to notify affected beneficiaries and inform them of their rights. We are pleased that CMS is taking this step in reaction to recent audits and investigations showing that plans were not informing beneficiaries that the agents who enrolled them were unlicensed. We also suggest, if CMS finds plans continuing to fail to comply with these rules, that CMS sanction the plans. We applaud CMS for including this regulation but are unclear how the plan knows when and if this has happened. Applications should therefore be required to contain the Agent or Broker's name and license number, as well as their National Insurance Producer Registry (NIPR) number when selling MA and Part D products. Linking an NIPR number on every MA and Part D enrollment done by a broker would make it easier to identify bad actors and to assist affected beneficiaries. Unlicensed agents found to have sold Medicare products in contravention of Medicare marketing rules should be prohibited from selling any further Medicare products. Finally, the process for following up with affected enrollees must include adequate safeguards, including a prohibition against steering beneficiaries towards other products offered by the same plan sponsor if a beneficiary wishes to make a plan change.

4. Customized Enrollee Data (§§ 422.111 and 423.128):

We support the intent to provide beneficiaries with more personalized information on out-of-pocket costs when they are deciding whether to stay in their current Medicare Advantage plan or switch to a new plan or original Medicare. However, we believe that without more research, this information could be misleading or confusing to beneficiaries rather than helpful.

If plans use data for the period of January through July, we are concerned that beneficiaries may not understand that the estimate is only based on the services they received during a portion of the current year. Beneficiaries may not understand that the costs are not for services for the entire year, which could be higher, particularly if they receive most of their health care services in the last part of the year. Also, the health care costs would be different during the next year if their health status changes and they require more or fewer health services. It is possible that beneficiaries will rely only on the estimate when making a decision to remain in a plan, rather than look at the information contained in the Annual Notice of Change, which will provide them with a fuller understanding of which costs are increasing.

Before CMS begins a pilot program, we believe that more research should be conducted to determine what information is useful to beneficiaries and what formats are easiest for them to fully understand. It is vital that the information provided actually help

beneficiaries make informed decisions. Once this research has been conducted, we would support a small pilot to test models, as long as such notices contain clear, unambiguous language explaining that the information provided is only an estimate based on services used for only part of the year and that out of pocket costs will be different if they use more or different services during the next year. Any language used to explain these caveats should be developed in conjunction with beneficiaries and beneficiary advocates. Of the three examples provided on page 71232, none is ideal. Table 7 provides the most helpful information with respect to services covered. However, this estimate should also include premiums for the year. It is necessary to include the cost of premiums to provide the beneficiary with a full picture of what his or her out of pocket expenses would be under the same plan in the following year.

Another option would be to require plans to use a minimum of 12 months of utilization data to make an estimate of costs for the following plan year. This would mean that the beneficiary would have been enrolled in a plan for two or more contract years. For example, for contract year 2012, the plan would provide an estimate for 2012 out of pocket expenses based on data from July 1, 2010 to June 30, 2011. The utilization pattern for this period could be used to provide an estimate of expenses for 2012. CMS should study the feasibility of this option and whether it provides a more reliable estimate since it will include a full year of utilization data. It may not be possible to use this data to make a comparison from the current plan year to the next plan year, since it would include utilization from a previous contract year. But, it might help provide a clearer picture of utilization patterns that could be used to develop an estimate based on the next plan year's cost structure.

CMS should also research models in which information from the ANOC is incorporated into the estimate. For example, the notice might say: "During 2011 you paid $500.00 for home health services, next year, if you use the same amount of home health care, you will pay $750.00. To learn more about the increase in cost sharing for home health care, see page 27 of your Annual Notice of Change.

CMS also requests comments on the usefulness of MA plans providing beneficiaries with periodic Explanation of Benefits (EOBs). We support requiring MA plans to provide beneficiaries with EOBs. Part D plans currently provide EOBs on a monthly basis. A monthly MA EOB would be a valuable tool for beneficiaries. This not only allows the beneficiary to monitor his or her out of pocket costs, but also allows the beneficiary to track the health care services he or she is receiving. The EOBs can also be used to enter information into Medicare Options Compare to get an estimate of out of pocket expenses based on services received during the current year. It is also a potential fraud detection tool, allowing a beneficiary to monitor whether his or her insurance company has been billed for services not received.

5. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§422.100 and §422.101)

We support the proposal to extend the mandatory MOOP and catastrophic limit requirements that apply to all local MA plans to Regional PPOs. We agree that doing so will make it easier for beneficiaries to understand and compare MA plans.

6. Prohibition on Use of Tiered Cost Sharing by MA Organizations (§422.262)

We support the proposed revision to 42 CFR §422.262 stipulating that MA organizations cannot vary the level of cost sharing for basic or supplemental benefits for any reason, including based on provider groups, hospital network, or the beneficiary's utilization of services. We agree that differential or tiered cost sharing based upon these factors is not transparent and can be deceptive and misleading in terms of cost to the beneficiary. In our experience, many beneficiaries sign up for MA plans, in part, due to the existence and predictability of set cost sharing amounts charged by their plan; tiered cost sharing, which is often hidden or difficult to ascertain, thwarts this purpose.

7. Delivery of Adverse Coverage Determinations (§423.568)

We appreciate the proposed amendment to allow Part D sponsors to provide notice of an adverse coverage determination orally, provided that they send a written follow-up notice within three calendar days. We are concerned, however, that the intent of the provision – to provide beneficiaries with information as soon as possible – will be diminished if beneficiaries must wait to receive the written notice to learn the reason for the denial and their appeal rights. Indeed, beneficiaries may be worse off if it takes longer for them to receive this information than current regulations allow.

We therefore ask CMS to add the following sentence to the proposed regulation:

> Oral notice must include the reason for the denial and information about how to request a redetermination.

We also ask CMS to issue guidance to plans to explain the information that is required and to develop model scripts for plans to utilize when making these phone calls.

8. Extension of Grace Period for Good Cause and Reinstatement (§§422.74 and 423.74)

We thank CMS for including these provisions. However, CMS states in its description that it would not expect a plan to find good cause in instance where an individual's legal guardian or authorized representative was responsible for making premium payments but failed to do so in a timely manner. Although we understand the thinking behind such a statement, there needs to be a good cause exception for actions or inactions by a legal guardian or authorized representative. For example, there should be an exception for when the statement is sent to an incorrect address. Also, unfortunately, as advocates for older people and people with disabilities, we are aware of occasions when a legal

guardian or authorized representative does not act in the best interest of the ward or incapacitated individual. A Medicare beneficiary should not lose the opportunity to seek a good cause exception and reinstatement when payment has not been made due to malfeasance or misfeasance by a legal representative.

9. Translated Marketing Materials (§§ 422.2264 and 423.2264)

We appreciate the intent of CMS to clarify the requirements that plans translate vital documents by adding regulations to current sub-regulatory guidance. We strongly object, however, to the content of the proposed regulation, most specifically, to the absence of any numerical threshold triggering translation obligations. We believe that the proposed regulation, which mirrors the current sub-regulatory guidance, sets the bar for plans far too low and, in doing so, fails to effectuate the requirements of Title VI. It also is inconsistent with interpretations of Title VI found in Department of Justice and Health and Human Services Department guidance,[9] and with recent interim final regulations published by HHS.[10]

Our specific concern is that the 10 percent threshold, without any numerical floor, is insufficient. As a practical matter, the 10 percent threshold means that, except for MA plans serving small benefit service areas (e.g., a plan serving San Francisco county, which has over 10 percent Chinese speakers), the only translation requirement on any plan will be Spanish. Such an outcome violates the Title VI rights of hundreds of thousands of other limited-English proficient beneficiaries.

In setting translation obligations for marketing materials, we urge CMS to weigh more thoroughly the factors in the HHS guidance concerning Title VI compliance in order to develop a standard that is more consistent with the goals of Title VI and with the needs of limited-English proficient beneficiaries. See particularly the four factor analysis at 68 Fed. Reg. at 47314-47316.

In that review, we propose that CMS change the current threshold to 5 percent rather than 10 percent and add a numerical minimum. Using 5 percent is consistent with Department of Justice and Health and Human Services Department guidance,[11] both of which provide a safe harbor of 1,000 persons or 5 percent of population served or likely to be encountered, whichever is lower.

