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July 15, 2008

Centers for Medicare & Medicaid Services
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Submitted Electronically: <http://www.regulations.gov>

RE: 73 Federal Register 28556 (May 16, 2008)

To Whom It May Concern:

California Health Advocates (CHA) submits comments to the proposed rules concerning the Medicare Advantage and Prescription Drug Benefit Programs referenced above. CHA is a non-profit organization dedicated to education and advocacy on behalf of Medicare beneficiaries in California. We work closely with the Health Insurance Counseling and Advocacy Program (HICAP), California's State Health Insurance Assistance Program (SHIP). We thank you for the opportunity to submit these comments.

Summary

The proposed regulations address some of the problems encountered by our clients and the clients of the advocates with whom we work, including:

- Eligibility, enrollment and care coordination in special needs plans (SNP).
- Elimination of the default auto-enrollment into Part D plans of dual eligible individuals with qualifying retiree health benefits.
- Calculation and assessment of the late enrollment penalty.
- Revisions to the definitions of incurred cost, negotiated prices, actually paid and administrative costs to ensure that beneficiaries do not pay inflated prices for their prescriptions.
- Limiting co-payments to the Part D negotiated price.
- Clarifications of the best available evidence (BAE) and other policies related to the low-income subsidy.

- Protections when premiums have not been paid by withdrawal from Social Security benefits as requested.
- Allowing treating physicians and, in Part D cases, other prescribers to file appeal requests.
- Increased civil money penalties.
- Codification of provisions of the marketing guidelines.

As indicated in more detail below, we support many of the CMS recommendations in these areas and include additional recommendations where we believe that the proposed rules do not go far enough to protect Medicare beneficiaries. We also request changes to two other regulatory provisions, one concerning special enrollment periods and one concerning Part C reconsiderations, that reflect the needs of our clients and that are in line with the general intent of the proposed regulations.

We are concerned, however, that some of the proposed rules either conflict with the Medicare statute or weaken existing beneficiary protections. In particular, we submit more detailed comments objecting to provisions concerning:

- Passive enrollment of plan enrollees into a new Medicare Advantage plan when the contract with their current plan is immediately terminated.
- Reduction in the timeline for notifying plan enrollees of non-renewal of a Medicare Advantage or drug plan contract.
- The implication that a drug plan's obligation to reduce cost sharing and premiums of low-income subsidy eligible individuals is contingent upon receipt of information from CMS or best available evidence (BAE).

Finally, these comments are being submitted after Congress approved H.R. 6331, The Medicare Improvement for Patients and Providers Act of 2008, but prior to this bill becoming law. We assume, of course, that should this bill become law, CMS will revise these Proposed Rules in accordance with the statutory language addressing many of the issues raised by the NPRM.

A. Proposed Changes to Part 422 – Medicare Advantage Program
§ 422.4. Types of MA plans.

We believe that enrollment in Special Needs Plans (SNPs) should be limited to the special populations the SNPs have chosen to serve. We urge CMS to go further than its current proposal and discontinue in its entirety its policy permitting disproportionate SNPs. To avoid hardship, existing non-special needs individuals can be grandfathered in.

As CMS notes in its preamble comments, its current policy concerning disproportionate enrollment dilutes the intended focus of SNPs on meeting the special needs of the population for which they were created (p. 28558). While the proposed policy regarding enrollment caps for non-special needs individuals is a significant improvement over

current policy, there is no justification for disproportionate SNPs at all. If a plan is created to serve a special population, it should organize all its resources to do just that.

The practical negative impact of CMS' current policies is most evident with SNPs designed to serve dual eligibles. Over 70% of SNP members are enrolled in dual-eligible SNPs, plans that have as their primary asserted advantage the coordination of Medicare and Medicaid benefits, providing more transparency, simplicity and comprehensive access for dual eligibles. When such SNPs are disproportionate SNPs, however, the opportunity to realize these potential benefits is significantly eroded. Plan documents must reflect both dual and non-dual payment levels, billing processes for duals and non-duals differ, and potential for coordination with states is limited because not all SNP members are on Medicaid rolls. The result is a plan that is confusing for providers and beneficiaries, negating the promise of seamless and simplified integrated health benefits.

Whatever small benefit there may be for the occasional non-qualifying family member who wishes to join a SNP is offset by the much greater disadvantages of having disproportionate SNPs at all. If CMS can justify specific exceptions to an "exclusive" enrollment policy, it could identify these in regulation or guidance. For example, provisions already exist for individuals who lose dual eligibility status but who expect to regain that status. Use of targeted guidance is far preferable to creating a flat "10% of your enrollment can be people who don't meet the special needs definition" policy. Even the 5% threshold proposed by MedPAC, though an improvement, is unnecessary. The statute authorizes disproportionate enrollment; it does not require it.

b. Ensuring Eligibility to Elect an MA Plan for Special Needs Individuals (§ 422.52, § 422.107(a)(1))

We support the general requirement in § 422.52 that SNPs have a process for verifying Medicaid eligibility or special needs status of an individual prior to enrollment in the SNP. It is important, however, that the process for verifying eligibility not place the burden of proving eligibility on the beneficiary and not substitute the judgment of the plan for the judgment of a physician.

Dual Eligible Special Needs Plans (D-SNPs). § 422.52 requires plans to have a process for verifying Medicaid eligibility. Details about this process are provided in § 422.107(a)(1) which requires plans to have a documented relationship with States in which they operate that allows them to verify eligibility for Medicaid and Medicare.

We support the regulation requiring SNPs to have a process for obtaining Medicaid eligibility information from States. Whether enrolling in a SNP or seeking access to the Low Income Subsidy (LIS), dual eligible beneficiaries should not bear the burden of proving their dual eligibility. Requiring SNPs to communicate directly with States will relieve beneficiaries of the burden of proving eligibility and will provide an important safety net in those cases where CMS systems do not yet reflect accurate Medicaid eligibility information.

We urge CMS to extend a similar requirement to all plans that offer prescription drug coverage or, at a minimum, all benchmark plans. Having such a process in place would allow plans to work directly with States to confirm LIS eligibility of enrollees without requiring beneficiaries to provide Best Available Evidence (BAE) or to wait for information to work its way from States to CMS to plans. The burden placed on sponsors and States by extending these requirements to all prescription drug plans would be minimal. Companies that sponsor both SNPs and other plans that provide prescription drug coverage would already be required to have these processes in place and once States established processes with SNP sponsors, it does not seem unreasonable to request that they expand that process to include additional sponsors.

While we support and urge the extension of this requirement, we do not believe that the plan-to-State process should replace plan-to-CMS information sharing. The statute requires the Secretary to deem dual eligibles as qualified for the Low Income Subsidy. In fulfillment of this obligation, CMS already collects information about Medicaid status, including institutional status, from States. CMS should continue to work to improve the accuracy of this data and should require plans to consult CMS systems before contacting States.

We do have concerns about privacy and marketing issues that could arise as a result of § 422.107(a)(1). It is crucial that plans and States do not develop arrangements that allow or require States to provide lists of dual eligibles to plans. This would violate the privacy of dual eligibles and make them a target of plan marketing. A State should only be permitted to share information with a plan about an individual who has submitted an enrollment request to or is already enrolled in that plan.

Finally, we note that the preamble claims that SNPs will be required to have a dual eligibility verification arrangement and information sharing on Medicaid providers and benefits immediately. The text of § 422.107(b), however, provides current SNPs three years to comply. There is no timeframe set for new SNPs.

See additional comments on § 422.107 below.

Chronic Condition SNPs. We do not believe that the approach suggested by CMS in the preamble, that plans develop a pre-enrollment qualification assessment tool, will be effective to prevent the improper enrollment into chronic condition SNPs that our clients continue to experience. Instead, we believe chronic condition SNP eligibility should be verified by reference to clinical criteria and that verification can likely only be obtained from a treating physician. Accordingly, if a treating physician is not willing to provide the verification, we do not believe enrollment should be completed.

If CMS decides to allow enrollment in a chronic condition SNP without physician verification, we believe that the intent to enroll should be verified with prospective members to ensure that they understand the consequences of enrolling into a chronic condition SNP, particularly when their treating physicians appear unwilling or unable to provide clinical verification of diagnosis of the requisite chronic condition.

c. Model of Care (§ 422.101(f))

We have been urging CMS to adopt regulations including specific requirements for SNPs for several years and we are pleased to see that what has heretofore appeared only in the Call Letters – for 2008 and 2009 – is now proposed for regulations. We are, however, puzzled by the vague and random content which, in our view, reflects CMS' lack of willingness to provide genuine oversight of SNPs.

The proposed regulation creates no real requirements for a model of care. The fact that many SNPs are profit-oriented managed care entities, with consequent incentives for minimizing provision of costly services, combined with the fact that the beneficiaries of SNPs are particularly vulnerable individuals by definition, makes it imperative that CMS act responsibly to regulate their activities. We urge CMS to develop a mandatory model of care for each SNP. The models of care should be based on the information CMS has gathered from PACE programs and state integrated care waiver demonstrations as to the most effective practices. At a minimum, the mandatory model of care should address the following elements:

Care Coordination

Care coordination must be an essential element of all SNPs for all SNP beneficiaries and should be readily available upon an enrollee's request or a determination by another source of the need for same. SNPs should be required to coordinate the care of enrollees in accordance with the care plans developed for each consumer or the evolving needs of the enrollee as presented to the SNP. Denials of care coordination must be appealable.

Network

SNPs must ensure that their provider networks meet the specific needs of their enrollees with respect to specialists, geographic spread, transportation needs, language and cultural access and access for people with disabilities. The networks of SNPs serving dual eligibles must comprise health care providers who accept Medicaid.

SNPs must ensure that all network hospitals have at least one network doctor and provider affiliated with the hospital to provide diagnostic and other ancillary services and that those providers deliver the ancillary services to enrollees.

SNPs enrolling dually-eligible beneficiaries must ensure that their network providers bill Medicaid for any beneficiary cost-sharing for a dually eligible enrollee or forgo cost-sharing for that enrollee. Cost-sharing could only be charged to the beneficiary to the extent that the state imposes cost-sharing under Medicaid on that beneficiary.

Additional benefit design requirements

SNPs must design their benefit package to offer supplemental health benefits that include care planning and benefit coordination. Additional supplemental health services must be relevant to the target population.

Supplemental health services offered to dual eligibles must augment and not frustrate access to services already covered through their Medicaid program. The benefit design for dual eligibles should ensure that dual eligible enrollees do not pay more in cost-sharing than they would under their Medicaid program.

Continuity of Care/Transition

SNPs must provide for continuity of care, including allowing for transition coverage of non-network providers, services and prescriptions for new enrollees and for enrollees entering a new plan year when a previously in-network provider is no longer in the network or when a previously covered service or prescription the enrollee requires has been removed from the benefit package.

Transition coverage must be provided for either six months or two visits to any given provider after the effective date of coverage, or the time necessary to complete a specific course of treatment.

Initial Assessment and Development of Care Plan

SNPs must, within a short period after the individual's enrollment, conduct an initial assessment of the individual's medical and social service needs and develop a care plan. If the individual does not want such an assessment, the SNP must document efforts it made to discuss same with the individual.

Copies of the assessment and care plan should be provided to the enrollee and to her primary care physician. The care plan is updated as needed and always after a change in the enrollee's situation.

