

Contract Year 2009 Draft Call Letter

Comment / Response Form

Contact Person's Name: Georgia Burke, National Senior Citizens Law Center

Email: gburke@nslc.org

Phone: 510-663-1055 ex. 303

Org Name	Section	Page #	Description of Issue or Question	Suggested Revision/Comment
National Senior Citizens Law Center (NSCLC)	Cover memo	1	Comments on how Medical Loss Ratio should be calculated	We believe that the publication of Medical Loss Ratio will provide beneficiaries with important information about how plans utilize their Medicare dollars and will help them determine which plan provides the best health coverage for them. We recommend that CMS adopt the method of calculating Medical Loss Ratio that was included in the CHAMP Act, HR 3162, which was passed by the House of Representatives in the 110th Congress.
NSCLC	Cover memo	2	Focus of the Call Letter	The Center for Medicare Advocacy appreciates very much the new focus on items aimed at protecting plan enrollees, including making them more informed and knowledgeable consumers. We also appreciate the additional focus on improved oversight and enforcement to make Part C and D work better for plan enrollees. The Call Letter states much more clearly than in the past that CMS will take corrective action when plans do not comply with CMS rules. We also ask CMS to issue regulations that include beneficiary protections to create enforceable rights for beneficiaries.
NSCLC	No Current Section		Best Available Evidence Policy	Per the settlement agreement in the class action lawsuit <i>Situ v. Leavitt</i> , information about the BAE was supposed to be included in model plan materials for plan year 2009. Since the BAE was not finalized until after many of those materials were created, we ask that CMS include the information in plan materials for 2010. This process should start with a more prominent mention of BAE policy and the new requirements added in the August 2008 memo to plans in the call letter.

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NSCLC	No Current Section		Serving Limited English Proficient Beneficiaries	A report released in December 2008 revealed that plan call centers are still failing to provide service to non-English speaking beneficiaries. Plans are also failing to provide translations of written materials. We encourage CMS to use the Call Letter to emphasize plan requirements regarding service to LEP beneficiaries.
NSCLC	Section A 2010 MA, MA-PD and Cost-Based Plan Calendar	7, 8, 9, 10		We appreciate that CMS is asking plans to submit marketing materials a week earlier than last year. We believe the additional time is need for CMS to review materials more thoroughly.
NSCLC	Section A 2010 MA, MA-PD and Cost-Based Plan Calendar	10	Oct. 31, 2009 CY 2010 standardized, combined ANOC/EOC is due to all MA and MA-PD members	We renew our request to CMS that the agency not use a combined ANOC/EOC. The ANOC includes important information about changes in health plan coverage. By itself it is often too dense for many beneficiaries who fail to grasp that their current plan will not be best for them in the following year. Combined with the EOC, the document is too long and too complicated and information about plan changes gets lost. Plans should prepare LIS-specific ANOCs and EOCs, rather than including LIS information in a rider. ANOCs and EOCs for SNPs should be tailored to the specific offerings of each SNP. All D-SNPs (not just those that are fully integrated) should have EOCs that are tailored to their dual enrollees and, therefore, should not need LIS riders.

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NSCLC	I. Contracting Process - Multiple and Low Enrollment Plan Offerings	12	Number of plans	<p>We support efforts by CMS to limit plan offerings when those offerings have low enrollment or are basically duplicative of other plan offerings by the same sponsor. 1) 42 USC 1395w-27(b) establishes minimum enrollment standards. Plans that do not meet those standards should not be renewed. 2) It is often very difficult for beneficiaries to distinguish among the multiple plan offerings by the same sponsor, generally because the differences in benefit packages are subtle and hard to distinguish, and the plans have the same or very similar names. When beneficiaries are presented with these choices, they can overlook increased cost-sharing that may not meet their needs. Additionally, when people are presented with too many choices they may end up making an inappropriate choice or no choice at all. We encourage CMS to issue rules that would limit plans to no more than a specified number of benefit designs in a service area. The limitation will actually promote choice by making the differences among the choices more distinguishable.</p>
NSCLC	I. Contracting Process- Multiple and Low Enrollment Plan Offerings	12	Transitioning enrollees into a similar plan	<p>We object to the passive enrollment of beneficiaries whose plan is eliminated into another, similar plan offered by the same plan sponsor. We believe that such passive enrollment violates the Medicare statute, 42 USC 1395w-21, which makes enrollment into a Medicare Advantage plan voluntary. An individual whose plan is not being renewed may be better served by returning to traditional Medicare or by enrolling in an MA plan offered by a different sponsor; the choice belongs to the beneficiary and not to CMS or the plan whose contract is terminating.</p>