Setting a numerical minimum is critical to protecting Title VI rights and preventing anomalies across regions. The numerical threshold is necessary to ensure that significant concentrations of LEP beneficiaries living in large, ethnically diverse areas can receive

[9] The DOJ guidance is found at 66 Fed. Reg. 5398 (Jan. 18, 2001); the HHS guidance is at 68 Fed. Reg. 47311, 47319 (Aug. 8, 2003). Both can be accessed at www.lep.gov .

[10] Interim Final Rules For Group Health Plans And Health Insurance Issuers Relating To Internal Claims And Appeals And External Review Processes Under The Patient Protection And Affordable Care Act, 75 Fed. Reg. 43330, 43337 (July 23, 2010).

[11] The DOJ guidance is found at 656 Fed. Reg. 50123 (aug. 16, 2000); the HHS guidance is at 68 Fed. Reg. 47311, 47319 (Aug. 8, 2003). Both can be accessed at www.lep.gov .

materials. To the extent that the current policy works at all, it imposes obligations primarily on Medicare Advantage plans operating in small PBP service areas with concentrations of particular ethnic minority groups. For example, under the current standard, despite the fact that nearly 200,000 people in Los Angeles County identify Tagalog as their primary language, plans in Los Angeles County are not required to translate materials into Tagalog since that language represents only two percent of the county's large and ethnically diverse population. Conversely, plans are required to translate materials into German in McIntosh County, North Dakota where 35 percent of the population (1,145 individuals) identify German as their primary language.

In setting a numerical minimum, we urge CMS also to also consider the recent HHS interim final rule governing certain translation obligations for non-Medicare health plans. See 75 Fed. Reg. at 43337. That interim rule uses plan participation at the start of the plan year as the measure. For a plan that covers 100 or more participants at the beginning of a plan year, the threshold is the lesser of 500 participants, or 10 percent of all plan participants.[12] For a plan that covers fewer than 100 participants at the beginning of a plan year, the threshold is 25 percent of all plan participants being literate only in the same non-English language. We believe it is critically important that language access requirements for Medicare beneficiaries be at least as comprehensive. It would be particularly unfair for individuals to find that once they qualify for Medicare, they get less access to translated materials than they had in the non-Medicare market.

We propose that CMS consider a standard that would combine elements of the DOJ and HHS guidance and the Interim Final Rule. Specifically, we would propose requiring translated marketing materials in any language that either is spoken by more than 5 percent of the general population in a plan benefit package service area or is spoken by more than 500 members of the plan, measured at the beginning of the plan year.[13] To determine compliance with the second prong of this test, plans would be required to ask all new members their preferred language and to maintain and compile such data.

Note that to the extent that CMS uses percentages to establish translation obligations, we support the agency's proposal to use percentage of the entire population in the service area. We were pleased to see the development by CMS of the HPMS Marketing Material Language Lookup, which gives plans a clear roadmap for determining their obligations under the current guidance. We believe that it is important to direct plans to use very specific demographic data so that plans can easily understand their translation obligations and to facilitate enforcement. If, over time, better data become available that are specific to Medicare populations, it would then be appropriate for CMS to revisit the question of whether another data set might be more appropriate.

[12]The HHS regulation encompasses individuals " literate only in the same non-English language," a term found in Department of Labor regulations. However, subregulatory guidance defines that term as covering individuals who do not speak English "very well," the same measure used by CMS.

[13] If a plan were new to a service area, it would be necessary to make some projections based on membership in other plans offered by the same sponsor or on service area averages. These details could be addressed in guidance.

We would like to repeat our request that the module be made public so that beneficiaries and advocates can see which plans are required to translate materials into which languages.