Reporting requirements

CMS should require reporting by SNPs that enables them to determine whether the services they are paying for are actually being delivered to beneficiaries. This would include encounter data on the types and numbers of services delivered, and this information should be made public so that beneficiaries can use it in selecting a SNP for enrollment.

Complaint process

To aid in monitoring, as well as to assist beneficiaries who are not receiving promised services, CMS should institute an effective complaint process for beneficiaries. Complaints should be investigated and also used in CMS monitoring activities and reports.

Dual Eligible SNPs

Dual eligible SNPs should be regulated in the following ways:

They should be required to clearly inform their enrollees and their providers that beneficiaries are entitled to full coverage of both Medicaid and Medicare services. D-SNPs with State contracts to provide full Medicaid coverage must automatically consider entitlement for a particular service under the second program when they have found that

an enrollee does not meet coverage standards for that service under the first program. D-SNPs without such State contracts must have staff well trained in the Medicaid program of the state in which they operate.

The CMS regulations should clearly specify the notice and appeal process that applies to beneficiaries of SNPs. This has been a source of confusion to at least some states.

Finally, plans must be required to make their model of care available to prospective members as part of marketing materials, and to members, their physicians and other specialized providers, as well as to the general public.

d. Dual Eligible SNPs and Arrangements With States (§ 422.107)

CMS states in its proposed § 422.107(b) that currently operating SNPs must be in compliance with its proposed requirement for arrangement with the state within three years of the effective date of the rule. We believe that the proposal both requires too little and promotes too much.

Immediate Need for Coordination of Benefits

The proposal requires too little. Allowing SNPs to enroll individuals for two years before they have the mechanisms in place to provide “special” services to them is inconsistent with the intent of the statute. Plans should only be allowed to operate as SNPs when they are in a position to offer a meaningful advantage to their enrollees, not when they are in negotiations that might lead to added value.

SNPs serving dual eligibles, regardless of whether they are Dual Eligible SNPs, must demonstrate the capacity to deliver or coordinate the SNP benefits with Medicaid services and with related social services, as the latter term is defined in regulations promulgated by CMS. Such capacity can be demonstrated (for Medicaid services) through a contract with the state to deliver Medicaid services or (for all services) through identifying core competencies, staff expertise and dedicated resources to coordinate all the health needs of their enrollees. CMS must identify specific areas in which the plan must demonstrate competence. Beneficiary-oriented plan materials must include clear and accurate information about the benefits available under the state’s Medicaid program that are specific to the state in which the plan is operating.

All enrollees of Dual SNPs and those enrollees of Institutional and Chronic SNPs who provide evidence of Medicaid at the time of enrollment must be treated by the plan as eligible for the full Part D Low-Income Subsidy. The SNP must initiate action to correct CMS’ records, if needed.

Enrollees of Dual SNPs who lose Medicaid eligibility during the year must be permitted to remain in the SNP through the end of the calendar year. The SNP must inform them of additional costs they will bear as a result of losing Medicaid coverage; such costs would

relate to non-Part D services only, as the beneficiaries would retain their full Part D low-income subsidy for the remainder of the year.

SNPs should demonstrate capacity to adequately serve dual eligibles, as discussed above, immediately; at a minimum through staff expertise in the Medicaid program of the state in which the SNP is operating. While it may take several years for a SNP to work out an arrangement with the state, especially if the arrangement is a contract to provide integrated Medicare and Medicaid services, it is not impossible for the entity to take the interim steps we propose.

We ask CMS to revise the proposed regulation to require that the SNP have an arrangement with the state concerning the capacities and areas we have identified – verification of Medicaid eligibility, liaison concerning Medicaid-covered services, liaison concerning Medicaid cost-sharing, and plan materials that take into consideration state Medicaid program services and cost-sharing.

Impact on State Managed Care Policies

The proposal promotes too much. We are very concerned about the effect of the proposed requirement that SNPs have a contract with the state within three years of the effective date of this requirement. We believe that CMS does not have the authority to require states to contract with all Medicare Advantage plans that CMS approves to serve as SNPs within their boundaries. Additionally, we are concerned that such a requirement may have the effect of requiring all dual eligibles to be enrolled in a state Medicaid managed care plan and/or a SNP, in contradiction of both Medicare and Medicaid law that give beneficiaries freedom of choice of provider. We note, for example, the discussion on page 28561 which appears to assume that states should provide and/or expand managed-care to their Medicaid eligible populations. The requirement for SNPs to negotiate with states must not be used as a back door route for pushing the expansion of Medicaid managed care. States and counties are in the best position to determine which vehicles are best suited to deliver Medicaid benefits to their citizens. We urge CMS in its regulations and in its dealings with the states to ensure that requirements for SNP coordination do not translate into a real or perceived mandate for expanding Medicaid managed care.

e. Special Needs Plans and Other MA Plans with Dual Eligibles: Responsibility for Cost-Sharing (§ 422.504)

We are pleased that CMS has recognized the need formally to direct MA plans concerning cost-sharing for beneficiaries eligible for Medicare and Medicaid. The regulation, however, should go farther than it does. The MA plan should be required to provide all its physicians and providers with specific information about when dual eligibles are not liable for cost-sharing. CMS has created a matrix and explanation of which duals get which cost-sharing protections; this should be included in information to providers. In addition to providing such information to all physicians and providers, the plan should be required to have a designated contact person knowledgeable about the

Medicaid program in the state in which the plan is operating who could answer questions from providers about cost-sharing obligations. Contract provisions between plans and providers should make clear that providers must provide dual eligibles with full cost-sharing protection, regardless of whether the provider has a Medicaid provider agreement with the state in question.

The language “when the State is responsible for paying such amounts” currently in the proposed regulation is misleading since, under 42 U.S.C. § 1396a(n)(2), the State might make no payment at all, but the beneficiary will still be excused from cost-sharing liability. Again, requiring plans to have a designated contact person to explain this to providers will provide beneficiaries greater protection.

Advocates have found it especially difficult to ensure the protections of the law for Qualified Medicare Beneficiaries (QMBs) who are not also eligible for full Medicaid benefits. Not all states provide QMBs with identification; plans should be required to provide cards to dual eligibles that reflect their Medicaid status so that providers are not confused as to how or whom to bill.

Plans should be required to arrange with the states in which they operate a process for providers to be reimbursed the cost-sharing for dual eligibles. The process might be a capitated payment to the plan or might require each provider to bill the State, but the providers should have a uniform, easy-to-use process. The preferred process should be that plans rather than providers collect cost-sharing owed from the State Medicaid agency.

Plans should be required to refund any cost-sharing inappropriately charged to dually-eligible beneficiaries.

All information to plan enrollees should clearly set out cost-sharing protections for dual eligibles.

Finally, plans should be held accountable, by CMS, for compliance with this provision.

2. MA MSA Transparency (§ 422.103(e))

While we believe that the availability of price and quality information is helpful, we are concerned that this provision can have unintended consequences. We believe MSA plans need more direction about the quality information they will report and the source of that information.

Information about cost of services needs to be tied in directly to information about quality of care. The regulation should require that MSA plans report quality and cost information in a manner that allows a beneficiary to determine whether a provider who charges more for a service provides better care. Beneficiaries who look just at cost may end up choosing a provider who is not right for them.

We are also concerned that the reporting of cost and quality information may have the unintended effect of steering MSA plan enrollees to providers for which the MSA plan reports prices. Plan enrollees may think that care is not available from other providers whose information is not included. The regulations should require MSA plans, at a minimum, to indicate that the information they make available is not complete, does not indicate the full range of providers who will accept the MSA plan, and that other providers who are not included in the list may offer the service for the same or lower cost and at the same or a higher quality of care.

3. Additional Recommended Changes to Part 422

a. Election of Coverage under an MA Plan (§ 422.62)

Although this section is not discussed in the proposed regulations, we believe it needs to be amended to speak to conditions that are addressed in the section on marketing. Specifically, we recommend amending § 42 CFR 422.62(b)(3)(ii) with the following language:

“(3) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that –

...

(ii) The organization (or its agent, representative, or plan provider) ~~materially misrepresented the plan’s provisions in marketing the plan to the individual~~ **has violated any of the rules governing the marketing of MA or PDPs contained in these regulations.”**

Currently, section 422.62(b) states the circumstances under which an individual can be entitled to a Special Enrollment Period (SEP) allowing him or her to disenroll from an MA plan and into fee for service Medicare or another MA plan. Subsection (b)(3)(i) provides for the circumstance in which “the organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:” and then specifies the provision of medically necessary or other services in accordance with the plan. Subsection (b)(3)(ii) allows for disenrollment if the organization (or its agent or representative) materially misrepresent the plan’s provisions in marketing the plan.

We recommend that (b)(3)(ii) be expanded to allow for a SEP whenever it can be shown that a plan or its representative violated any marketing regulation. This proposed change would provide CMS with an additional enforcement tool to ensure that plans and their representatives follow all of CMS’ rules regarding marketing and enrollment. It would also provide advocates and CMS with a more straightforward way of determining whether an individual is entitled to a plan disenrollment.

For example, in the District of Columbia, plan agents and representatives are targeting low-income neighborhoods and knocking on people’s doors to sell them plans they do

not need and cannot use. (This includes homebound Medicare beneficiaries.) If an agent cold calls beneficiaries or solicits them by knocking on their door unannounced, in violation of Medicare regulations, the plan is using illegal means to enroll those beneficiaries. Beneficiaries, particularly ones with diminished capacity due to age or mental disability, or limited literacy, could sign up for plans without understanding all of the consequences of doing so.

In these cases, even if the agent or representative does not misrepresent the plan's provisions, that agent or representative (and the plan for which he or she works) should not be able to profit from the illegal action and the beneficiary should not be stuck in a plan that was illegally marketed to him. Advocates have worked with clients who cannot remember what was said to them and do not necessarily keep the marketing materials the agent has brought to the beneficiary's home. Therefore, we would be unable to show that the beneficiary was enrolled due to a misrepresentation. In these cases, it should be sufficient that the beneficiaries can say that the agent cold called them and/or came to their house in a door-to-door solicitation in order to sign them up for an inappropriate plan.

b. Reconsideration by an independent entity (§ 422.592)

As part of the CMS review of areas of the Part C appeals process that create problems for Medicare beneficiaries, we ask that you also make changes to the section concerning submission of evidence by beneficiaries at the reconsideration level of review conducted by the independent review entity (IRE), CHDR Maximus.

Under the current system, IRE reconsiderations are generally limited to evidence and argument submitted by the MA plan. The CHDR Manual actually acknowledges that they rely on relationships with the MA plans and the material submitted by the MA staff in making their reconsiderations, and interprets the beneficiary's right to submit evidence "in person" as meaning that a beneficiary can "hand deliver" evidence to the CHDR headquarters. Sec. 4.3 REDETERMINATIONS, QIC Reconsideration Procedure Manual. We hear from many beneficiaries and advocates across the country that it is difficult for them to contact CHDR about a pending case, and when they manage to do so, they are discouraged from participating by CHDR staff.

We ask CMS to amend § 422.592, to include a provision specifically stating that the beneficiary's right to submit allegations of fact and law, in writing and verbally at the MA stage of reconsiderations (§422.586) also applies at the IRE stage of reconsiderations. Information could be submitted by telephone, fax, or e-mail.

