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ATTN: CMS-4085-P  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
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Submitted Electronically: <http://www.regulations.gov>

**RE: Notice of Proposed Rulemaking (Pub. Oct. 22, 2009)  
42 CFR Parts 417, 422, 423 et al.**

To Whom It May Concern:

The Medicare Rights Center submits the following comments to the Notice of Proposed Rulemaking (NPRM) published on Oct. 22, 2009. The Medicare Rights Center is a national, non-profit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. We thank CMS for the opportunity to submit these comments.

Our comments are organized in accordance with the Table of Contents to the NPRM.

### **Overarching Comments**

#### **Steps Toward Improving Plan Performance and Consumer Choice**

The Medicare Rights Center agrees with the overarching goals for the Part D and Part C programs articulated in the proposed rule to establish a clear set of rules of the road for Part D and Part C plans and a comprehensive set of protections for people with Medicare enrolled in these plans.

In particular, the Medicare Rights Center supports CMS proposals to clarify its authority to terminate Part D and Part C plans for failing to meet *any* of the requirements established by CMS or for falling short on performance measures related to the delivery of safe and effective health care. Consumers will benefit from having a more manageable array of plan choices that includes only those plans that meet the highest standards.

In addition, the Medicare Rights Center fully supports CMS’ proposal to require all Medicare Advantage (MA) plans to establish an out-of-pocket limit covering all Medicare services. This will provide important financial protection for consumers in poor health who may require extensive medical treatment and ensure that MA plans can no longer design benefit packages that discriminate against people with Medicare who are in poor health.

This protection, along with limitations on cost-sharing for particular services or prescription drugs, move the Part C and the Part D programs toward a system that allows consumers to make apples-to-apples comparisons among like plans. Such standardization allows consumers to focus on key decision points—premium levels, provider access and plan quality, that enables consumer choice to drive system-wide improvements in plan quality and efficiency. The Medicare Rights Center looks forward to working with CMS on further improvements to the program that will benefit consumers and the Medicare program.

The Medicare Rights Center also recommends that CMS take the following steps to improve program transparency and ensure consumers with limited English proficiency have appropriate access to languages services.

Beneficiaries and their advocates require complete access to CMS guidance materials:

In a number of places throughout the NPRM, CMS indicates that it will make information available through Health Plan Management System (HPMS) memoranda. For example, CMS indicates it could use HPMS to announce the methodology and amounts for acceptable out-of-pocket caps and cost-sharing, and to distribute standardized marketing materials.

We ask that such information be made available through the Call Letter and other public documents, and that information sent via HPMS (with the exception of privileged communication with specific plans) be made publicly available on CMS’ website. Access to HPMS memoranda is currently restricted to plan sponsors. Information provided to plan sponsors through HPMS is not routinely made available to beneficiaries and their advocates. When HPMS is used to communicate beneficiary-related information, advocates are denied the opportunity to respond to any requests for comments and are denied immediate access to information they need to assist beneficiaries.

CMS should issue regulations concerning language access:

We endorse the concerns raised by the National Senior Citizens Law Center (NSCLC) in its comments to these proposed regulations over the absence of specific requirements with respect to either interpreter services or written translations of marketing documents and other plan communications with beneficiaries. We agree with their proposed regulatory language as well as their comments about the importance of CMS enforcement of current Section 30.6 of the Medicare Marketing Guidelines.

## **II. A. Changes to Strengthen CMS Ability to Distinguish Applicants**

- **Notice of Intent to Apply (§ 422.501 and 423.502)**

We support the proposed changes 1) to require applicants to demonstrate that they have met all requirements outlined in the MA/Part D applications; and 2) to decline to consider materials submitted after the 10 day period following notice of intent to deny an application.

The first proposed change protects Medicare beneficiaries by emphasizing the importance of following all Medicare rules, without an organization making its own determination that some rules are more important than others, or that some rules can be ignored. The second proposed change ensures that an applicant organization is committed to the Medicare program and has the administrative capacity to provide additional information when requested.

- **Deny Applications Based on Past Contract Performance (§ 422.502(b) and 423.503(b))**

In order to ensure that only high-quality plans are participating in Part C and Part D, it is critical for CMS to take into consideration the past performance of plan sponsors and organizations, including their completion of a previous corrective action plan. Since the MA and Part D programs have been in existence, there have been some consistently poor-performing plans that have been allowed to continue in the program. This provision protects beneficiaries by giving CMS greater authority to weed out poor-performing plans out of the programs.

- **54644: Network Adequacy (§ 422.112)**

CMS proposes to compare a plan's proposed network with the prevailing community patterns of health care delivery in the service area of the plan. We agree that community patterns of health care delivery provide a good general benchmark. We caution CMS to recognize that distinguishing between urban and rural settings may not be an accurate measure of adequacy, however. Vulnerable beneficiaries living in urban areas where the percentage of providers is higher may have just as much difficulty in accessing care as do rural beneficiaries, particularly if they do not have access to adequate transportation.

To address the needs of the most vulnerable beneficiaries, regardless of where they live, we ask CMS to include the following factors which are derived from access standards for Medicaid managed care plans (§ 438.206):

1. The mode of transportation regularly used by Medicare beneficiaries, particularly those who are dually eligible for Medicare and Medicaid and those who rely on transportation for older and disabled individuals. Beneficiaries who rely on public transportation have difficulty accessing providers that are not on public transportation routes. They may not be able to get to such providers even if the providers are located within the 30 minute/30 mile benchmark for people who travel by car. Additionally, even for providers who are accessible by public transportation, travel time by public transportation may be substantially longer than travel time by car, exceeding 30 minutes when car travel would be within the benchmark. Finally, some transportation programs for older and disabled individuals, particularly those offered by independent and assisted living facilities, have a more restrictive mileage limit than 30 miles. Beneficiaries who rely on this mode of transportation are not able to access providers within the current mileage benchmark.