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NSCLC	I. Contracting Process - Dual Eligibles and Cost-Sharing	12, 13		<p>We appreciate the extension of cost-sharing protections for dual eligibles to all MA plans. This, in fact, reflects statutory protections and CMS guidance that pre-dates MIPPA. Requiring a provider contract provision that enrollees not be held liable for cost-sharing that should be paid by Medicaid programs is a good step towards reducing the billing problems encountered by duals. We suggest addition of the regulatory language that all contracts must state that the providers will "(A) Accept the MA plan payment as payment in full, or (B) Bill the appropriate State source." 42 C.F.R. 422.504(g)(iii). PFFS plans should be required to mail the contract provision to deemed providers. We also agree that plans must inform providers of Medicare and Medicaid benefits and eligibility rules on a frequent basis since many are not aware of how the rules work. We believe that CMS has the authority to require this provision in plan contracts with providers in order to implement and enforce required cost-sharing protections for dual eligible beneficiaries.</p>
				<p>(cont'd)  All plans serving dual eligibles should be required to work with the Medicaid agency in the state in which they operate to assure that their statement of Medicaid benefits provided to their providers is accurate.</p>

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NSCLC	II Benefit Design - Cost Sharing Guidelines	12, 13	Criteria to improve transparency in OOP costs	<p>We are pleased that CMS wants to improve transparency so that beneficiaries may predict more easily their OOP costs in a particular plan. It is very important that plans not be allowed to carve out from their out-of-pocket limits any Part A/B services; moreover, the inclusion of all such services in the cap should be required to be stated in marketing materials. We often encounter beneficiaries with large medical expenses who were unaware that the services they require are excluded from the OOP maximum advertised by the plan. We also agree that plans should be encouraged to have a set OOP maximum. Again, beneficiaries can make comparisons more easily if all plans have the same OOP amount. We have the following suggestions to improve these protections for beneficiaries: 1)The proposed OOP threshold of \$3,400 is too high. Nearly 50% of all Medicare beneficiaries have incomes below 200% FPL. In the insurance context, catastrophic costs are capped at about 10% of income. Using this standard, the OOP threshold should be about \$2,000.</p>
				<p>(cont'd)</p> <p>2) When considering whether co-insurance is discriminatory, CMS should look to the more complete list of services included on page 14 rather than the list on page 13. . The costs for home health care under some plans can be prohibitive, particularly in plans that impose charges on a per-service basis. Additionally, home health services and DME are often associated with chronic care. Plans that charge substantially more than traditional Medicare for these services may also be looking to discourage people with chronic conditions from enrollment.</p>