B. Proposed Changes to Part 423 – Medicare Prescription Drug Benefit

1. Passive Election for Full Benefit Dual Eligible Individuals Who Are Qualifying Covered Retirees (§423.34)

We are pleased that CMS is taking steps to address the problem caused by auto-enrollment into a prescription drug plan of full-benefit dual eligible individuals who are qualifying covered retirees. We suggest several amendments to help effectuate the changes intended.

First, we believe the regulations should apply to all individuals who are automatically enrolled in a Part D plan. Advocates have had clients who have lost employer coverage when they were automatically enrolled in plans as a result of becoming eligible for one of the Medicare Savings Programs. The proposed regulation as currently written will not benefit these clients.

Second, the regulations should state that the notice will advise such individuals to discuss the impact of Part D coverage *with their group health plan administrator or personnel office*. Many retirees may not know where to get the appropriate information. Advising them just to discuss the impact of Part D enrollment may seem like a reminder to discuss the action to be taken with family members and not with knowledgeable representatives of their group health plan.

Third, we ask that the regulation state that notice will be provided “to such individuals *or their representatives*.” Some of the affected individuals may lack the capacity to understand the notice and the action that needs to be taken. If CMS is aware that these individuals have someone who is acting on their behalf, notice should be sent to that individual.

Fourth, the proposed rule will not help individuals enrolled in employer plans that do not receive the subsidy, even if those plans would reduce or eliminate retiree coverage if the beneficiary is enrolled in a Part D plan. We ask CMS to consider ways to extend protection to those individuals.

Fifth, we understand that CMS is using retroactive disenrollment on a case-by-case basis to assist beneficiaries whose retiree benefits have been jeopardized by auto enrollment. We urge CMS instead to establish a Special Enrollment Period (SEP) that would allow retroactive disenrollment from Part D plans for any beneficiary who was auto enrolled in a plan that conflicted with a retiree plan, whether or not that plan received a CMS subsidy. This SEP for auto enrolled dual eligibles would be consistent with and an extension of the more general SEP related to creditable coverage in the latest proposed changes to the enrollment guidance (see Draft §30.4.4(14) in MA enrollment guidance).

Finally, we hope that CMS will allow beneficiary representatives the opportunity to review the notice that will be sent to qualifying covered retirees who become dual eligibles. We encourage CMS to make these notices available in languages other than English to ensure that all beneficiaries receive the information.

2. Part D Late Enrollment Penalty (§ 423.46)

We have had continuing concerns about the role that drug plans play in the process for obtaining creditable coverage information and believe the regulations need to confirm that CMS has the ultimate authority to determine whether previous coverage is creditable, thereby obviating the imposition of the Late Enrollment Penalty (LEP).

We agree that the statute requires that individuals be provided an opportunity for independent review by CMS or an independent review entity of the decision to impose a LEP. However, we believe that: beneficiaries should have and are entitled to the full array of appeal rights, and not be limited to the reconsideration level of review; that beneficiaries should have an opportunity to correct a LEP determination at any time; that documentation requirements for beneficiaries changing plans should be simplified; and that the current guidance concerning waiver of the LEP for individuals receiving the Low Income Subsidy should be incorporated into the regulation.

Full Appeal Rights

We believe that beneficiaries should have and are entitled to the full array of appeal rights, and should not be limited to the reconsideration level of review. A LEP imposes a financial burden on a beneficiary for life; we see no justification for curtailing full appeal rights and CMS has provided none. The vaguely defined one-step appeals process proposed by CMS is particularly onerous because, as CMS is aware, the population of Medicare beneficiaries includes a disproportionate number of individuals who are ill, in institutions, limited English proficient or otherwise face barriers to promptly responding to notices and exercising appeal rights.

The proposed regulation does not provide any information about the reconsideration process to beneficiaries and their representatives. It says that individuals may request reconsideration “consistent with §423.56(g).” That section establishes the right of an individual who is not adequately informed that previous drug coverage was not creditable to apply to CMS to have the coverage treated as creditable. It does not set forth the procedures for requesting a reconsideration. We ask that CMS incorporate into the regulations the procedures outlined in § 80.7 of Chapter 18 of the Medicare Prescription Drug Manual. At a minimum, the regulations should include the time frames for submitting an appeal, the entity that will be conducting the appeal and how the appeal is to be submitted, the evidentiary requirements, and the time frames for the independent review entity to act.

Finality

We also have a fundamental objection to any appeals process, especially one that uses a relatively short 60 day appeal deadline, which imposes an absolute bar to correction of a beneficiary’s Late Enrollment Penalty record, a record that, if incorrect, results in lifetime application of the penalty.

The question of whether a LEP is applicable is primarily an issue of fact, including such questions as: whether and when the individual was enrolled in another plan; whether that plan offered credible coverage, which is not a beneficiary-by-beneficiary determination; whether the beneficiary was living abroad during the Initial Enrollment Period; and whether the beneficiary received the Low-Income Subsidy. If an error has been made about those facts, an individual should be able at any time to bring forward information that corrects that error. While we accept that, for reasons of administrative efficiency, it may be appropriate in some instances to require action within procedural timeframes in order to get retroactive correction of Late Enrollment Penalties, it is unjust to saddle a beneficiary with a lifelong penalty prospectively because of a factual error that can be corrected. We note that the proposed regulation provides that decisions “may be reviewed and revised at the discretion of CMS,” a provision that, we hope, recognizes this concern. This general provision, however, is inadequate. The regulation should, at least, set out a simple procedure whereby a beneficiary can, at any time and without a showing of good cause, submit evidence with respect to the elimination or mitigation of a Late Enrollment Penalty.

Changing Plans

We are also concerned about the burden placed on beneficiaries who change Part D prescription drug plans if they have to document that they have had continuous drug coverage under Part D since their Initial Enrollment Period by providing information about every plan in which they have been enrolled. It should be sufficient for enrollees to state on their application that they have had drug coverage under a Medicare Part D drug plan and that they currently do not pay a Late Enrollment Penalty. It will be much easier for CMS to make the verifications, since CMS will need to notify their former prescription drug plan of their disenrollment, and since CMS should have records of all the drug plans in which they were enrolled.

Low-Income Subsidy Recipients

CMS should add to its Late Enrollment Penalty regulation its current guidance that waives the Late Enrollment Penalty for beneficiaries receiving the Low-Income Subsidy. CMS correctly has determined that imposition of the Late Enrollment Penalty acts a strong deterrent for enrollment for beneficiaries who qualify for the Low-Income Subsidy. The rationale for waiver of the penalty will continue to be applicable in future years.

3. Medicare Prescription Drug Benefit Program Definitions

a. Subpart C – Benefits and Beneficiary Protections (Definitions)

i. Incurred Costs (§ 423.100)

We support incorporating into the definition of incurred cost the current CMS policy of counting towards true out of pocket costs (TrOOP) the nominal co-payments assessed by Patient Assistance Programs (PAPs). The proposed rule requires that documentation of the cost sharing be submitted to the plan consistent with the plan's processes. We ask that CMS require plans to include information about such processes in their Evidence of Coverage and other documents given to beneficiaries.

ii. Negotiated Prices (§ 423.100)

We support a revised definition of “negotiated prices” that would ensure that the price used to calculate total drug spending and coinsurance rates is **never higher** than the reimbursement rate, including any dispensing fee, negotiated between the pharmacy or other dispenser of prescription drugs and the Part D plan or its pharmacy benefit manager (PBM) intermediary.

Although the definition proposed by CMS would accomplish this goal, it fails to protect consumers from higher prices caused by the failure of Part D plans to pass through manufacturer rebates and other indirect price concessions at the point of sale. The proposed definition also does not prevent Part D plans from charging higher prices or using these higher prices to calculate drug spending and beneficiary cost-sharing, when these prices are the result of negotiation between related parties (Part D sponsor and PBM, PBM and pharmacy, or Part D sponsor, PBM and pharmacy) or when higher prices for specific drugs are used to defray administrative costs.

In our experience, the use of the so-called “lock-in” pricing model, in which the prices plan sponsors pay the PBMs are used to calculate spending and coinsurance rates, results in substantially higher prices for consumers, particularly for many widely prescribed generic drugs. These prices are substantially higher than the reimbursement rates established for network pharmacies and often higher than widely available retail prices, indicating that the PBM is keeping the “spread” between the price it receives from the Part D sponsor and what it pays network pharmacies. Whether this spread is a disguised payment for administrative services, or simply a hidden revenue source for the PBM is irrelevant. It is a cost shift to the consumer that is not related to the cost of the drug.

These higher prices can have the effect of pushing consumers into the coverage gap earlier in the year than would occur if the total drug spending were based on the price negotiated with the pharmacy. The preamble to the proposed rule also explains that these higher “lock-in” prices are used to calculate coinsurance rates as well as to calculate “actuarially equivalent” copayment rates. In effect, plans that use these inflated prices do not provide the minimum standard benefit required under the statute. Average beneficiary cost-sharing between the deductible and the initial coverage limit is no longer equivalent to 25 percent of the cost of drugs. By inflating the drug price to include the “spread” retained by the PBM, the benefit is diluted and consumers effectively pay more than an average of 25 percent. Similarly, because the initial coverage limit is based on prices that are inflated to include the PBM spread, enrollees in plans using this pricing model have an initial coverage limit that is based not on total drug spending but on total drug

spending plus administrative expenses and PBM revenue. Once the PBM spread is subtracted from total drug spending, the initial coverage limit can be substantially lower than the amount established by statute.

We find it deeply troubling that the lock-in pricing model tends to raise prices for commonly prescribed generics. Consumers generally have switched to a generic because of coverage restrictions imposed on brand name drugs in the same therapeutic class, to reduce out-of-pocket spending and to avoid falling in the Part D coverage gap. It is unfair that these consumers, after taking action they thought would lower their costs, should be subject to a pricing model that not only fails to deliver the full savings benefit of generic substitution but could also push them into the coverage gap earlier in the year.

The lack of transparency in the “lock-in” pricing model also puts consumers at a disadvantage. In our experience, consumers selecting Part D plans tend to focus primarily on the monthly premium and, to a lesser extent, the coverage and copayments associated with classes of drugs, such as generics. Consumers may be attracted to a Part D plan because it offers low premiums, low copayments and/or gap coverage for generic drugs, yet be unaware that these lower costs are financed by the use of inflated prices for these generics. Moreover, these inflated prices can push them into the coverage gap earlier in the year and raise their costs once they are in the gap. Our comparison of Part D plans on medicare.gov shows that plans charging the highest prices for generic drugs most subject to a “spread” between pharmacy and PBM reimbursement can cost consumers hundreds of dollars more per year, even though they charge premiums and provide coverage and copayments for generics that would seem to provide consumers with a cost advantage.

The “lock-in” pricing model also results in higher prices for consumers when they are in the deductible or coverage gap phases of the benefit. If consumers are aware of their rights, and unfortunately many are not, they can pay the lower usual and customary price for their medicines and mail receipts into their plan so that their incurred costs count toward the out-of-pocket limit. It is unfair and unrealistic to expect most people with Medicare to be aware of this option, which is only now being codified into regulation. Moreover, it places an additional burden on consumers, pharmacies and plans even as these higher prices are justified as a way to pay for the costs of administering the benefit. Congress’ intent in guaranteeing access to negotiated prices in all phases of the benefit was surely intended to ensure access to prices that are lower than those charged cash customers. It defies belief to argue that a Part D plan can meet this requirement by providing access to prices that are higher than the price paid by cash customers because of the spread retained by the PBM.