2. Whether the location provides physical access for enrollees with disabilities. By definition, the Medicare population includes a higher percentage of individuals with chronic conditions and functional limitations that may preclude them from accessing providers who otherwise meet the CMS access standards. Plans that service this population, particularly SNPs for people with chronic conditions, need to ensure that their provider network can accommodate people with disabilities.
3. Delivery of services in a culturally competent manner. Plans should be required to ensure that their networks include sufficient providers who can deliver services in a culturally competent manner to all of the populations within the service area, including providers who offer specialized services utilized by relevant populations. Plans should have mechanisms in place to ensure that they and all of their network providers can offer services to enrollees with limited English proficiency.

We request that these additional factors be included in regulatory language, paralleling the Medicaid regulations.

- **Corrective Action Plans (§ 422.506(b)(3); 422.510(c)(1); 423.507(b)(3); 423.509(c)(1))**

We agree that CMS should focus on the outcome of a corrective action plan (CAP), rather than the development of the plan. The proposed regulation would accord the MA organization at least 30 calendar days, instead of 45 days, in which to develop and implement a CAP.

- **Procedures for Imposing Intermediate Sanctions and Civil Money Penalties (§ 422.756; 423.756)**

CMS is proposing two changes to the rules for intermediate sanctions and civil money penalties under Parts C and D: 1) requiring plans to hire an independent auditor to give information to CMS, and 2) requiring the plan to undergo a “test period,” so that CMS can determine whether it should lift the sanction. These are improvements over the current system.

## II. B. Changes to Strengthen Beneficiary Protections

- **Broker and Agent Requirements under Parts C and D.**

CMS solicits comments on the capacity of SHIPs to serve additional beneficiaries. The Medicare Rights Center works closely with the New York HICAP program and with SHIPs in other states. Without additional resources, it is unlikely that SHIP programs can handle significantly more beneficiaries. We have heard from many programs that the current AEP is particularly onerous due to substantial changes in both MA and prescription drug plans (PDPs). Several states report that the demand for help exceeds their capacity to assist beneficiaries. We refer to the comments submitted by the Health Assistance Partnership and the National Council on Aging for further detail.

We recognize that providing additional funding and resources for SHIP programs may take legislative action. CMS can help, however, through its efforts to limit the number of plan

options and to provide standardization among benefit packages. These changes would make it easier for SHIP volunteers to understand the options that are available in their communities and would reduce the amount of time it takes to analyze options and find the best plan for each person. Each SHIP program would then be able to serve more beneficiaries.

CMS also seeks comments on whether the use of brokers and agents should be limited to certain times of year (open enrollment and annual enrollment periods), or to selected groups of beneficiaries, to better focus CMS monitoring. We share CMS' concern that agents and brokers have inherent financial incentives when selling Medicare products. In addition to these financial incentives, we still find agents and brokers who are not adequately informed or trained to counsel Medicare beneficiaries on all their options. They may be knowledgeable about the plans they sell but not about all plans available to Medicare beneficiaries. They may not be knowledgeable about eligibility for Medicare Savings Programs and other state Medicaid programs, and how these programs interact with Part C and Part D plans.

Limiting agent/broker activity to the AEP and OEP would have only a small effect on the incidences of marketing misconduct. The limitation would protect dual eligibles, who can change plans at any time, others with Special Enrollment Period rights, and newly eligible Medicare beneficiaries. However, agents and brokers already target their efforts during these two enrollment periods. Much of the marketing misconduct occurs during the AEP and OEP.

In addition, we recommend instituting the following protections:

- Require any beneficiary's change of Medicare-related plans (Part D, MA, Medigap) performed with the assistance of an agent/broker to be accompanied by a Replacement/Suitability Form to be completed by the agent. This would require the agent to articulate in writing why a proposed change in plans would purportedly benefit the Medicare beneficiary. Such forms, required in some states when Medigap policies are being changed, serve as an added layer of protection for beneficiaries (and accountability for agents).
- CMS should require all agents to use their National Insurance Producer Registry (NIPR) number when selling Medicare products so that individual agents and sales can be tracked more easily.

- **Required Use of Standardized Materials Under Parts C and D** (§ 422.2262 and § 423.2262)

We have previously requested that CMS require plans to use standardized marketing material language and format when such materials have been developed by CMS. We believe such communication materials help beneficiaries understand how their current benefits and cost-sharing requirements will be changing and help them compare their current plan with other plan options.

We caution CMS that standardized materials should be sufficiently tailored to the intended recipients, particularly dual eligibles. For example, current materials about MA plan

terminations are not tailored to dual eligibles enrolled in those plans and have created a great deal of fear and confusion.

Additionally, we request that beneficiary advocates have an opportunity to review and provide input into the development of standardized materials. We also ask that the materials be distributed through a system that is open and transparent to all interested parties, including advocates and state agencies.

- **Involuntary Disenrollment for Failure to Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)**

CMS proposes to increase the grace period required prior to involuntary disenrollment for failure to pay plan premiums under Parts C and D from one month to two months. The proposed language says “at least” two months. We ask you to add language that says an organization or sponsor may offer a longer time period.

- **Maximum Allowable Out-of-Pocket Cost Amounts (§ 422.100)**

CMS proposes to improve beneficiary protections by limiting cost sharing in several ways. First, all local MA plans would be required to have an out-of-pocket (OOP) maximum for services covered by Medicare Parts A and B, and the maximum would have to meet an annual limit set by CMS. Second, MA plans would be precluded from imposing cost-sharing for A and B services that is higher than levels CMS determined annually to be discriminatory. Third, MA-PDs and PDPs would be precluded from establishing tiered cost sharing for prescription drugs that exceeded levels annually determined by CMS to be discriminatory. These requirements would prevent plans from using discriminatory benefit designs that disadvantage and discourage enrollment by individuals in poor health with higher than average use of health care services. These benefit parameters would also bring some level of standardization to MA plans and PDPs, making it easier for beneficiaries to compare their potential out-of-pocket liability under different plan options.