In addition to percentage and numerical thresholds, we also urge CMS to require that any plan sponsor that markets to individuals in languages other than English must provide the enrollment package documents to prospective members in the language in which the marketing took place. Thus, for example, if a plan advertises on radio or in magazines in a non-English language or if plan representatives hold marketing events in a non-English language, then the plan must provide all enrollment materials in that language. This requirement should apply whether or not the language meets thresholds. If a plan sponsor makes the business decision to market in a non-English language, it is a simple matter of consumer protection that the sponsor should be required to provide all information that CMS considers essential to an informed consumer choice in the language in which the sponsor has chosen to market. The need for these protections is manifest. Advocates report repeated instances in which limited-English proficient beneficiaries were sold plans in their own language, often with representations that proved untrue, and were then asked to sign English-only documents that they did not understand. It is of critical importance that these individuals can get not just slick marketing mailers and high pressure sales pitches, but also vital plan documents that tell them precisely what plan benefit packages include, what their rights are and how to access benefits.[14]

We recognize that the enhanced translation requirements we propose impose some burden on plan sponsors. Nevertheless, those burdens are not excessive. Most plan sponsors are large national organizations with billions of dollars in revenue. Even smaller MA plans have multi-million dollar budgets. Many already comply with translation requirements imposed by states. In California, for example, all managed care plans are subject to "threshold language" requirements that are more stringent than proposed by CMS, even absent Title VI requirements. See CA Health & Safety Code Sec. 1367.04. Moreover, because CMS is increasingly relying on standardized model marketing materials, it would be possible for CMS to itself translate some of these documents and/or provide opportunities for pooling of resources by plan sponsors to avoid duplication of costs.

[14] A similar consumer protection requirement related to voluntary marketing efforts appears in the food labeling regulations of the Food and Drug Administration. FDA requires that all mandatory information on a food label appear in English. If, in addition, a food manufacturer chooses to put information or statements in a non-English language on its labels, the manufacturer must include all FDA required information in that language as well. See 21 C.F.R. Sec. 101.15(c)(2) ("If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.").

E. Strengthening CMS Ability to Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and to Remove Consistently Poor Performers

We thank CMS for its increased focus on enforcement and sanctions. The Part C and Part D programs are made stronger by increased oversight and diligence to program compliance. MAOs and Part D sponsors are more likely to comply with program requirements, thereby improving the quality of care beneficiaries receive. The Medicare program, including the Medicare trust fund, will be strengthened if consistently poor performers are not rewarded with contracts.

1. Expand Network Adequacy Requirements to Additional MA Plan Types (§ 422.112)

We support CMS' goal of ensuring that any MA plan that meets Medicare access and availability requirements through directly contract with network providers does so consistent with current regulatory requirements. We believe, though, that CMS should revisit whether any MA plans should be allowed to operate without establishing an adequate provider network. While consumer advocates have less experience with MSAs due to their relative dearth, we have extensive experience with the problems inherent to non-network PFFS plans. Over the last several years, many beneficiaries have enrolled in PFFS plans only to find that no or very few providers in their area agree to accept the terms and conditions of such plans. We appreciate that part of the goal of §162 of the Medicare Improvements for Patients and Providers Act (MIPPA), which requires PFFS plans offered in "network" areas with at least two local coordinated MA plans to establish their own provider network, was to require more PFFS plans to establish networks upon which enrollees can rely for access to providers. We believe that this rule now in effect is certainly improving access to providers for PFFS enrollees in network areas. PFFS plans offered in non-network areas, though, are still able to operate under the old rules, which still foster potential access to care problems if providers do not agree to accept a plan. With both non-network PFFS plans and MSAs, there is still the potential that no or few providers in a given service area will accept the plan and/or agree to treat an enrollee We believe that minimum access standards, in the form of an adequate network of providers, should apply to all types of MA plans, including MSAs and non-network area PFFS plans.

3. Release of Part C and Part D payment data

CMS should take steps immediately to release Part C and Part D summary payment data for research, analysis, and public information functions. Release of such data comports with the increased focus on transparency of government policies and payments and helps promote accountability.

The payment data are needed to allow researchers the opportunity to provide an independent and impartial analysis of payment policies and the effect they have on the Part C and Part D programs, particularly as payment policies come under greater scrutiny in the current economic environment. Beneficiary advocates need the information to help

in their analysis of the current Part C and Part D programs and in analysis of future, anticipated payment reform proposals that may limit or otherwise reduce the current Medicare program.

Since CMS is proposing the release of summary data only, we anticipate that the data will not be released in a manner or format that allows for disclosure of personal health information. Similarly, we fail to see how the data CMS intends to release will be proprietary in nature. Again, the summary nature of the data should make it difficult to attribute the data to a particular plan. Also, the data that will be released will not be for the current year. Given changes in payment structures, benefit packages, and other plan requirements, the data should not have implications for future competitive bidding processes.