Besides consumers, state pharmaceutical assistance programs (SPAPs) that coordinate with Part D also pay higher prices when they pick up cost-sharing for SPAP members enrolled in Part D plans that use “lock-in” pricing. This makes it more expensive for states to provide wrap-around coverage for Part D and more expensive to extend such coverage to other people in need not currently eligible for SPAP coverage, such as people with disabilities.

To reiterate, we support adoption of a definition of “negotiated price,” that, at a minimum, ensures that the price used to determine cost-sharing, total drug spending, and beneficiary liability in the deductible and coverage gap phases of the benefit, is never higher than the reimbursement rate negotiated between the Part D plan (or its intermediary) and a network pharmacy. We are disappointed, however, that, even if CMS adopts such a definition, consumers enrolled, or considering enrollment, in plans that use the lock-in model will have no way of knowing that they may be victimized by the inflated prices under this model, until the new definition becomes effective for the 2010 plan year. In the interim, we recommend that CMS use marketing guidance to require plans using lock-in prices to inform current and prospective plan members of the higher prices they may pay under this model. In addition, these plans should inform current enrollees whenever they purchase a drug that is higher due to “lock-in” pricing and advise consumers of their rights to pay any lower price available during all phases of the benefit.

The proposed definition of “negotiated prices,” however, will not solve all the problems with Part D drug pricing that put consumers at a disadvantage. In particular, the failure of Part D plans to pass on the rebates and other price concessions from brand name drug manufactures results in consumers paying higher prices for brand name drugs than the prices “actually paid” by Part D plans.

Research conducted for the Medicare Payment Advisory Commission (MedPAC) shows that the prices charged by Part D plans for drugs that may also be covered under Part B are usually higher than the Part B reimbursement rate. The Part B reimbursement rate is itself 6 percent higher than the Average Sales Prices, a measure which is meant to reflect the price, net of manufacturer rebates, actually received by PBMs, insurers and other providers. Therefore, the B-D price differential indicates that these manufacturer rebates are not passed through to lower the prices paid by consumers. Since these drugs are primarily high-cost specialty drugs, and the price differential between Parts B and D is substantial, this means that beneficiaries who need these medicines to treat cancer or other serious and life-threatening diseases or prevent rejection of transplanted organs, often pay thousands of dollars more per year because of Part D plans failure to use the rebates they receive to lower consumers prices.

Instead of lowering the consumer prices, manufacturer rebates are used to lower premiums, pay administrative costs or increase the profits of Part D plans. As CMS recognizes in the preamble to the proposed regulations, using higher drug prices to pay costs that should be derived from premiums dilutes the insurance principle. In effect, beneficiaries who purchase brand name drugs generate rebate revenue that Part D plans use to subsidize coverage (through lower premiums) for beneficiaries who do not take these drugs. This effect is particularly pernicious in the case of high cost specialty drugs—medicines that are generally not “discretionary” but, instead provide the only hope for the beneficiary's survival. Already burdened with the high out-of-pocket costs associated with a serious illness like cancer, these patients must pay prices that, because they are not reflective of the price net of rebates paid by the Part D plans (or their PBMs,

specialty pharmacies or other intermediaries), are used to subsidize the profit margins and administrative costs of their Part D plan.

To correct this cost shifting onto the sickest, most vulnerable beneficiaries, and to restore the insurance principle to Part D, we recommend that CMS adopt a definition of “negotiated price” which accords with the proposed definition of “actually paid,” (which we also support). The effect of this definition would be to have the retail price paid by the beneficiary during the deductible and coverage gap, the price used to calculate cost-sharing and total drug spending under the benefit, reflect the actual price, net of rebates and other price concessions, that is paid by the Part D plan, or its intermediaries (such as a PBM).

We believe this definition of negotiated price is fully in accord with the statutory language. According to § 1850D-2 (d)(1)(B), “negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.” A more reasonable reading of the statute would hold that “negotiated prices should reflect **all** price concessions, rather than only those concessions that the “part D sponsor has elected to pass through to Part D enrollees at the point of sale,” which is the definition proposed by CMS.

Whatever definition of negotiated price is adopted in the final rule, we are concerned that no definition of negotiated price will prevent consumers from being charged inflated prices because the negotiation between the Part sponsor (or its PBM) allows certain network pharmacies to pocket the “spread” on certain generic drugs. This practice is especially pernicious when Part D plans use lower copayments to steer beneficiaries to pharmacies that use higher prices than other network pharmacies.

We are aware of at least one major Part D plan which sets substantially higher prices for certain generic drugs purchased through a mail order service offered by a national pharmacy chain than it charges to enrollees who use “brick-and-mortar” pharmacies. This national pharmacy chain has substantially more market leverage to secure lower prices for generics than independent pharmacies and there are no higher dispensing costs associated with these drugs. It appears the Part D plan and its mail order pharmacy are colluding to disadvantage both consumers and the Medicare program through the use of inflated prices. Beneficiaries who use the mail order service during the initial phase of the benefit are likely unaware that they are being pushed into the coverage gap more quickly because higher prices are being used to calculate total drug spending.

Similarly, we are aware of one Part D plan where the plan sponsor, its PBM and a national pharmacy chain, are all related entities. This plan charges among the highest prices for commonly used generics, according to data on medicare.gov. Under the proposed definition, such inflated prices could not be used when plan enrollees used a network pharmacy that received a lesser rate as reimbursement. But, the plan sponsor could still use these higher prices to calculate the benefit if its in-house mail-order pharmacy, or the pharmacy chain that is part of the PBM, is the entity that is allowed to

pocket the spread. This plan could use lower copayments for mail-order or for “preferred” network pharmacies to steer enrollees to pharmacies that allow the parent company to benefit from the spread, even as the customer is pushed closer to the coverage gap because these inflated prices are used to calculate drug spending.

We recommend that CMS, and, where appropriate, the Office of Inspector General, exercise appropriate oversight to ensure that contracts among related parties do not result in higher prices or a diluted benefit for consumers or in increased spending by the federal or state governments. Similarly, prices agreed to between Part D plans and network pharmacies must bear a reasonable relationship to the underlying costs of drugs. Part D plans should not be allowed to manipulate drug prices in order to undermine the statutory benefit parameters or to shift costs onto beneficiaries who need specific drugs.

b. Subpart G – Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage [Definitions and Terminology, § 423.308]

i. Actually Paid (§ 423.308)

We support the proposed change to the definition of “actually paid.”

ii. Administrative Costs (§ 423.308)

We support the proposed change to the definition of “administrative costs.”

4. Limiting Copayments to a Part D Plan’s Negotiated Price (§423.104)

We thank CMS for clarifying that negotiated prices must be provided to the beneficiary at all times, including during the deductible and coverage gap phases and when the negotiated price is less than the applicable cost-sharing. We ask that CMS continue to monitor negotiated pricing issues and take corrective action against plans that do not pass negotiated prices on to their enrollees as required.

5. Timeline for Providing Written Explanation of Plan Benefits (§423.128)

We applaud CMS for codifying the requirement that plans provide an explanation of benefits (EOB) in a timely manner. We are concerned, however, that the time frame proposed - providing the EOB to plan enrollees at the end of the month following the month in which benefits were provided - will create a near two-month information gap, which is too long a time period for many people. The EOB contains important information about total drug expenditures as well as about beneficiary out-of-pocket expenditures. Beneficiaries rely on this information to approximate when they will reach the coverage gap and have to pay the full cost of their drugs, and whether and when they may be eligible for catastrophic coverage. We continue to hear complaints from

beneficiaries, particularly dual eligible beneficiaries, who believe that they are eligible for the reduced cost-sharing at the catastrophic level but are told at the pharmacy that they are still in the coverage gap. They should not have to wait nearly two months to determine whether they and the plan agree about the stage of coverage they are in. The delay creates a financial hardship for beneficiaries who have not been assessed proper cost-sharing. It means that more beneficiaries will have the burden of going through the onerous process to get reimbursement if they have paid improper cost-sharing.

We suggest instead that plans should be required to send the EOB as expeditiously as possible, but no later than the 15th of the month following the month in which an enrollee uses Part D benefits.

6. Low Income Subsidy Provisions

a. Low Income Cost-Sharing and Payment Adjustments for Qualified Prescription Drug Coverage (§ 423.329)

We support any efforts by CMS to ensure that plans are provided accurate, expedient payment for services provided to beneficiaries.

b. Lesser of Policy for Low-Income Subsidy Individuals (§ 423.782)

We applaud CMS for incorporating this guidance into regulation. The Low Income Subsidy (LIS) is clearly intended to reduce, not increase costs for eligible beneficiaries. Receiving the LIS should never leave a beneficiary worse off.

c. Using Best Available Evidence to Determine Low-Income Subsidy Eligibility Status (§§ 423.772, 423,800)

We support CMS's decision to incorporate the Best Available Evidence (BAE) policy into the regulations. The policy represents a lifeline to beneficiaries who are waiting for CMS systems to reflect appropriate co-pay levels.

The BAE policy, however, is not a perfect solution. The very process of providing BAE is tantamount to making the beneficiary re-prove her eligibility for the LIS, or, in the case of those deemed eligible for LIS, prove eligibility where the statute and regulations have already said they are eligible without having to apply. We, therefore, make the following recommendations.

The Proposed Amendments

We agree with CMS's proposed definition of BAE in § 423.772, understanding that examples of the particular documents or kinds of information that qualify as BAE will be updated regularly by CMS through guidance, rather than regulation. We appreciate that the definition does not specify that the beneficiary must provide the BAE. It is important

that plans accept BAE provided by beneficiaries, pharmacists, other providers, States, CMS and others.

We also support the inclusion of § 423.800(d). As with § 423.772, we agree with CMS that it is better to reserve details about the BAE process for guidance. **Current guidance should not need to be included in the text of the regulations nor should a specific version of the guidance be referenced.** Including any text of the current guidance or referencing the June 27, 2007 CMS memorandum would only cause confusion when new guidance is released (as is planned under the terms of the settlement agreement in Situ v. Leavitt, see below). A general reference to CMS BAE guidance is enough.

We do believe, however, that additional language must be added to § 423.800(d). Pursuant to a recently reached, though not yet court approved, settlement agreement in the class action lawsuit Situ v. Leavitt, CMS has agreed to release new BAE policy guidance. This new guidance requires plans to not only accept BAE, but to also assist beneficiaries who claim to be subsidy eligible but cannot provide BAE. If CMS hopes to enforce this new element of the BAE policy, it is important that it be included in the regulation. We propose the following addition to §423.800(d).

(d) Use of the best available evidence process to establish cost-sharing. Part D sponsors must accept best available evidence as defined in §423.772 of this part, **assist beneficiaries who claim to be subsidy eligible but are unable to provide acceptable evidence of subsidy eligibility**, and update the subsidy eligible individual's LIS status in accordance with a process established by CMS, and within a reasonable timeframe as determined by CMS.