We support CMS’s proposal to require all MA plans to establish a out-of-pocket maximum for all A and B services at, or below, a threshold level determined annually by CMS. It is impossible for beneficiaries in poor health to predict what combination of services or products—hospitalization, outpatient hospital care, treatment with Part B drugs, radiation therapy or durable medical equipment—they may require during the course of a plan year. The best protection against potentially bankrupting medical expenses is a comprehensive out-of-pocket limit, and beneficiary counselors advise their clients to look for such a limit when selecting an MA plan. As a result, plans without such a limit are less likely to receive enrollment from beneficiaries with above-average need for services when consumers are aware of the important protection provided by an out-of-pocket limit. When consumers are not alerted to look for the presence and level of an out-of-pocket limit, those in poor health may face out-of-pocket costs that threaten their financial security and jeopardized their access to care.

A regulatory requirement to provide an out-of-pocket limit is necessary because CMS’ efforts to use the annual Call Letter and the benefit review process to encourage provision of a out-of-

pocket cap have not been fully successful. While the terms of the 2010 Call Letter did result in additional plans establishing an out-of-pocket limit at the CMS-recommended threshold, there remain many plans that do not include such a limit in their benefits (and leave enrollees liable for high out-of-pocket costs for coinsurance), establish a limit well above the CMS-recommended level or exclude some A and B services from their out-of-pocket caps. These benefit designs discourage enrollment by beneficiaries with high health care needs, particularly when there are alternative plans with out-of-pocket caps at, or below, the CMS-established threshold. Plans that advertise an out-of-pocket cap, but exclude important services, are particularly confusing to consumers. § 422.100 should be clarified to ensure that all Part A and Part B services are included in the out-of-pocket cap. We often encounter beneficiaries with large medical expenses who were unaware that the services they require are excluded from the out-of-pocket maximum advertised by the plan.

We note that, in the 2010 Call Letter CMS established an out-of-pocket threshold that represented the 85<sup>th</sup> percentile of projected beneficiary spending in 2010. While it is important that CMS establish a threshold that provides a cap benefiting a significant percentage of Medicare beneficiaries, consideration should also be given to establishing a threshold that ensures access to care remains affordable to low and moderate income beneficiaries. Almost half of all Medicare beneficiaries have incomes at or below 200% of the federal poverty level. We suggest that, in future years, should health care reform legislation be enacted, CMS consider an out-of-pocket limit that accords with cost-sharing protections to consumers of similar income levels who purchase insurance through any health insurance exchange. Beneficiaries who are enrolled in MA plans should not be required to pay more out of pocket than younger populations who receive health insurance through the new health care marketplace.

- **Maximum Cost-Sharing Amounts (§ 422.100; 423.104)**

We support CMS' proposals to establish maximum allowable cost-sharing amounts for Parts A and B Services and for prescription drugs.

We urge CMS to clarify that the authority made explicit in 422.100 will continue to be used in the annual Call Letter to prohibit MA plans from imposing cost-sharing greater than Original Medicare for specific services, including dialysis, chemotherapy and other Part B drugs and skilled nursing facilities. An assessment of whether a benefit design is discriminatory must be made by both comparing MA plans to Original Medicare and other MA plans.

One important protection would be to preclude plans from requiring "up-front" cost-sharing. For example, a plan currently may charge a daily co-payment for the first 20 days of skilled nursing facility care (SNF) (where traditional Medicare charges no co-payment), and less than traditional Medicare charges for days 21-100. Because most people do not receive 100 days of Medicare SNF coverage, the beneficiary may pay more in the MA plan than in traditional Medicare, even with an out-of-pocket limit.

CMS also asks for comments on the approach it intends to take to determine maximum levels of cost sharing. The process to be used needs more clarity. We are particularly interested in understanding how CMS would evaluate the prior year's experience. Cost-sharing on its face

may not seem discriminatory, and may be offered by a large number of sponsors, but may have a discriminatory effect. The above example concerning how MA plans assess cost-sharing for SNF care is a good example. On its face the cost-sharing under a plan that assesses a co-payment for the first 100 days of SNF care may not seem to exceed cost sharing for 100 days of SNF care under traditional Medicare. But when claims data for SNF benefits under the plan are analyzed, they may show that the overwhelming majority of beneficiaries only receive 20 days of SNF care, for which they would have had no cost sharing under traditional Medicare.

Similarly, MA plans that impose a per-day charge for inpatient hospital stays should be evaluated to determine whether the total in per-day charges is significantly higher than the deductible under Original Medicare or than per-day charges under other MA plans for beneficiaries requiring lengthier hospital stays.

In addition, § 423.104 should be clarified to ensure that all tiers, including specialty tiers, may not exceed the levels determined by CMS to be discriminatory. In particular, cost-sharing under the non-preferred tier can be discriminatory when its co-payments or coinsurance exceed the standard coinsurance rate of 25 percent and the tier includes drugs or biologics for which there is no therapeutic equivalent on a preferred or generic tier. We have particular concern about plans that use the non-preferred tier when coverage of non-formulary drugs is secured on appeal. In some cases, cost-sharing under the non-preferred tier can approximate, or even exceed, the negotiated price of the drug. That means that, after clearing the substantial hurdles required to secure a drug on appeal, the beneficiary pays nearly the same, or exactly the same amount, as she would if she paid the full price for a non-formulary drug. We recommend that CMS require plans to use the standard coinsurance rate, for example on the specialty tier, for non-formulary drugs covered on appeal.

- **Prohibition on prior notification by PPO, PFFS and MSA Plans (§ 422.2, 422.4, 422.105(b))**

We thank CMS for proposing to prohibit PPO, PFFS, and MSA plans from providing for lower cost-sharing where prior notification rules have been satisfied. We agree with CMS that this requirement is confusing and misleading. We have found several plans that charge exorbitant cost-sharing requirements (up to 75%) for expensive items such as durable medical equipment when requirements have not been met, essentially denying coverage for medically necessary, Medicare-covered items and services.