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NSCLC	II Benefit Design - Plan Corrections for 2010	14	Plan corrections for 2010	We appreciate the greater scrutiny by CMS reflected in this language on plan correction. Beneficiaries need to know that the information about plan benefit packages made available on Medicare Compare is accurate and up-to-date. When plans change their benefit packages, even through a correction process, beneficiaries may discover after they enroll that the benefit design is not as they had expected based on their original research. The clear direction from CMS concerning the need to submit accurate information to avoid a corrective action warning will help ensure the accuracy of the information that beneficiaries require.
NSCLC	II Benefit Design - Preventive Services Incentives	14-16	Guidelines for incentives	We agree that MAOs should help promote the use of Medicare preventive benefits. As CMS states, the use of incentives should be directed at enrollees, not potential enrollees, and should be directed towards using the services and not an outcome. We agree that incentives should not be advertised as a plan benefit or included in the bid as a benefit, but costs related to incentives should be included with other non-covered benefit costs. We urge CMS to allow an appeals/grievance procedure that enables a beneficiary to access rewards/incentives.
NSCLC	II Benefit Design - Part C Supplemental OTC Benefit	16-18	Update to guidance	The updated guidance helps clarify when a plan may provide a supplemental OTC benefit and how the benefit should be provided. By listing the categories in Appendix I CMS helps standardize the items that may be offered and helps in the beneficiary comparison process. Including Appendix I in the Managed Care manual will help ensure that the information is available to beneficiaries and their advocates and will promote transparency in this regard. In addition, we think it important that in marketing materials and other beneficiary communications, plans provide information that allows duals to distinguish between items that they would receive in any case as part of their Medicaid benefit and items that are genuinely additional. OTC coverage is one example but there are many more for MA plans.

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NSCLC	II. Benefit Design - Public Health Emergency	18-19	Use of waiver authority	We appreciate CMS's willingness to allow plans and in some cases require plans to undertake actions necessary to accommodate beneficiary needs during an emergency. Access to benefits is particularly important in emergency situations when beneficiaries are least able to navigate cumbersome systems.
NSCLC	II Benefit Design - Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit	19 -21	Clarification of policy	Much confusion surrounds payment for home infusion drugs. Despite the fact that MA-PDs are supposed to provide all A/B and D services, some plans reject payment as not covered under Part D when the plan should be making payment under Part B. We encourage CMS to monitor beneficiary complaints in this regard, particularly when plans offer bundled services under Part C. We support \$0 cost-sharing when the bundle of home infusion services is provided as a mandatory supplemental Part C benefit as another way to improve transparency for beneficiaries and to promote access to home infusion drugs. CMS may wish to include in the Call Letter statements reminding plans that, whether or not they choose to bundle, they still have an obligations to ensure that appropriate Part D coverage is offered for covered home infusion drugs.

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NSCLC	III Bidding - Rebate re-allocation	21-22	Rebate reallocation	<p>We appreciate the reminder to plans that they cannot use the rebate re-allocation process to change their basic A/B benefit package and premium. We also appreciate that CMS may not reallocate rebate reductions by increasing cost sharing for more limited-use services such as inpatient, SNF, and home health care unless other reductions that apply more generally have been made first. However, we continue to question why the first priority of rebate reductions should be to return to the target Part D premium. Plans that have to increased their cost sharing for the more costly services in order to keep a \$0 or reduced Part D premium are still discriminating against sicker beneficiaries who utilize these services. Additionally, when plans use rebate dollars to reduce their Part D premiums to \$0, the \$0 premium is used in the calculation of the low-income subsidy (LIS) benchmark amount. This artificially reduces the benchmark and results in fewer LIS-eligible plans in most regions.</p>
				<p>(cont'd) If plans are allowed to apply rebate dollars to reduce their Part D premium, then their pre-rebate Part D premium should be used in calculating the LIS benchmark.</p>
NSCLC	IV Quality and performance Measures	22	Part C Quality reporting	<p>We ask CMS to require all Part C plans to report on and disclose information on racial and ethnic disparities in the use of health services by plan enrollee, and on plan policy, practices and procedures to assist beneficiaries with limited English proficiency.</p>
NSCLC	IV Quality and performance Measures	23-24	CAHPS Survey Administration	<p>We appreciate the role of CMS in approving the survey vendors to conduct the survey on behalf of MA and Part D contracts, in drawing the sample of enrollees for each contract, in overseeing the approved vendors, and in analyzing the data.</p>