We oppose the change made to § 423.800(b). The phrase inserted at the beginning of paragraph (b) implies that a plan's obligation to reduce cost sharing and premiums of subsidy eligible individuals is contingent upon receipt of information from CMS or BAE. As mentioned in the preamble, the sponsor's obligation under § 1860D-14(c)(1)(B) to reduce cost-sharing and premiums for LIS recipients is not contingent. A subsidy recipient is entitled to the benefits of the subsidy regardless of whether CMS has transferred the information to the plan or the plan has been provided BAE. We believe that the current regulatory language of §423.800(b) – without the proposed introductory clause – more accurately reflects plan requirements and individual entitlements. We support the BAE as a policy which creates an alternative for beneficiaries experiencing a delay in the transfer of subsidy information. We do not, however, support the BAE as the only alternative.

Enforcement

For the BAE policy to function as an effective safety net, it must be enforced. We are pleased with CMS' comments in the preamble to the regulations that the new language will put it in a stronger position with respect to plan compliance with the BAE policy. Since LIS recipients, by definition, do not have the means to pay full price for

medications and await reimbursement, when a plan, or plan employee, fails to understand or follow the BAE policy, low income beneficiaries are left without medically necessary medications. Unfortunately, this happens all too often.

The number one complaint about the BAE policy that advocates hear across the country is that plans refuse to follow it. Plans do not know about the BAE policy, do not know what documents count as BAE, do not know how to accept BAE and/or do not know how to update plan systems once they have received BAE. The lack of understanding is not limited to plan customer service representatives. Many call center supervisors and plan government liaisons have failed to implement properly the BAE policy to ensure that low income beneficiaries get the medications they need.

Given the serious consequences that result when plans fail to follow the BAE policy, we urge CMS to use its enforcement authority more vigorously to address deficiencies in plan compliance. We would appreciate further elaboration of CMS' plans for enforcing the BAE policy once the regulation is in place.

Refining the Policy

Finally, we appreciate that the proposed language of the regulation provides CMS with the flexibility to continue to refine and improve the policy. CMS should convene a workgroup of plans, pharmacists, state Medicaid offices and beneficiary advocates to further develop an efficient, expedient and effective process for sharing information – all the while ensuring that the burden of proof does not fall upon the beneficiary. Improvements to the current BAE process could include allowing pharmacists to use information in their systems to update LIS status, developing standards for documents required to prove Medicare Savings Program (MSP) eligibility, limiting the amount of time that plans have to retain records relied upon to update LIS status and limiting plans' ability to pass this responsibility on to pharmacists. Of course, the changes to the BAE agreed to in Situ v. Leavitt will also improve the BAE policy.

Additional Proposals

We urge CMS to adopt two additional amendments designed to address the problems caused when CMS systems fail to identify timely individuals who are subsidy eligible.

- The proposed regulations include a new requirement that Special Needs Plans serving dual eligibles establish a process for obtaining information from States about a beneficiary's Medicaid status. We urge CMS to extend this requirement to all plans that offer prescription drug coverage or, at a minimum, all benchmark plans. See our comments to §§ 422.52, and 422.107(a)(1).
- **§ 423.800(c)**. Even with the BAE policy in place, we remain concerned that some Part D enrollees will continue to pay excess amounts for their coverage and their prescriptions between the effective date of their subsidy and the date their Part D plan is notified of their subsidy eligibility. Although § 423.800(c) currently requires Part D

sponsors to reimburse enrollees for any such amounts, judging from the experience of advocates trying to help Part D enrollees obtain any reimbursements from their Part D plans, as well as the June 2007 Government Accountability Office report documenting the failure of CMS to monitor Part D sponsors' reimbursements to dual-eligible enrollees, we strongly believe that Part D sponsors are not in fact providing the required reimbursements

We believe Part D sponsors will not issue these reimbursements unless the Secretary clarifies that plan sponsors have an affirmative duty to review their enrollees' prescription records for this time period and to automatically issue appropriate reimbursements. It should be made clear that enrollees do not have to request this reimbursement, as Part D sponsors have access to all of the necessary information.

We propose the Secretary make the following amendment to § 423.800(c):

(c) Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy. **Within 30 days of notification that an individual is eligible for the low-income subsidy, whether or not a reimbursement request has been received from the individual, the Part D sponsor offering the Part D plan must review the individual's records of premiums paid and covered prescriptions purchased during the time between the individual's effective date of eligibility for the subsidy and the date the Part D sponsor's records correctly reflect the individual's subsidy and, based on the plan's records or other proof provided by the individual or organizations paying cost-sharing on behalf of the individual,** reimburse the subsidy eligible individuals, and organizations ~~paying cost-sharing on behalf of such individuals,~~ any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

7. Certification of Allowable Costs (§ 423.505)

We support this provision.

8. Change of Ownership Provisions (§ 423.551)

We support this amendment. It is important that beneficiaries who are enrolled in a plan that is sold mid-year continue to receive the benefits promised to them at the time they enrolled in that plan.

Proposed Changes to the MA and Prescription Drug Benefit Programs

1. Authorization of Automatic or Passive Enrollment Procedures (§§ 422.60 and 423.32)

The proposal to passively enroll beneficiaries into another Medicare Advantage (MA) plan if their plan contract is terminated violates the Medicare statute and should be rejected. Individuals in a MA plan whose contract is terminated should be reenrolled into traditional Medicare for their Part A and Part B coverage.

The statute does not provide the Secretary the authority to enroll beneficiaries into MA plans. Medicare is premised on freedom of choice of health care provider and of delivery mechanism. 42 U.S.C. 1395a specifically states,

Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services.

Because the Medicare Advantage program takes away the freedom to obtain services from any health care provider who accepts Medicare, enrollment in a Medicare Advantage plan must be voluntary and the choice belongs to the beneficiary. 42 U.S.C. § 1395w-21(a) says:

Choice of Medicare benefits through Medicare+Choice plans.—

(1) In general.—Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this title—

(A) through the original Medicare fee-for-service program under parts A and B,

or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1860D-1.

The reasoning behind the proposed regulation blurs the distinction between the Medicare Advantage program and a Medicare Advantage plan. As the statute indicates, a beneficiary chooses a Medicare Advantage plan, not the Medicare Advantage program. Each MA plan is different. Individuals who choose a Medicare Advantage plan do so, hopefully, only after a careful analysis of that particular plan's cost-sharing and provider networks. The fact that a beneficiary decides, after such an analysis, that a particular plan can meet her needs, does not mean that any other MA plan would be able to meet her needs.

In addition to violating the beneficiaries' right to make their own decision about how to receive Medicare benefits, enrolling beneficiaries into a MA plan they did not choose for themselves exposes them to great risk. The new plan may not have the right providers in their network or may apply cost-sharing and premiums the beneficiary cannot afford or would not have agreed to be subject to. In order to sufficiently protect beneficiaries under the proposed regulation, CMS would have to make a detailed, individualized analysis for every MA enrollee who is affected by the plan termination. CMS has announced no plans to do so.

Providing notice to individuals who are passively enrolled in a different MA plan is not an effective protection. As some beneficiaries do not understand the notices about their passive enrollment, so that they do not realize what has happened to their healthcare until a substantial period of time has passed, provision should be made for such beneficiaries to retroactively disenroll.

We propose that instead of enrolling beneficiaries facing a MA plan termination into another MA plan, they be defaulted in traditional Medicare – just as they would if they were first entering the Medicare program – and a PDP. Beneficiaries facing a PDP plan termination should be enrolled into another PDP. While we believe that passive enrollment into a Part D plan also is problematic, we recognize that, without passive enrollment into a drug plan, affected individuals will lose all drug coverage in these situations. Unlike with a Medicare Advantage plan, this is the only way to ensure continued access to medications since there is no drug benefit in the traditional Medicare program for them to fall back on. CMS should use Prescription Drug Event data to ensure that beneficiaries are enrolled in the least expensive available PDP that covers all of their current medications.

We realize that our proposal may also cause disruptions in care. There is no process that will eliminate disruptions in care caused by plan terminations. However, at least in traditional Medicare, beneficiaries have broad access to providers and a standard set of benefits.

In order to limit the negative consequences of the disruption, these beneficiaries should be granted a Special Enrollment Period (SEP) during which they can elect a new MA plan or PDP. This SEP should last 6 months or until the end of the next Annual Election Period, whichever is longer, and should provide the beneficiary with the option of choosing a retroactive enrollment date no earlier than the first day of the first month after the plan termination. The retroactive provision is necessary to blunt the negative impact of the disruption in coverage.

Finally, in any situation where CMS is terminating a plan, or a plan is terminating mid-contract year, CMS should notify the local State Health Insurance Program in the affected area of the names and addresses of all enrollees in that plan who will lose coverage and the effective date of same.

2. Involuntary Disenrollment for Nonpayment of Premium (§§ 422.74 and 423.44)

We support this modification to the regulations that prohibits a plan from disenrolling a beneficiary who has monthly premiums withheld from her Social Security check for failure to pay the premium. Especially during 2006 and 2007, we heard from many beneficiaries who were unable to resolve problems with their Social Security deductions and payments to plans and who received much conflicting information from SSA, from CMS and from plans. While it is important that CMS establish this principle and include

this requirement, we urge CMS to add a requirement that a plan cannot involuntarily disenroll, for failure to pay the amount of a benchmark premium, a beneficiary for whom the plan has received BAE indicating his/her entitlement to the full premium Low Income Subsidy.

Loophole for Transfer to Direct Bill Status

In its preamble discussion of a different section of the proposed rules (§§ 422.262 and 423.293), CMS casually states that where it is unable to “effectuate the premium withhold option” for beneficiaries, it will set those beneficiaries back to direct bill and in such cases, plans can bill the beneficiaries, and presumably, disenroll them for failure to pay. This creates a huge loophole in the §§ 422.74 and 423.44 protections as well as in the §§ 422.262 and 423.293 protections. The confusions over premium withholding have been so massive and intractable that CMS must establish clearer procedures for beneficiaries who find themselves in this situation. We propose that any beneficiary who is put into direct bill status by CMS because of the failure of the premium withholding system be protected from disenrollment for failure to pay premiums for the duration of the plan year. This would not preclude the plan from seeking payment for the premiums under a payment system that complies with the retroactive payment protections described in proposed regulations §§ 422.262 and 423.293.

3. Disclosure of Plan Information (§§ 422.111 and 423.128)

We applaud CMS for codifying its requirement that all plan disclosures required at the time of enrollment be made available no later than October 31st each year, in advance of the Annual Election Period. We ask CMS to articulate the penalties for plans that fail to adhere to this requirement, since there have been plans that have made these disclosures far too late in each of the past three years.

4. Retroactive Premium Collections and Beneficiary Repayment Options (§§ 422.262 and 423.293)

We support the important protections contained in these provisions for beneficiaries with regard to payment of their premiums. If the beneficiary is without fault in failing to pay a premium, and has built up an arrearage, repayment should be over the same period of time that the arrearage represents. We urge CMS to adopt additional protections as discussed below.

Definition of “Without Fault”

With respect to retroactive collection of premiums, CMS should include a definition of “without fault” in the regulations so that all MA/PDP enrollees have a clear understanding of their rights and so that those rights are uniform across plans.