CMS discusses the release of data in the preamble to the regulations but does not include any regulatory requirement. We urge CMS to put the release of summary payment data into a regulation to ensure that researchers and beneficiary advocates will have access to the information in future years.

4. Payment for Multi-Ingredient Drug Compounds (§ 423.129(d)

The proposed rules have the potential to increase substantially beneficiary cost-sharing for drug compounds. CMS proposes that beneficiaries be charged a co-payment corresponding to the tier of the most expensive Part D ingredient for all Part D ingredients of the compound. Additionally, the proposed rule allows pharmacies to balance bill for the cost of non-Part D covered ingredients.

We are very concerned that the proposed ruled will create an access problem for beneficiaries, either because they will not be able to pay when balanced billed or they will not be able to get the medications because pharmacists will stop providing them if components of the compound are not paid for.

We urge CMS to reconsider these proposed changes and not to adopt a policy that will create access problems for beneficiaries.

Section F—Other Clarifications and Technical Changes

2. Cost Plan Enrollment Mechanisms (§ 417.430)

We are supportive of including electronic enrollment methods for cost-plans. As more and more people with Medicare have access to electronic forms of communication, many prefer to take enrollment actions electronically. We advise CMS also to also keep in place the traditional paper application format, to meet the needs of those people who do not have access to or do not chose to use electronic means of communication.

With regard to notice delivery options, we would again caution that traditional mailing should be required by plans unless they are explicitly and proactively informed by beneficiaries that they would prefer electronic communications only. Forcing people to

receive information electronically may result in people missing important information if they do not use electronic means of communication.

4. Part D Transition Requirements (§ 423.120)

Long term care pharmacies are required to provide written notice within three days of a temporary fill of medication. CMS proposes to require only one written notice to be sent to the beneficiary in the case of multiple seven day or less prescription fills in order to purportedly alleviate confusion among beneficiaries upon receiving multiple notices containing essentially the same information about repeated seven day or shorter fills. Our main concern is to assure that beneficiaries receive clear, timely information to allow them to make necessary decisions regarding their health and well-being. We understand that receiving multiple notices in a short period of time about the same thing can be confusing to some beneficiaries. As such, we believe that one notice is sufficient at the start of a period of multiple short-term fills; however, prior to conclusion of the transition period we urge sending another notice to clarify how many seven day or shorter fills were made. All such notices must clearly and with specificity state that the information conveyed applies to multiple fills of the exact same medication in the initial 90 day period as well as the actions beneficiaries and long term care facilities must take to assure future access to needed medications needed beyond the transition period.

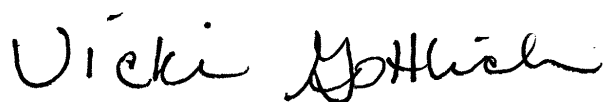
5. Revision to Limitation on Charges to Enrollees for Emergency Department Services (§ 422.113)

We have been concerned about plans passing costs on to beneficiaries who are seeking emergent or urgently needed care. While we recognize that the $50 limit on out-of-pocket costs for Emergency Room services is several years old and not necessarily in line with the increasing costs of emergency services, this charge is in line with the charges imposed by commercial health insurance plans and appears to be sufficient to deter unwarranted Emergency Room visits by people with Medicare who elect to receive their Medicare through Medicare Advantage.

We would accordingly caution CMS that beneficiaries' financial responsibility must be limited to enable Medicare beneficiaries to continue to appropriately access the emergency services they need, so they do not defer needed care due to high co-payment rates.

The undersigned organizations thank you for the opportunity to submit comments on the 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.

Sincerely,



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On behalf of:

Alzheimer's Association
California Health Advocates
Community Legal Services (Philadelphia)
Empire Justice Center
Families USA
Florida Legal Services
Legal Services for the Elderly (Maine)
Medicare Advocacy Project of Greater Boston Legal Services on behalf of its eligible clients
Medicare Rights Center
National Academy of Elder Law Attorneys
National Committee to Preserve Social Security and Medicare
National Senior Citizens Law Center
Northwest Health Law Advocates