- **Requirements for LIS Eligibility Under Part D (§ 423.773)**

We agree that the proposed change will help streamline the deeming/redeeming process. It will assist in the continuity of LIS-eligibility for affected individuals.

CMS also requests further input on auto-enrollment procedures. While there have been improvements over the last three years (including the new LI NET program which we hope will represent an improvement), we remain concerned about the impact that the random auto-enrollment and reassignment processes have on low income Medicare beneficiaries – particularly

dual eligibles. We have four general concerns that we do not believe will be addressed by the new LI NET program:

1. Enrollment Delays. Even with recent system upgrades that were implemented as part of the settlement in the class action lawsuit in *Situ v. Leavitt*, the time it takes to provide dual eligibles with Part D coverage remains too long. Delays in enrollment result in coverage gaps that can be life threatening to individuals who simply do not have the means to incur, even temporarily, out-of-pocket costs. CMS should be working to refine CMS, state and plan systems to improve the speed of this process.

We recommend several policy changes as steps to addressing delays.

- CMS should promulgate regulations requiring states to transmit state MMA files more frequently than once per month. Over 20 states have already elected to submit files more than once per month. More frequent file transfers are critical to ensuring that dual eligibles are enrolled into plans quickly.
- Second, CMS should require states to continue to provide Medicaid coverage to a dual eligible until the individual's Part D enrollment actually takes effect. Even with prospective enrollment systems we continue to hear stories of individuals who have Medicaid first and then become Medicare eligible experiencing gaps between the time their Medicaid drug coverage stops and their Medicare drug coverage begins. Requiring states to continue to provide coverage would not be inconsistent with CMS' interpretation of the statute. The effective date of enrollment in Part D and termination of the Medicaid benefit would still be the first day of dual eligibility. States would provide the benefit until Part D enrollment was confirmed. States would then be liable for returning any federal financial participation (FFP) received (as they are already required to do for any retroactive benefits they provided to a dual eligible), and Part D plans would be responsible for reimbursing states (as they are already required to do for any retroactive benefits provided by a third party payer).
- Finally, CMS should make adjustments to current disenrollment procedures. In the last year we have heard a number of stories of dual eligibles who were disenrolled from plans, but not immediately re-auto-enrolled into a plan resulting in a significant coverage gap. This gap seems to occur when plans submit disenrollment information after CMS has conducted its early month auto-enrollment sweep. Requiring plans to provide advance notice of potential disenrollments of duals could help. Plans could also be required to submit disenrollment information in advance of the auto-enrollment sweep.

2. Random auto-enrollment and reassignment. The surest way to maximize the auto-enrollment and reassignment process is to enroll beneficiaries into plans that actually cover their drugs. We

have heard from some CMS contractors that beneficiary-centered assignment or reassignment is currently possible. Studies have shown that beneficiary-centered assignment would actually save money. We understand that the agency has, in the past, held the opinion that the statute prohibits assignment or reassignment that considers the drug needs of the beneficiary. We disagree with this interpretation with regard to reassignment and hope that the agency will reconsider its approach with regard to reassignment.

Beneficiary-centered reassignment is not prohibited by the statute or its implementing regulations since the “random” assignment requirement found in each only applies to a beneficiary who had not yet enrolled in a plan. See 42 U.S.C. § 1395w-101(b)(1)(C) and 42 C.F.R. § 423.34(d). A separate regulation, 42 C.F.R. 423.34(c), provides CMS with the authority to reassign beneficiaries. This regulation makes no mention of the need for the reassignment to be random. To the contrary, the regulation implies that CMS is conducting the reassignment to protect the beneficiary and a non-random assignment is needed in this case to accomplish that goal. Ensuring the beneficiary is enrolled in a plan that covers their drugs is just as worthy a goal as ensuring they are enrolled in a plan with a premium below the benchmark.

In addition to protecting beneficiaries, beneficiary-centered assignment would incentivize benchmark plans to offer comprehensive and robust formularies. Plans that offer comprehensive benefits at low prices would be rewarded with enrollees while those plans that offer limited benefits would lose out on the automatic enrollments.

3. LIS recipients in non-benchmark plans. Over 2 million LIS recipients are enrolled in non-benchmark PDPs. This number is projected to rise to 2.5 million in 2010. This represents a significant number of individuals who are paying more for coverage than envisioned by the statute. It is our suspicion that, in most cases, LIS recipients affirmatively enrolled in these plans when they were benchmark plans. They remained in the plans after not being included in the reassignment process by virtue of their ‘chooser’ status. We encourage CMS to evaluate how choosers have been impacted by the current process. In particular, the agency should identify the number of choosers who: 1) affirmatively switch plans every fall; 2) affirmatively switch plans during the year; and 3) are involuntarily disenrolled due to non-payment of premiums.

4. Accurate, LIS specific information. To help LIS recipients make informed decisions, the notices they receive must be tailored to their circumstances. Too often, plan materials are written for non-LIS recipients with riders or brief notes that relate to LIS recipients. Given the prevalence of LIS recipients – both within the general Part D population and within benchmark plans – materials sent to LIS recipients should be tailored specifically to them.

- **Special Enrollment Periods Under Part D (§ 423.380)**

We thank CMS for expanding the special enrollment period for dual eligibles to all LIS-eligible individuals.

- **Transition Process Under Part D (§ 423.120(b)(3))**

We are pleased that CMS is proposing to include specific transition requirements in its proposed regulations. The availability of transition supplies of drugs is critical for care continuity for beneficiaries who change plans or whose plans change formularies. We support the proposal but suggest two changes to strengthen the proposed regulations.