Limiting Beneficiary Liability

We also propose that if the beneficiary is without fault and the plan has made no prior efforts to collect the back premiums, the plan shall be limited to collection of three months' premiums. If a beneficiary is without fault and demonstrates that repayment would cause hardship, s/he should have back premium repayment waived, with the party at fault (the plan, CMS, or SSA) absorbing the cost of the back premiums. Since CMS has expressed concerns about anti-kickback provisions and plan waiver of premiums, we propose that this waiver system be operated by CMS or its designee, rather than by the plans. Notices from plans to beneficiaries concerning back amounts due should be required to include notice of the right to request a waiver.

Leaving beneficiaries vulnerable to unlimited potential liability of back premiums imposes an unfair burden. This concern is most acute for beneficiaries receiving the Low Income Subsidy who, by definition, are least able to absorb unexpected expenditures and who, if they had known of premium liabilities, could have changed to zero premium plans using their continuous Special Enrollment Period. For this group, the payment issue is not just one of hardship for paying a legitimate debt but also one of lack of notice that would have allowed them to mitigate their losses.

Advocates are aware of a recent example of the problem. At the beginning of 2007, a group of low-income beneficiaries who had been "choosers" were left in a plan that had lost its benchmark status. Throughout all of 2007 and almost half of 2008, they received no notice of premiums due. Recently, they have been told that they owe premiums for the entire period, stretching well over a year. To make matters worse, they could have moved to a zero premium plan operated by the same plan sponsor had they realized that premiums were owed.

We also note that instituting a system as we've proposed would be a significant improvement on the current state of affairs. Currently, CMS can punish plans for failure to provide proper notices to beneficiaries and can subject them to significant fines; however, no mechanism is in place that allows CMS to direct plans to compensate beneficiaries for the injury they suffer as a result of notice violations. Reasonable limits on back payments would be a step in the right direction. (See also our comments re: § 423.760 on compensation of beneficiaries.) To the extent that notice delays beyond three months are the fault of CMS systems, we believe that the issue of absorption of loss should be one between CMS and plans. Beneficiaries should not bear the brunt of excessive system errors.

5. Prohibiting Improper Billing of Monthly Premiums (§§ 422.262 and 423.293)

We support this modification to the regulations that prohibits a plan from direct billing a beneficiary who is in premium withhold status.

Loophole for Transfer to Direct Bill Status

See comments to §§ 422.74 and 423.44 above.

No Billing If BAE is Received

CMS should include a requirement that any beneficiary for whom the plan receives BAE indicating his/her status as entitled to the full Low Income Subsidy cannot be billed for benchmark premiums.

6. Non-Renewal Notification Timelines (§§ 422.506 and 423.507)

We strongly object to the proposal to reduce the requirement that plans provide advance notice of non-renewal from 90 days to 60 days. Beneficiaries need as much time as possible to understand what is happening and to make decisions about their health care. The process of choosing a new plan can be daunting for some beneficiaries. SHIPs and other advocates who assist the affected beneficiaries need the longer time frame, especially when large numbers of beneficiaries are affected. The work of assisting beneficiaries in this situation is in addition to the normal increase in SHIP case loads that arise during the annual enrollment period.

Moreover we urge CMS to codify here the Special Enrollment Period that lasts from October through January of the following year for members of non-renewing plans.

7. Reconsiderations (§§ 422.578, 422.582, 423.560, 423.580)

We support the change that enables physicians and other providers to be able to request reconsideration on behalf of a beneficiary without being formally named as a representative. We have also heard from many physicians, advocates and beneficiaries about delays in the appeals process caused because the physician needed to obtain an appointment of representative form from the beneficiary.

Any means by which the Part D appeals process can be simplified and streamlined for beneficiaries and physicians is welcome. Many beneficiaries do not pursue appeals because the current system is too complicated and they do not understand their rights. Allowing physicians to request reconsideration from the plan will expedite this process and help to ensure that more beneficiaries take advantage of their rights.

We believe the difficulties physicians and beneficiaries face in navigating the coverage determination process are also caused by the lack of uniformity in coverage determination processes among plans. For this reason, we urge CMS to use this rulemaking to further improve the process by revising § 423.578 to require uniform coverage determination and reconsideration procedures across plans. Experience with Part D has shown that the variations in procedures among plans is a burden, particularly

on physicians and other providers who must deal with many different plans on behalf of their patients. We ask CMS to consider changing its regulations to require that all plans use uniform coverage determination and reconsideration procedures to be established by the agency. The burden of uniformity on plans will be modest while the benefit to enrollees and their providers will be substantial. Uniform practices would increase transparency and make it easier for physicians, advocates and beneficiaries to navigate the system. Uniform requirements also would make it easier for CMS to monitor and rate plan performance in this important area.

We also urge CMS to further improve the regulation of reconsiderations by changing §423.590 to provide that, if a plan fails to meet its deadline and further fails to forward the enrollee's request within 24 hours of the expiration of the adjudication timeframe, the enrollee may immediately request review by the IRE. Advocates report that, although adjudication timeframes have been in CMS guidance since the introduction of the Part D benefit, they have seen required timeframes repeatedly ignored, including the required timeframe for forwarding files to the IRE. In light of these persistent issues, we urge CMS to strengthen this regulation by also providing that, if a plan does not forward the file within the required timeframe, the affected beneficiary may directly bring the appeal to the IRE.

We also are concerned that, except for retrospective self-reporting by plans, there is no mechanism for the IRE or CMS to monitor whether plans are meeting their decisional deadlines. Beneficiaries not represented by persistent advocates who know the rules may face unacceptable delays. We urge CMS to develop a mechanism whereby coverage determinations are tracked in real time so that beneficiary rights to timely action can be protected.

8. Civil Money Penalties (§§ 422.760 and 423.760)

We support CMS' proposed revision to §423.760, which would allow CMS to calculate a civil monetary penalty (CMP) of up to \$25,000 for each enrollee "directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency." This revision appropriately recognizes that the scope of noncompliance – the number of beneficiaries affected or likely to be affected – is relevant to the amount of the penalty. For this reason, we also oppose an upper limit on penalties. If a Medicare Advantage organization's or Part D plan's noncompliance has affected many beneficiaries, and if the other factors identified at §423.760(a) (including degree of culpability, harm, nature of the conduct, and history of prior offenses) indicate extremely poor conduct, then the penalty should reflect the seriousness and pervasiveness of the noncompliance. In addition, CMS should ensure that the amount of the penalty is more than the cost of compliance. If it is not, then sponsors of Medicare Advantage and Part D plans will consider noncompliance just the cost of doing business.

We make several additional suggestions.

1. CMS should develop regulatory mechanisms to require Medicare Advantage and Part D plans to compensate beneficiaries who are harmed by their practices. If calculating actual out-of-pocket costs to beneficiaries proves too difficult in particular cases, then the regulations should provide an easily-calculated amount (such as three times the monthly premium) or a flat amount (such as \$500) that each affected beneficiary would receive. The compensation to beneficiaries would be the greatest of actual out-of-pocket costs, three times the monthly premium, or \$500.
2. CMS should repeal § 423.760(b)(2), which limits the penalty for uncorrected deficiencies to no more than \$10,000 per week. This amount is remarkably low. Penalties for uncorrected deficiencies must be large enough to encourage organizations – that are, as is regularly reported, generating substantial profits via their Medicare products - to correct deficiencies. The provision of any limit guarantees that the penalty will not be connected to the seriousness and pervasiveness of the noncompliance.
3. CMS should repeal § 423.760(b)(3), which limits the total penalty to \$100,000 when a Part D plan improperly terminates its contract with CMS. The regulation, at § 423.758, authorizes a penalty of \$250 per enrollee, or \$100,000, whichever is greater. There is no reason to create the upper limit for large plans with more than 4,000 enrollees.
4. CMS should amend § 423.762 to set limitations for the settlement of civil money penalties. The current language allows any type of settlement, including the virtual elimination of the penalty. We propose that no more than 35% of the penalty may be deducted in any settlement. This percentage corresponds to the reduction of civil money penalties if nursing homes choose not to appeal the deficiencies and remedies.

9. Medicare Advantage and Prescription Drug Program Marketing Requirements (Proposed New Subparts V)

In addition to other marketing requirements, with respect to Medicare Advantage Special Needs Plans (SNPs), marketing materials, summary of benefits and evidence of coverage must state explicitly how the SNP benefits coordinate with and supplement Medicaid, including a list of all SNP supplemental benefits and how they differ from those offered by Medicaid. They must articulate the costs to consumers, taking into account the Medicaid coverage available for some of the costs. Materials must be state-specific. Enrollment brokers or sales agents must be trained accordingly.

a. General

On the one hand, we appreciate that CMS is placing many provisions that previously existed only in sub-regulatory guidance into regulations so that they carry more legal weight. On the other hand, we believe that these provisions continue to fall well short of adequately addressing serious problems stemming from the marketing and sale of Medicare Advantage and Part D plans. Further, CMS' reiteration of many pre-existing rules and reliance on definitions contained in guidance (but not articulated in the

proposed rules) confirms the opinion of many beneficiary advocates that some of these rules will continue to be casually followed, if at all, by plan sponsors. The regulations should contain specific, federally enforceable definitions rather than reliance upon sub-regulatory guidance.

Medicare beneficiaries still encounter a bewildering array of plans available in their local areas, each with varying benefits, making informed decision-making particularly difficult. In order to adequately address both marketing misconduct and beneficiaries' informed decision-making about what plans might best suit them, we believe that a number of structural changes must be made to the Medicare Advantage and Part D programs. Many of these changes – we recognize – would require legislative action by Congress, including giving states more regulatory authority over Medicare Advantage and Part D plans sponsors, efforts to standardize MA and Part D plan benefits, and making the Part D benefit available through the Original Medicare program. There is much more that CMS can do, though, within its regulatory authority to better protect Medicare beneficiaries. In short, we believe that the measures outlined in these proposed rules are an important first step, but ultimately fail to adequately address and prevent ongoing marketing misconduct.

b. Marketing Materials and Marketing Requirements

i. Definitions Concerning Marketing Materials (§§422.2260, 423.2260)

We believe that at least two types of plan-generated materials that are not currently subject to CMS review should be included within the definition of marketing materials: 1) plan press releases; and 2) materials used in the education of beneficiaries and other interested parties.

According to CMS' Marketing Guidelines, “[p]ress releases are not considered marketing materials and do not need to be submitted for review, even if such materials contain marketing information (i.e., a description of plan benefits or cost sharing).” (p. 9). While it is not realistic to expect CMS to review plan press releases prior to dissemination (including the file and use procedure), we believe that CMS should reserve the authority to review the accuracy of the information in press releases issued by plan sponsors that describe plan benefits, structure, etc., and take corrective measures against a plan that has inaccurate and/or misleading information in such releases.