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NSCLC	Section A. V. Compliance and Monitoring; Section B. X. Compliance Monitoring	24 - 25; 72-73+C49	Response to CMT	Requiring plans to comply with specific time frames for complaint resolution helps ensure that beneficiaries have access to medically necessary services. We ask that CMS modify the time frames to incorporate the language regarding expediting Part C and Part D coverage requests and appeals, so that all complaints would be resolved within the time frame stated or earlier <u>as the health care of the beneficiary requires</u> . We appreciate that plans that do not meet the thresholds will be considered out of compliance.
NSCLC	V Compliance and Monitoring - Audit approach	25	Audit approach	We remind CMS that the statute at 42 USC 1395w-227(d)(1) requires that at least one-third of MA plans be audited annually. We agree that CMS should focus on high risk areas such as enrollment and grievances and appeals, and would suggest that CMS continue to include marketing violations as a high risk area. We also agree that organizations that demonstrate poor performance should be targeted. CMS should look to complaints from previous years to help determine poor performance.
NSCLC	VI Enrollment	26	Enrollment	The mandatory use of the online enrollment center will simplify the enrollment process for many beneficiaries and help ensure that they are enrolled in the plan of their choice. It will also protect them against efforts by some plans to enroll beneficiaries in more costly plans or MA plans when they really chose PDPs. We appreciate that plans will be required to check the OEC on a daily basis so that enrollments can be processed as quickly as possible.
NSCLC	VII Grievance, Organization Determinations, and Appeals	28	Evidence of Coverage and Formulary Information	1) We agree with the requirement that plans send the relevant Evidence of Coverage and formulary with every file appealed to the IRE. This requirement may help expedite decisions at both the ALJ and IRE levels of review and will ensure that complete and accurate information is available. 2) We also ask that CMS continue to monitor compliance with time frames for resolving coverage determinations and reconsiderations.

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NSCLC	IX Special Needs Plans - Model of Care	28, 29	Model of Care	<p>The section of the call letter discussing Special Needs Plans includes many references to new plans for the 2010 plan year. MIPPA section 164(b), however, precludes the designation of new plans in the 2010 plan year, continuing the moratorium first put in place in the Medicare, Medicaid and SCHIP Extension Act of 2007 governing the time period 01/01/08-12/31/09. CMS should eliminate all references in this entire section to new plans. It is essential that CMS review (and subsequently audit) model of care (MOC) information submitted by all SNPs in great detail to ensure that SNPs are providing the special services, including care management and care coordination, that they allege they provide. Plans should have to demonstrate how they will serve people with limited English proficiency, who are disproportionately represented in, at least, the dual eligible population. Assessment and annual reassessment is required by MIPPA; CMS should add language that requires reassessment as needed when the beneficiary's circumstances change.</p>
				<p>(cont'd) We agree that information needs to be specific to each SNP, particularly where a plan sponsor offers more than one SNP. However, the language concerning development of the care plan should be strengthened. The plans should be required to consult with the individual unless such consultation is impossible and with anyone the individual chooses to have involved in the care planning. If consultation with the individual is impossible, the plan should consult with the individual's delegated surrogate. If the language is not strengthened, it will be too easy for plans to develop a care plan designed for their convenience without considering the interests of the enrollee. Without seeing all the questions plans will be required to answer describing their care management, it is difficult to assess how valuable this information will be, but we are concerned that the questions require Yes or No answers, without more.</p>