First, we urge that CMS strengthen the current proposed § 423.120(b)(3) by providing the same transition protections to individuals requiring long term care in community-based settings as are provided to those living in institutions. Whether in an institution or in the community, these individuals have high needs and are medically vulnerable. They cannot change drug regimens quickly or easily and any adjustments to their prescription drugs must be undertaken with great care. Moreover, a consistent policy of regulatory neutrality in treatment of individuals who receive long term care services, whether in an institution or in the community, is essential to meeting CMS's broader goal of rebalancing long term care and facilitating home and community based options. We propose changing § 423.120(b)(3)(iii)(A) to say:

“In the outpatient setting, except as described in (B) below, . . .” and changing § 423.120(b)(3)(iii)(B) to say “for enrollees receiving long term care, whether in an institution or in the community . . .”

Second, we urge that CMS require plans to send out notices to individuals who receive transition supplies within three calendar days, rather than three business days. CMS has, throughout its guidance on Part D notifications, including most specifically on notifications about exceptions and appeals, moved away from setting deadlines in business days and set calendar day deadlines instead. We urge CMS to be consistent with that direction here as well. A calendar day requirement is clearer and easier to enforce. Moreover, beneficiaries use pharmacies 24 hours a day, seven days a week and plans need to be set up to handle transition notifications on the same schedule. Particularly during holiday periods, giving plans 3 business days to mail a notice, combined with the normal delays in the mails can severely cut into the time a beneficiary needs to try a different drug and/or request a formulary exception. For these reasons, we propose changing § 423.120(b)(3)(iv) to read “Ensure written notice is provided to each affected enrollee within 3 **calendar** days of the temporary fill.”

- **Part D Sponsor Responsibility For Retroactive Claims Adjustment Reimbursements And Recoveries (§ 423.464, 423.466)**

CMS proposes several changes to this section to address coordination of benefits among state pharmaceutical assistance programs (SPAPs) and Part D plans, particularly with regard to retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries.

We believe that new § 423.464(e)(1)(vi), which precludes an SPAP from engaging in midyear plan or non-calendar year changes on behalf of a substantial number of its members, is over broad. An SPAP should be allowed to make such changes where doing so is in the best interests of SPAP-eligible individuals, for example, when the Part D plan is not complying with its

contractual obligations to the SPAP or is not complying with its contractual, statutory, and regulatory obligations under Part D.

We ask that a reference to the time frames in § 423.466 be added to new § 423.464(g) (2), regarding reimbursement for excessive cost-sharing and premiums for low-income subsidy eligible individuals. We suggest amending the section to read,

“...have been processed in accordance with the timeframes in § 423.466(a) and in accordance with the requirements in § 423.800.”

However, while CMS did address coordination of benefits and reimbursements by plans to SPAPs and other health insurance plans, CMS did not address issues related to beneficiary reimbursements. Individuals who are eligible for LIS, either through direct application or as a result of being deemed through their application to a Medicare Savings Program or Medicaid, experience a delay in receiving the benefit as a result of the time it takes to process their enrollment. In addition, the start date for LIS benefit is one month retroactive the date of application. For this reason, a beneficiary's effective date of coverage will be earlier than when the beneficiary actually sees the benefits. Under § 423.800 (c), plans are supposed to automatically reimburse beneficiaries for the premiums and cost-sharing made during this period. Unfortunately, these automatic reimbursements often do not occur and when they do, they are late or otherwise problematic. Furthermore, although CMS proposed to codify timelines for coordination of benefits, no such timelines for reimbursements made under § 423.800(c) exist; this means that beneficiaries can go months or years before they receive reimbursements if reimbursements are even actually made.

CMS should revise § 423.800(c) to reflect the plan's affirmative obligation to automatically reimburse excess premiums and cost-sharing paid by current Part D members who newly qualify for LIS. Part D plans have the necessary information in their system to reimburse beneficiaries as required by § 423.800(c). Beneficiaries should not have to request this reimbursement. We propose 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 individual and organizations 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.

In addition, beneficiaries are often unaware that they are owed this money and as a result are unable to pursue the reimbursements on their own. CMS should require plans to notify

beneficiaries that this money is owed to them and this notification should include itemized accounting of the reimbursement. Sometimes, when a beneficiary actually does receive a reimbursement, the reimbursement includes both the money owed to them and to the SPAP. The beneficiary does not know that the reimbursement is an overpayment to them; this puts the beneficiary at risk of committing fraud if they deposit or cash this reimbursement.

Regardless of the complexities involved in the coordination of the benefits, plans are required to make these reimbursements to beneficiaries by law. Not doing so, for any reason, violates the plain language of the regulation.

- **Absence from Service Area for More Than 12 Months Under Part D** (§ 423.44)

We agree with the proposed change.

- **54663: Prohibition of Mid-Year Mass Enrollment Changes by SPAPs** (§ 423.464(e))

While we appreciate the desire of CMS to have SPAPs enroll on a cycle that is consistent with the Part D plan-year cycle, we are concerned that the proposed regulation, as written, goes farther than necessary to address the issue. Specifically, the proposed regulation imposes an absolute ban on mid-year mass disenrollments and enrollments by SPAPs, whether or not the SPAP has a justification for a mass change. SPAPs should have the right to change enrollments for beneficiaries mid-year if such a change reflects a determination by the SPAP that a plan is not serving its members adequately. We suggest that proposed § 423.464(e)(1)(vi) be changed to read as follows:

*Does not **routinely** engage in midyear plan or non-calendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf. **An SPAP may, however, conduct a non-routine mass enrollment change in situations where the SPAP has determined that such an enrollment change would serve the needs of its members and has provided CMS with prior notification of the reasons for such action.** (New language in bold.)*

This modification to the proposed regulation addresses CMS's concerns about routine mid-year disenrollments and also gives CMS an opportunity to engage in a dialogue with an SPAP planning a mass disenrollment, while allowing SPAPs the autonomy to make changes in unusual cases where they believe such action would best serve their members.