The Marketing Guidelines also state that “[m]aterials used in the education of beneficiaries and other interested parties” are not subject to CMS review as long as the materials are deemed to be “education” which is defined as “[i]nforming a potential enrollee about MA or other Medicare Programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific plan or limited number of plans” (CMS Marketing Guidelines, pp. 94 and 6, respectively). Such materials are subject to inaccurate or misleading information, particularly since plans

may have financial incentives to describe the types of products they offer more favorably than other coverage options available to Medicare beneficiaries.

ii. Review and Distribution of Marketing Materials: File and Use (§§422.2262, 423.2262)

We appreciate CMS' revision of its file and use policy to treat all plan sponsors equally. We urge CMS to employ continued vigilance over plan materials, and suggest adding a requirement that plan sponsors file their marketing materials with state regulators, so that states will be able to differentiate between CMS-approved vs. unapproved material and take action accordingly.

iii. Guidelines for CMS (§§422.2264, 423.2264)

We suggest adding to the explanation of “adequate written description” of marketing materials subject to CMS review in 422.2264(a)(1) and 423.2264(a)(1) an explanation of how a particular MA or Part D plan may interact, if at all, with other types of coverage (e.g., Medicare supplemental insurance, retiree coverage, Medicaid, etc.) as well as an articulation of the danger of losing such coverage as a result of enrolling in the MA or Part D plan.

We are pleased to see the issue of language access addressed in subsection (e) of these proposed rules. We believe, however, that the current provision is inadequate in that it does not meet the requirements of the prohibition against national origin discrimination affecting limited English proficient persons based on Title VI of the Civil Rights Act of 1964, nor does it comport with HHS's own guidelines with respect to such requirements. *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311(Aug. 8, 2003). Plans, as contractors with CMS, have a duty to comply with the requirements of Title VI. *Id.* at 47313. CMS has an obligation both to give clear direction to plans with respect to that duty and to ensure plan compliance.

To provide plans with appropriate guidance and a benchmark against which plan performance can be judged, we propose substituting a new §422.2264(e) as follows:

In reviewing marketing material or election forms under §422.2262 of this part, CMS determines that the marketing materials—

*** * ***

(e) Include translations of vital documents for each eligible Limited English Proficient language group that constitutes five percent or 1,000 persons of the population of persons eligible to be served in the plan's service area, whichever is less. For purposes of this subsection, the term “vital documents” shall mean all plan documents and correspondence for which CMS has established model or required language and other documents which CMS may designate in accordance Title VI policy guidance issued by the Office of Civil Rights of the Department of Health and Human Services.

This requirement is consistent with the safe harbor provisions found in the guidance set out by HHS’s Office of Civil Rights. *Id.* at 47319.

v. Standards for MA and PDP Marketing (§§422.2268, 423.2268)

The introductory clause in this proposed rule should add to “MA organizations” a catch-all phrase that includes all agents, brokers, other plan representatives selling or promoting the plan or acting on behalf of the organization, in order to more clearly articulate and ensure that plans are held liable for the conduct of these other parties. While CMS Marketing Guidelines do note that certain activities by direct employees or contractors are considered marketing by the organization, we believe that culpability and liability for marketing misconduct should more clearly attach to plans and should be articulated in regulatory language. The more plans are held responsible for the activities of “rogue agents” the more effort they will expend to oversee the activities of those selling their plans.

The following comments are broken down by subsection/issue in this proposed regulation:

(a) cash or other monetary rebates

We applaud CMS for imposing a prohibition on cash or other monetary rebates as an inducement for enrollment, but suggest that the first sentence include the phrase “or the appearance thereof” in order to prevent the practice of pitching certain plan benefits as a cash rebate to enrollees. Our experience shows that many agents pitch plan benefits in a manner that leads prospective enrollees to believe that they will indeed receive cash or other monetary inducements if they enroll – for example, debit cards for over-the-counter pharmacy benefits, and Part B premium rebates.

We strongly urge CMS to remove the second sentence of 422.2268(a), which creates an ambiguity with respect to the clear prohibition outlined in the first sentence. Further, it is unclear whether the example of “legitimate benefits” described here refers to “optional supplemental packages” that are that offered by certain MA plans for an extra premium, or rather to a separate type of insurance product – limited benefit indemnity plans that pay out a cash benefit when an enrollee uses certain services (sometimes referred to as Medicare Advantage “gap” or “plus” plans). We are gravely concerned that, through this proposed language, CMS may be sanctioning the sale of products that are being marketed to supplement MA plans, but do not comply with state and federal laws relating to Medicare supplemental insurance (Medigap) plans.

(b) limitation on type of promotional items offered

We support CMS’ efforts to place limitations on promotional items offered, and applaud the inclusion of meals regardless of value. Marketing at meals or other gatherings often

lead to mass enrollments, many of which are unsuitable because the time is not taken to ensure the plan being sold is appropriate for each individual.

(c) discriminatory activity

We appreciate CMS' efforts to limit discriminatory activity by plan sponsors and others selling MA and Part D products. In the Marketing Guidelines, CMS notes that “[o]rganizations may not engage in discriminatory practices such as targeting marketing to beneficiaries from higher income areas or implying that plans are available only to seniors rather than to all Medicare beneficiaries” (CMS Marketing Guidelines, p. 117). As discussed below in subsection (m), we believe that the grandfathering of plan names with exclusionary names such as “senior” are discriminatory and should be prohibited – regardless of how long a particular plan has been using that name.

(d) unsolicited means of direct contact

We appreciate elevating the current prohibition on unsolicited door-to-door marketing from guidance to regulation, as well as the expansion to other unsolicited means of direct contact. If enforced, this provision will help prevent agents who stake out hospitals, senior centers and accost seniors on the street.

Although CMS currently prohibits unsolicited door-to-door sales, this practice is still occurring with little visible consequence to agents or plans sponsors, in part because it is difficult to track and it is under-reported by victims. In order to effectively curb this practice, CMS must take affirmative steps in addition to placing this prohibition in regulation. We propose that CMS implement reporting requirements that enable plans and CMS to identify and prevent unsolicited door-to-door sales. We believe that all in-home enrollments should be flagged, and agents should be required to document how an invitation for an in-home presentation was secured. Since in-home sales are more prone to abusive sales practices, plans must be required to document how agents arrange for each in-home sale, and that information should be audited by CMS and, if appropriate, state regulators. If, as suggested in subsection (g) that plans can have a pre-visit documentation requirement for scope of sale, they can and should have a similar way to document how in-home visits are arranged.

We appreciate that the definition of prohibited “unsolicited means of direct contact” includes calls to a beneficiary “without the beneficiary initiating the contact” (commonly referred to as “cold calling”). We urge CMS to more clearly define “cold calls” as any unsolicited telephone call without the beneficiary initiating the contact, including calls to follow up to plan mailings when no other contact by the beneficiary has been made. Using this definition, CMS should unambiguously require that “cold calls” are prohibited. Similar to the discussion of cross-selling below, both the insurance industry and CMS have also argued that unsolicited calls to offer information to beneficiaries with whom the company has a pre-existing relationship would be permitted. This carve-out would apparently mean that anyone enrolled in another insurance product offered by the same company (e.g. a Medigap policy, Part D plan or even life insurance, home owners,

or auto by subsidiary of the parent company, etc.) – or who has purchased a product sold by the same agent – could get unsolicited calls. Allowing such exceptions would effectively gut this provision, and should not be allowed.

(f) prohibition on cross-selling

We agree that agents should not be permitted to cross-sell non-health care related products during a sale of Medicare products. We believe the provision should be expanded to also bar cross-selling of all non-Medicare related products, such as indemnity, dread disease and other “health products.” Consumers already face difficult decisions regarding their Medicare coverage options and should be allowed to focus on these diverse coverage options without the added complications of considering add-on health products that may in fact duplicate Medicare coverage.

In addition, we fear that there may be broad exceptions read into this requirement concerning pre-existing relationships with both plans sponsors and agents that would undermine its intent. For example, will companies that already sold a particular beneficiary a product be allowed to market other products offered by the same company (e.g. target current PDP enrollees for MA enrollment), and will agents who have already sold a product to someone be allowed to market health and non-health related products to the same individual all at once? We believe that an agent who has a pre-existing relationship with an individual client can come back later to sell other products; any hardship experienced by an insurance agent is far outweighed by the beneficiary protection against being sold multiple, complicated, and often unrelated products at once.

(g) scope of sales appointment

We appreciate CMS’ efforts to limit the scope of the sales appointment to health care products agreed to in advance and that the plan is required to document this scope prior to the appointment. Documentation of the scope of the sales appointment should be completed by the plan (or its agent) prior to the appointment and should not merely be an acknowledgement form that the beneficiary is required to sign. The document should not simply be a protection for the plan without providing meaningful protection for the beneficiary. Once a sales appointment has begun, agents have the opportunity to employ high pressure sales tactics to both sell an unsuitable plan and obtain the beneficiary signature on an acknowledgement.

(h) 48-hour cooling off period

We appreciate CMS’ effort to impose a cooling off period related to in-home appointments. We believe that this is a step in the right direction, but will generally only protect individuals who are certain ahead of time what type of plan they wish to consider (e.g., “I want a Part D plan and I don’t want to talk about anything else”).

(k) location of sales presentations and application collection

We appreciate CMS' efforts to prevent sales activities in provider offices or other places where health care is delivered, but we ask CMS to more clearly define "health care setting" in regulatory language. We would urge CMS to expand this prohibition to include educational activities sponsored and/or delivered by plan sponsors in these settings as well (also see discussion below in (l) concerning sales v. educational events). In addition, in order to curtail marketing abuses occurring at pharmacies (or in close proximity to them), we believe that CMS should prohibit any sales, education and application collection at pharmacies. If pharmacies are located in larger retail stores, such activity should also be prohibited in any part of the retail store.

(l) conduct at educational events

We appreciate CMS' efforts to restrict sales activities at educational events, however we are concerned that all too often the distinction between these different activities are blurred when agents are in the field trying to generate business, and may not be subject to appropriate oversight and monitoring by CMS and plan secret shoppers. We believe that the definitions of "education" and "marketing" that appear in CMS' Marketing Guidelines should be included in the regulatory language (further, we are concerned that the definition of "educational events" in the preamble may inadvertently narrow the definition of educational activity, in part, by implying that such events by necessity have multiple vendors).

Beneficiary advocates have reported numerous instances of agents and brokers offering to provide and/or advertising "educational events" about "Medicare changes" or "Medicare Part C" (or other similar general topics) at senior housing complexes or other facilities, only to end up distributing and collecting plan applications. Sales activities at these events often lead to mass enrollments of beneficiaries, which usually reflect insufficient time spent with each prospective enrollee to determine whether or not the particular plan is his/her best option.

We note that the Marketing Guidelines require that flyers and invitations to sales presentations must include statements such as "a sales representative will be present with information and applications." We propose that this requirement be included in the regulations, along with a corresponding requirement that flyers, invitations and any verbal descriptions of presentations intended or pitched as "educational events" contain language to the effect that "this is an educational event only and no sales activity will be conducted, including the distribution or collection of plan applications."

In addition, plans and their agents should report both sales and educational events to CMS so that CMS and plan secret shoppers can be present and enforce the prohibition on marketing at educational events.

(m) plan names

While we appreciate CMS' attempt to address confusion surrounding plan names by prohibiting the use of names that "suggest a plan is not available to all Medicare beneficiaries", we are disappointed that there is an exception to this rule, and that CMS is not doing more to reduce general confusion in the marketplace caused by MA and Part D plan names. By grandfathering in plan names that were in effect as of a certain date, CMS continues to allow plans to use the name "senior" or other designations that discourage enrollment by individuals under 65 who are eligible for Medicare based upon disability. We believe any inconvenience or confusion experienced by current enrollees of those plans following a name change (e.g., eliminating "senior") would be far outweighed by reducing the current confusion of prospective enrollees who face myriad choices of plan names, many which now are specially tailored to specific populations (e.g., special needs plans for individuals with certain disabling or chronic conditions).