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				<p>(cont'd)</p> <p>Since models of care of what now distinguish SNPs from other MA plans or delivery models, they should be fully described in all plan marketing materials and should be available to the public through CMS.</p>
NSCLC	IX Special Needs Plans - Institutional Equivalent SNP - Level of Care Assessment Tool	29, 30	State assessment tool	<p>Thank you for clarifying that I-SNPs cannot provide bonuses or payment differentials to independent assessment entities for qualifying members for the I-SNP. We suggest that this provision include a reminder of the enforcement actions CMS will take for violating this provision and/or for failing to meet the burden of demonstrating adoption of state practices. We urge CMS to emphasize to plans that assessments also require attention to the needs of Limited English Proficient members and a proper assessment cannot be performed unless either the assessor speaks the language of the member or there is competent interpretation. Moreover cultural competence training is critical for appropriate assessments. These issues apply to all SNPs and also are important not just for assessments but also for provision of care and care coordination.</p>
				<p>(cont'd)</p> <p>Furthermore, because CMS is requiring plans to use the same assessment tool that the State would use to qualify the individual for state Home and Community Based Services, we suggest that it would make sense to require the I-SNPs also to assist beneficiaries to qualify for those services.</p>

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NSCLC	IX Special Needs Plans - SNP QIP and CCIP	30-32	QIP and CCIP	<p>Care model assessment through the QIP or CCIP programs should include evaluation of how well the model services beneficiaries with limited English proficiency. We question the validity of the first example of a QIP for dual eligible SNPs. Many state Medicaid programs already pay for transportation services. In those states the add-on transportation services from the SNP may not provide any additional benefit than already exists, at least for full dual eligibles, and so may not demonstrate higher utilization rates of primary care and preventive health services. A more appropriate example for D-SNPs is evaluation of the ease with which beneficiaries get all services they need under both Medicare and Medicaid and how well providers are complying with cost-sharing protections for both full dual eligibles and those who are only Qualified Medicare Beneficiaries. CMS should evaluate carefully what added services provided by SNPs are truly extra services for Medicaid recipients.</p>
				<p>(cont'd)</p> <p>Also for all MA plans, dual eligibles should be able to see clearly on all plan materials what "added" benefits are already covered by Medicaid and individuals marketing those plans should be required to assist duals with making those distinctions.</p>

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NSCLC	IX Special Needs Plans - Chronic Condition SNPs	32-34	Chronic condition SNPs targeting more than one condition	<p>More than a third of all Medicare beneficiaries - over 15 million people - have three or more chronic conditions and significantly more beneficiaries have two or more. We believe that all Medicare beneficiaries, but especially those with chronic conditions, could benefit from care coordination and thus find the very existence of C-SNPs to be problematic. (The fact that CMS requires all MA plans, not just SNPs, to conduct chronic condition improvement programs suggests that CMS recognizes the pervasiveness of chronic conditions among the Medicare population.) Since C-SNPs do exist, like CMS, we believe that they must demonstrate their special attributes in order to be of value to their enrollees. We have concerns that, without additional clarifications, C-SNPs can design plans around the 15 severe or disabling chronic conditions identified by CMS that are not distinguishable from other MA plans.</p>
				<p>(cont'd)</p> <p>To further ensure that C-SNPs are providing something of value beyond what is required of all MA plans, we ask CMS to: 1) reconvene a panel of independent national experts to develop a refined list of severe or disabling chronic conditions that meet the statutory definition; 2) develop minimum average risk scores to help determine eligibility for a C-SNP; and 3) monitor benefit structures, provider networks, formularies and models of care to ensure that the C-SNPs are providing extra value to the beneficiaries they allegedly target.</p>
NSCLC	IX Special Needs Plans - Verifying chronic conditions	34	Verification	<p>We ask CMS, when conducting audits of verifications of chronic conditions, to review the entity that verifies the chronic condition. We believe that verifications should be conducted/provided by the enrollee's treating physician and not by the plan or an entity that contracts with the plan to do independent verifications.</p>