- **Nonrenewal Beneficiary Notification Requirement Under Parts C and D** (§ 422.506; 423.507)

We appreciate the return to the 90 day notification requirement. We also ask that notification requirements mandate different personalized notices to different populations, particularly dual eligibles. As stated earlier, the notices sent to dual eligibles this year did not address information

specific to dual eligibles. They contained incorrect information about continued Part D coverage and eligibility to purchase a Medigap policy, for example.

- **Notice of alternative Medicare plans available to replace non-renewing plans (§422.506(a)(2)(ii); 423.506(a)(2)(ii))**

We strenuously object to the proposed change that would allow plan sponsors and organizations to place outbound calls to enrollees in plans that they are terminating to tell them who to call to learn about enrollment options. This provision creates a major marketing loophole, and allows plans to steer enrollees to other plans offered by the same sponsors and organizations, regardless of whether those plans are best for them.

Beneficiaries need to be provided with information about all options, including returning to traditional Medicare. That information should be provided by CMS or by a neutral, trained counselor. Furthermore, CMS should make clear that any sponsor that markets plans when notifying beneficiaries of plan terminations will be considered to be violating marketing rules.

- **Timeframes and Responsibility for Making Redeterminations Under Part D (§ 423.590)**

We commend CMS for strengthening notice requirements concerning plan redeterminations under Part D. In all redeterminations, but especially for expedited redeterminations, it is imperative that the beneficiary be made aware of a plan's decision as soon as possible. For adverse redeterminations, this allows the beneficiary to initiate the next step of the appeals process in an expedient manner. However, CMS should specify that the time limit for appealing an adverse decision still begins according to the date on the notice. It is difficult to confirm oral notice and relying on the date of oral notice creates an opportunity for bad actors to misuse the system at the expense of the beneficiary.

In addition, we ask CMS to address issues related to plan escalation requirements. Under § 423.590 a plan is required to escalate appeals automatically to the Independent Review Entity (IRE) if the plan does not issue a decision in a timely manner. It is our experience that some plans fail to follow this requirement. We ask that CMS clarify in the regulation that while plans are always required to forward the information if decisions are not issued in timely manner, beneficiaries may also send a request for review to the IRE if they have not received a decision within the regulatory timeframe. In addition, we ask that CMS monitor plans and determine whether plans are escalating cases appropriately, and if they do not escalate cases as a result of the failure to meet regulatory timeframes, that plans are subject to sanctions.

- **Requirements for Requesting Organization Determinations Under Part C (§ 422.568)**

We appreciate CMS's receptiveness to concerns about the "absence of express regulatory authority allowing enrollees to request standard organization determinations both orally and in writing." This clarification will help to standardize the appeals process further and allow beneficiaries to more immediately access the appeals process. However, we are concerned about

properly tracking a beneficiary's oral request for appeals. Without any confirmation given to the beneficiary that the appeal has been received and initiated by the plan, if the plan does not issue a timely decision, it is difficult for the beneficiary to prove that the plan has not abided by regulatory timeframes, and as a result the case should be escalated to the next level of appeal. Please require the development of a mechanism by which a beneficiary may confirm an oral request for review by the plan.

- **Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§ 423.568)**

We have some concerns about the proposed modification to § 423.568(b), concerning the timeframe for a Part D sponsor to notify an enrollee of a payment determination. CMS proposes to extend from 72 hours to 14 calendar days the timeframe in which a plan sponsor can make a determination and make payment on a request for payment. While we recognize that the extended time period may prevent plans from automatically denying such a request in order to comply with the current 72 hour period, we remind CMS that paying out-of-pocket for the full cost of a prescription drug causes financial hardship for many beneficiaries.

For example, many beneficiaries must pay out of pocket when they are denied coverage because a drug is off-formulary or subject to a utilization management tool. For these individuals, the proposed regulatory change raises serious issues. Of particular concern for formulary denials is the fact that the 14 day coverage determination timetable pushes the entire appeals process back. Under current regulations, a beneficiary has the chance to get a decision from a decision-maker outside the plan at the IRE level well before a 30 day prescription runs out. Adding an extra eleven days to that process makes it highly unlikely that a beneficiary will get that decision in time.

- **Additional suggestions for amendments to Part C and Part D appeals regulations concerning appeal rights**

The Medicare Rights Center has previously requested CMS to consider other amendments to the Part C and Part D appeals regulations with regard to notice of appeal rights. We renew our request here.

- **Public Availability of Compendia Listings**

Under the current regulations, in order to obtain coverage for an off-label use, the drug's use must be favorably listed in specific compendia, or in the case of cancer drugs, in peer reviewed medical literature. However, subscriptions to these compendia and other materials are very expensive and the public and the IRE do not have ready access to these listings. For this reason, we ask that CMS require plans to include literature or compendia entries used in coverage determinations as part of the case file so it is available to both the IRE and the enrollee.

- **§ 422.562 General Provisions**

This section, which sets out an overview of the MA grievance, notice and appeal processes, should be amended to include information about the hospital and other provider notice and QIO processes (§§ 422.620 through 422.628). Without this information, the “overview” is misleadingly incomplete. This can be accomplished by the following:

1. Insert a new § 422.562(b) entitled **Responsibilities of MA providers**. This subsection should state that providers, including hospitals, must give their patients notices when services are denied, reduced or terminated as provided in §§ 422.620 to 422.628. The current §§ 422.562(b) through (d) should be renumbered as §§ 422.562(c) through (e).
2. An additional subsection should be added to the current subsection (b), **Rights of MA enrollees**. (This will be renumbered as (c), as stated above.) The new subsection, (c)(2), would state that MA enrollees have the right to receive information from their medical service providers, including hospitals, of the availability of processes for appealing provider decisions (as opposed to MA organization decisions) denying, terminating or reducing services. It would make reference to § 422.620 (hospital decisions); § 422.624 (SNF, HHA, CORF decisions); § 422.626 (fast track appeals to IREs); and the new § 422.626 (Part B services).