We believe CMS should take further steps to address the bewildering range of plan names. The sheer number of plan offerings coupled with plan names that have nothing to do with the delivery of health care (e.g., gold, golden, silver, green, secure, advantage, senior, complete, duet, etc.) exacerbate confusion in an already confusing Medicare marketplace. In some cases, a company may offer multiple plans of the same type, using a similar name; in other cases, plans have used names that have mislead consumers as to the type of plan, or the availability of providers affiliated with the plan. We believe that CMS should prevent plans from using similar names for multiple products as well as names that can mislead prospective enrollees about who can enroll (e.g. "senior") as well as services and providers available through the plan (e.g., "any provider, anywhere"). At a minimum, CMS should require plans to add a parenthetical plan type designation at the end of the plan name in advertising and pre-enrollment marketing materials (e.g., ABC Plan HMO).

(o) other activity prohibited in marketing guidelines

Marketing Protections for Limited English Proficient Beneficiaries

We are very concerned that the proposed rules do nothing to strengthen regulation of marketing to limited English proficient beneficiaries. It is the experience of advocates that some of the most egregious and common marketing abuses have been inflicted upon limited English proficient beneficiaries. We urge CMS to adopt additional provisions in its standards for marketing at §423.2268 so that beneficiaries targeted by plans understand what they are being asked to buy. Note that these proposals are distinct from our proposal for changes in §423.2244(e) with respect to translations required by Title VI obligations. Rather, they are basic consumer protection provisions to prevent misleading or fraudulent marketing that should be adopted without regard to and in addition to Title VI obligations.

First, we urge that CMS require that, regardless of the percentage of population in a plan's service area that speaks a particular non-English language, any plan sponsor that

chooses to market a plan or plans in a language other than English through mass media (billboards, magazine and TV ads, etc.) must also have vital documents such as the Annual Notice of Change, application forms, Explanation of Coverage, formularies and summaries of benefits in the languages in which they advertise.

Second, to ensure that such individuals understand what is being marketed, we urge CMS to adopt regulations that require that, for any marketing or sales presentation conducted in whole or in part, in a language other than English, vital documents must be provided to beneficiaries in the same language as the presentation.

These two requirements do not force plans to market in any language. They merely provide basic consumer protections if a plan chooses to do so. As such, they are comparable to requirements of the U.S. Food and Drug Administration with respect to food labeling. That agency requires that all foods be labeled in English. It permits additional labeling in a non-English language but requires that if any representation on a food label is made in a non-English language, then all required information on the label must be in that language as well as in English. See 21 CFR §101.15(b)(3).

To implement these proposals, we suggest inserting the following into §423.2268, prior to the current subsection (o):

In conducting marketing activities, a Part D plan may not—

* * *

(o) Market a plan through mailings or mass media in a language other than English without having available vital documents such as application forms, Evidence of Coverage documents and Summary of Benefits translated into each languages in which the plan is marketed. For purposes of this subsection and subsection (p), the term “vital documents” shall mean all plan documents and correspondence for which CMS has established model or required language and other documents which CMS may designate in accordance Title VI policy guidance issued by the Office of Civil Rights of the Department of Health and Human Services.

(p) Conduct any in-person marketing in a language other than English without providing vital documents in all languages in which the plan is marketed.

Other Marketing Protections

In addition to the marketing rules articulated in these proposed rules and in CMS’ Marketing Guidelines, there are other steps that CMS and plans can take to ensure that Medicare beneficiaries are making informed decisions about how they wish to access their health coverage. We propose the following measures:

Implement reporting requirements that enable plans and CMS to identify and prevent mass enrollments (i.e., multiple enrollments at one location in a short period of time, e.g.

after a sales presentation). Mass enrollments at sale presentations should trigger increased plan efforts to verify suitability of the product for the new enrollee and should be discouraged or barred in the commission structure for agents. When multiple enrollments are made at one event over a short period of time, there is often insufficient time for agents to explain products to and answer questions from individual enrollees.

Plans should monitor monthly enrollment figures for individual agents in order to ensure that high production does not indicate a failure to adequately explain suitable coverage options to consumers. Commissions, production bonuses and other compensation offered by plan sponsors create incentives for agents to maximize sales volumes, but high monthly enrollment figures may signal unsuitable sales. Plan sponsors need to monitor high volume agents and agencies to ensure that they are following the plan sponsor's suitability guidelines and Medicare marketing rules.

Prospective enrollees should be presented with other options to learn about their full range of Medicare-related plans, such as SHIP counselors. MA and Part D sales should follow existing Medigap rules concerning statements about referrals to counseling assistance (see, e.g., NAIC Model to Implement the NAIC Medicare Supplemental Insurance Minimum Standards Model Act, Section 18A).

Enrollees should be told when their enrollment is effective and that they can change plans prior to the effective date. We also believe that it is important, with the inherent pressure of in-person selling, that beneficiaries have an opportunity for buyer's remorse. We propose that for any in-person enrollment in a Part C or D plan by a broker or agent, the agent must verbally and in writing, inform the beneficiary of the effective date of the election and of the fact that the beneficiary may change plans at any time prior to that effective date.

vi. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§§422.2272, 423.2272)

(a) allocation of marketing resources

While we appreciate that subsection (a) requires that MA plans demonstrate that marketing resources are allocated to marketing to both Medicare beneficiaries who are under 65 and disabled as well those 65 and over, we reiterate our objections stated in the discussion re: §§ 422.2268 and 423.2268(m) above that the discriminatory names of certain plans (such as "senior") are grandfathered.

(b) confirming enrollment and understanding

We note that subsection (b) requires plans to "[e]stablish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan and understand the rules applicable under the plan." Since this provision is not discussed in the preamble to the proposed rule, we are uncertain about what is required by this provision. For example, does this mean that current rules applicable to PFFS plans, such

as out-bound verification calls, will now apply to all MA plans? If so, we acknowledge that this is certainly a step forward, but urge CMS to impose more stringent standards concerning verification calls. For example, plans should be prohibited from offering any financial or other incentives to plan representatives conducting such calls based upon retention of new enrollees. Further, such plan representatives should have adequate training to handle questions that may arise off-script and plans should be able to handle all prospective and current enrollees with limited English proficiency. It is particularly important that, with respect to MA plans, such calls include confirmation of an understanding by the beneficiary of requirements concerning use of in-network providers.

(c) licensed agents and state appointment laws

We support the inclusion of state licensure requirements for agents in these regulations. As an additional consumer safeguard and means of tracking agent activity, we believe that all MA and PDP enrollment applications should include the National Insurance Producer Registry (NIPR) license number.

We appreciate CMS' recognition of the importance of state agent appointment laws, but we are concerned about and disagree with CMS' continued position that such laws are pre-empted under federal law. By preventing the application of any state fees pursuant to the state appointment process, and requiring plans only to report to states that they are acting "consistent with the appointment process" may undermine states' ability to enforce their own appointment laws. We believe that CMS should revise this section to clarify that state agent appointment laws are enforceable against MA and Part D plan sponsors.

The preamble indicates that CMS will not require plan customer service representatives (CSRs) who provide benefit information, answer factual inquiries from beneficiaries and process enrollments to be state-licensed insurance producers. This exemption is appropriate if plans do not tie compensation of CSRs to enrollments processed (or retention of current enrollees) and are not steering beneficiaries to specific products. This exemption does not preclude CMS from requiring plans to provide adequate training of CSRs on Medicare rules and plan benefits, similar to the training required of marketing agents.

vii. Broker and Agent Requirements (§§422.2274, 423.2274)

(a) agent/broker commissions

We are pleased that CMS is seeking to regulate compensation that plan sponsors pay agents and broker selling their products, since it is our belief that compensation paid to agents is a prime factor behind the epidemic of marketing misconduct occurring since early 2006.

We urge CMS to more clearly define "commission or other compensation" in regulatory language. We suggest that the term "commission" be defined as "any compensation paid to an agent or broker for the sale, enrollment, or renewal of a Medicare beneficiary in an

MA plan [or Part D plan, where applicable], including any production bonus or other incentive amount paid to the agent or broker for marketing activities.” This definition should also clearly include any trips, goods or other incentives plan sponsors routinely use to push agents and brokers to maximize enrollment.

We would like CMS to clarify the provision in subsection (a)(2), which implies that commissions must be the same for all plans and all plan product types offered by the organization’s or sponsor’s parent. While language in the preamble is somewhat clearer, we believe that this provision should be more clearly defined in regulatory language in order to prevent alternate interpretations by plan sponsors. Furthermore, while we believe this provision is certainly a step in the right direction since it would apparently prohibit plans from offering higher commissions for one of their products (e.g. a PFFS plan) vs. another of their products (e.g. an HMO), there is nothing in this proposed rule preventing plan sponsors from paying higher commissions for their MA line of business vs. their Part D line of business (if they provide both). Further, nothing prevents plan “A” from paying much higher commissions for their products than plan “B”, which could provide agents with continuing incentives to sell “A’s” products over “B’s” regardless of whether it is the right product for an individual client.

In order to truly minimize agent financial incentives to steer people to certain plans based upon their own financial gains, we believe that CMS should set a maximum level for all commissions for both MA and Part D plans. Absent establishment of a standard and level commission for all such products, CMS should set a range of limited compensation and impose an overall limit. CMS actuaries have access to information necessary to enforce this through the plan bid process.

(b) agent/broker training and (c) testing

We appreciate that CMS is extending current requirements applying to agents selling PFFS plans to agents selling all MA and Part D plans.

We are concerned that training is not comprehensive enough and testing is not rigorous enough. Training should include how MA and Part D plans coordinate, if at all, with other kinds of insurance, such as Medigap, retiree and each state’s Medicaid program where the plan’s products are sold. Agents should also be trained about the dangers that beneficiaries might lose current coverage through other sources if they enroll in an MA or Part D plan. Further, agents should be trained with state-specific information, including, for example, eligibility for state-specific programs and Medicaid programs (including whether a state’s Medicaid program covers coinsurance for MA plans). Agents should also be trained in cultural competency, as well as how to address issues related to limited-English proficient beneficiaries, and beneficiaries with disabilities, including cognitive impairments.

(d) CMS and (e) state requests for information

This requirement should be expanded to require plan sponsors to cooperate with state inquiries even when the identity of the licensed (or unlicensed) agent is unknown. Reports of abusive marketing from consumers often do not include information that can identify the producers. With information about the enrollee, plans can provide states with information regarding the agent that produced the enrollment, and states can take appropriate disciplinary action if warranted.

viii. Employer Group Retiree (§§422.2276, 423.2276)

We are concerned that marketing materials developed by MA plans for members of an employer group are not subject to CMS prior review and approval, even though some PFFS plans submit bids to offer coverage to retiree plans. The marketing information that plan sponsors submit to employers is often incomplete and contains the same gaps in information as materials provided to enrollees. Many SHIP programs report hearing from retirees who have been put into PFFS plans, but are profoundly confused about how these plans work. We believe that marketing materials for employer groups should be subject to CMS prior review in order to ensure that plans are providing at least the minimum in accurate, important information about plan structures, provider access and benefits.

We thank CMS for the opportunity to submit these comments on the proposed rules.

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