- **§ 422.565 Provider notice requirements** (new).

A new section is needed to describe the provider notice procedure at the appropriate place in the regulatory scheme (e.g., following the description of the grievance procedure and before the description of the organization determination procedure). The purpose of adding this section is to layout the full appeal process in a coherent sequence so that readers will understand how the provider notice requirements interrelate with the organization determination provisions.

1. The new § 422.565 would briefly reference the procedures set out in §§ 422.620 through 422.628 by which providers (including hospitals and Part B providers) are required to give notice when services are denied, reduced or terminated, and the situations in which IRE review is available.
2. An alternative to briefly describing these procedures here, and then continuing to describe them more fully at the end of Subpart M would be to move §§ 422.620 through 422.628 up to this place in the regulations.

- **§ 422.568(c) Standard timeframes and notice requirements for organization determinations**

The current § 422.568(c) erroneously and confusingly states that an enrollee is entitled to a written notice of an organization determination to discontinue or reduce the level of care for an ongoing services only when she “disagrees” with the decision. This provision effectively denies notice of appeal rights to enrollees in many situations. CMS has stated that it is only intended to

apply to Part B services, but nothing in this regulation states that it applies only to Part B rather than all Medicare services. Furthermore, even if it applied only to Part B services it would be unacceptable, as it is unclear as to how enrollees can register their wish to appeal and thus receive a notice.

1. § 422.568(c) should be amended to strike the phrase “or if an enrollee disagrees with an MA organization’s decision to discontinue or reduce the level of care for an ongoing course of treatment.”

- **§ 422.628 Notifying enrollees of Part B appeal rights.**

A provision is needed to give enrollees notice that they must request an organization determination from the MA in order to appeal an adverse decision concerning Part B services. The current lack of such information prevents enrollees from appealing adverse decisions about Part B services. This provision should parallel the notice requirements of § 422.620, **Notifying enrollees of hospital discharge appeal rights** and § 422.624, **Notifying enrollees of termination of provider services**

1. The new § 422.526, **Notifying enrollees of Part B appeal rights**, would describe how enrollees must be informed of the process for appealing denial decisions by Part B Medicare providers. These would include decisions that services requested by the enrollee will not be provided that are made by providers other than hospitals, SNFs, HHAs, and CORFs. Such Part B providers include physicians, physician assistants, nurse midwives, psychologists, nurse anesthetists, nurse practitioners, clinical nurse specialists, outpatient hospitals, providers of diagnostic tests, outpatient therapists, rural health clinics, federally qualified health centers, ambulatory surgical centers, providers of DME and prosthetic equipment, and ambulances.
2. The new section would state that when such Part B providers have decided that a requested service should be denied or, (if the service is part of a course of treatment), terminated or reduced, they must give the enrollee a written notice. The written notice would explain that if the enrollee wishes to appeal the denial, she must start the process by filing a claim with the MA for an organization determination (according to § 422.568), and inform the enrollee how to file such a claim.

- **§ 423.562(a)(3) Notifying Part D enrollees of right to seek a coverage determination**

Beneficiary advocates continue to believe that § 423.562(a)(3), which requires plans to arrange with network pharmacies to either post or distribute the generic notice to contact the plan to obtain a coverage determination, does not provide adequate notice to beneficiaries of their rights when a drug plan does not cover or provide for a prescription. When a notice is posted in compliance with this provision, it is often posted in an inaccessible place and is often very hard

to read. A beneficiary who does not see or who cannot read the notice because of its placement receives no information about steps that she or he can take.

We have previously requested that a coverage determination, with an explanation of the reason why a drug is not covered and an explanation of appeal rights, be provided at the point of sale. As an alternative, we request:

1. § 423.562(a)(3) should be amended to eliminate the option for network pharmacies to post the generic notice, and to require plans to arrange for all network pharmacies to hand the beneficiary the generic notice every time a prescription is not covered. If the notice is distributed to the beneficiary, the beneficiary will at least understand that s/he has an option to question the non-coverage. Since the notice is generic and applies to all plans, the pharmacy will not be burdened by having to distribute different notices for each plan.

We thank you for considering our additional suggested changes to the Part C and Part D appeals regulations.

- **Representatives (§422.561, 422.574, 422.624)**

We appreciate the proposed change that would allow a representative to act on behalf of an enrollee and request a grievance.

- **Disclosure Requirements Under Parts C and D (§422.111(g) and 423.128(f))**

We believe that disclosure about a sponsoring organization's performance and contract compliance deficiencies serves two purposes. First, it acts as deterrence to plans to ensure that they comply with rules and contract requirements. Second, it provides plan enrollees with information they need to assess the quality of care they are receiving from a sponsor. Therefore, we believe that disclosure should not be limited to only those instances when a beneficiary would be afforded the opportunity to act on the information.

## **II. C. Changes to Provide Plan Offerings With Meaningful Differences**

- **Bid Submissions – Ensuring Significant Differences (§423.252, 423.265)**

We thank CMS for recognizing that benefit packages must represent significant differences to ensure meaningful choice. In too many markets, plan sponsors offer multiple plans that cannot be distinguished without the assistance of an actuary, as our colleagues at the Medicare Advocacy Project in Boston state.

Nevertheless, we do not believe that differences in formularies should be the sole or primary criterion for judging differences in plans. Despite CMS' statement that "all submitted formularies must be sufficiently robust to pass our rigorous formulary reviews," we worry that using measures such as the percentage of unique generics offered or percentage of utilization management requirements would encourage sponsors to offer a barebones, highly restrictive

formulary as a baseline against which other offerings could be compared. This approach particularly penalizes LIS beneficiaries who can only afford benchmark plans and who are least able to navigate barriers such as utilization management controls.

We also ask CMS to revisit the issue of MA plan nomenclature. The Medicare Improvements for Patients and Providers (MIPPA) requires Part C and Part D plan sponsors to include the type of plan in the plan name. Nevertheless, we continue to find plan sponsors using the same name for all of their plans of a particular type, ex. “Gold HMO” or “Silver PPO.” Beneficiaries who are offered four Gold HMOs have difficulty distinguishing among the plans. As a result, they may unknowingly enroll in the incorrect Gold HMO, and cannot identify in which HMO they have enrolled should questions arise. Beneficiaries would be better served if sponsors were required to give each individual plan a different name, such as Gold HMO 1, Gold HMO 2, etc.

- **Bid Review Process**

We agree that a bid should only be approved if its plan benefit package is substantially different from the plan benefit packages in the sponsor’s other submitted bids.

- **Transition Process in Cases of Acquisitions and Mergers (§422.256, 423.272)**

We agree that a two year transition period should be sufficient in the case of a merger or acquisition of MA or Part D plans.

- **Non-Renewing Low Enrollment Plans (§422.506(b)(1)(iv), 423.507(b)(1)(ii))**

We have consistently stated that the number of plans offered to beneficiaries makes meaningful choice of a high-quality option difficult. The elimination of consistently low-enrollment plans will help achieve the goal of improving beneficiary choice. We ask CMS to ensure that the guidelines used for determining when a plan is a low-enrollment plan, and when low-enrollment should not be used as a criterion for rejecting a bid application are transparent and available to the public.

## **II. E. Changes to Improve Data Collection for Oversight and Quality Assurance**

We support the decision by CMS to take a more active, regulatory approach to oversight and enforcement.

The proposed regulatory changes will increase data collection, provide beneficiaries with additional information with which to make plan comparisons, and overall improve quality of plans.

## **II. F. Changes to Implement New Policy**

- **Protected Classes of Concern Under Part D (§ 423.120(b)(2)(v))**

We believe that CMS interpretation of the statutory language of MIPPA would require the continuation of current protections for the six classes of clinical concern (antidepressants, antipsychotics, anticonvulsants, antineoplastics, antiretrovirals and immunosuppressants). In practice, to obtain coverage for a non-formulary drug under Part D, people with Medicare are required to try and fail every other drug in the class before obtaining coverage. Given the seriousness of the conditions treated by these drugs in the aforementioned classes, the clinical distinctions among those treatments and the urgency of maintaining stable treatment regimens, it is inappropriate to require beneficiaries to go through such an onerous process. We urge CMS to also consider whether the presence of utilization management restrictions, including prior authorization, step therapy and quantity limits, may, like formulary exclusions, similarly cause “major or life threatening clinical consequences” by delaying or preventing treatment with the appropriate medicines(s) in these classes.

## **II. G. Changes to Clarify Various Program Participation Requirements**

- **Visitor/Traveler Benefit Under Part C (§ 423.74)**

There is much confusion surrounding the visitor/traveler benefit. Many beneficiaries have found the benefit does not provide them with the access to Medicare –covered services they expected to have when outside their plan’s network. The proposed change will provide additional clarity and require the plan to furnish all Part A and Part B services, as well as option supplemental benefits, at in-network cost-sharing.

- **Formulary Requirements- Development and Revision by a P & T Committee (§ 423.120)**

We agree that P & T committees should review and approve all clinical PA criteria, step therapy protocols, and quantity limit restrictions. We also ask that the committees be required to look at utilization management restrictions as a whole to determine whether a plan’s formulary is overly restrictive. In theory, we agree that P & T committees should not have to approve administrative PA criteria such as “B vs. D” drugs, but our experience is that plans utilize these administrative criteria as excuses not to cover drugs. It would be useful for the P & T committees to review the administrative criteria to make sure they are being applied properly.

- **Access to Covered Part D Drugs (§ 423.120)**

We ask CMS to consider ensuring access to Part D covered drugs at the plan level, and not just at the sponsor level. Sponsors may include fewer choices of network pharmacies for their less expensive or basic plans. This causes problems for LIS-eligible individuals, many of whom do not have the resources to travel to network providers.

- **Medication Therapy Management (§423.153)**

We support the proposed regulatory thresholds describing the maximum number drugs and chronic conditions and the expected annual drug costs to determine eligibility for medication therapy management programs. We support the mandatory use of an opt-out mechanism for

beneficiary participation in MTMP and the requirement that all MTMP include interactive, person-to-person consultation performed by a pharmacist or other qualified provider. We applaud CMS for its commitment to ensuring Part D plans make available robust MTM programs.

- **Extending MA Marketing Requirements to Cost Program Plans (§417.428)**

Thank you for extending the MA marketing requirements to cost plans. We request that CMS apply the same scrutiny to marketing activities of these plans as it applies to MA plans and PDPs.

## **II. H. Changes to Implement Corrections and Other Technical Changes**

- **Application of Subpart M to Health Care Prepayment Plans (§ 417.840)**

Thank you for ensuring that enrollees in Health Care Prepayment Plans have the same appeal rights as enrollees in Medicare Advantage plans.

- **Intermediate Sanctions (§ 422.750(a), § 423.750(a))**

Thank you for the proposed amendments to these sections. We believe strong oversight and enforcement by CMS protects beneficiaries and improves the quality of care they receive.

## **Conclusion**

Many of the proposed changes will provide additional protections for Medicare beneficiaries. Our comments are designed to suggest additional ways to make Part C and Part D work better for Medicare beneficiaries. We believe, however, that the greatest protection will come from increased oversight of plan sponsors and organizations and from strict enforcement of all applicable rules and regulations. The proposed changes to the oversight and sanctioning provisions suggest that CMS is moving in this direction.

We thank you for the opportunity to submit these comments. We look forward to working with you to implement necessary changes, and to call your attention to problems that may arise.

Sincerely,

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