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NSCLC	IX Special Needs Plans - C-SNP Nonrenewals	36	Existing dual eligible SNP members	We ask CMS to clarify that enrollees in plans whose contracts are not renewed cannot automatically be transitioned to other MA plans for the reasons stated above.
NSCLC	IX Special Needs Plans - Transitioning Dual Eligible and I-SNP enrollees	37	C-SNP SEP	We object to any proposal to move individuals who no longer qualify for SNP eligibility into a different MA plan without their having made the choice to remain in an MA plan. As stated previously, the statute clearly states that enrollment in an MA plan is voluntary; transitioning enrollees to a different plan violates the statute. The decision to enroll in any MA plan should be made after an individualized assessment of the best way to receive Medicare services. Another MA plan offered by the same provider may not be the best option for everyone; an MA plan offered by another sponsor or a return to traditional Medicare may make more sense. Each beneficiary should make the choice for him/herself.
NSCLC	IX Special Needs Plans - Reminder about SEPs for C-SNPs	37	D-SNP requirements to contract with state Medicaid agencies	We find the current stance of CMS, which allows C-SNP enrollment throughout the year but does not include a SEP for beneficiary disenrollment, to be very troubling. At the very least, beneficiaries who find a C-SNP does not meet their needs should have the opportunity to disenroll. We also have concerns about the special marketing advantage currently given to C-SNPs in light of the failure of many C-SNPs to demonstrate that their quality of care coordination merits this unique treatment.

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NSCLC	New Dual Eligible SNPs required to contract with state Medicaid agencies	37, 38	Payment	<p>We agree with CMS that D SNPs best serve their population when they have strong connections to the Medicaid program in the state in which they operate. MIPPA requires that plans tell prospective enrollees the benefits and cost sharing protections under their Medicaid program and which of those are offered under the SNP. (But as CMS has noted elsewhere, SNPs must provide the same cost-sharing protections as are available to duals under Medicaid and under CMS regulations.) We believe CMS's language as to the nature of the state-SNP collaboration/cooperation should be stronger. Plans are required by regulation to have eligibility verification arrangements with states and to identify and share information about Medicaid provider participation. The latter requirement is essential, as plans have, in the past, been approved as D-SNPs that have no Medicaid providers in their networks. This is unacceptable and unworkable for duals. While the statutory requirement for a contract with the state is waived for plans that do not expand their service area, CMS should still require all plans to coordinate with the state i</p>
NSCLC	X. PFFS Plans	38, 39	Clarification of policy variations in cost sharing	<p>We appreciate the reminder to plans that failure to pay deemed providers at the the traditional Medicare payment rates is a significant compliance concern. We ask CMS to continue to monitor the problem and take appropriate action when violations are found. PFFS plans that serve dual eligibles must inform all their providers - through contract, where applicable and through other notice for deemed providers who do not have a real contract - of the cost-sharing protections described elsewhere in this document.</p>

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NSCLC	X. PFFS Plans Prior notification	40, 41		<p>We thank CMS for further clarifying the difference between prior authorization/referral and prior notification, and for reminding PFFS plans that they are prohibited from using prior authorization or referral. We also thank CMS for reminding plans that they must cover a service if they did not receive prior notification. We urge CMS to issue proposed rules to prohibit the use of prior notification, but in the meantime, to prohibit it through this Call Letter. Plan prior notification requirements are generally not transparent. Information about the differences in cost-sharing is often found in a footnote. The process for prior notification may not be adequately explained. Providers may be unaware of prior notification requirements when they prescribe or order an item or service for the beneficiary. Many of the items or services subject to prior notification are ordered or prescribed when the beneficiary is experiencing or has just experienced a health care crisis.</p>
			Transparency and LEP	<p>(cont'd) The notification requirement places an extra burden on them at a time when they are trying to deal with changes in condition.</p>
	XI. MSA	42	Employer and Union-Sponsored Group Health Plans	<p>We applaud CMS for its concern about transparency but note that for MSA information as well as all other information provided to beneficiaries, the lack of translated materials means that a great many beneficiaries, as a practical matter, have no good information access.</p>
NSCLC	XIII	44	Timeframe	<p>We ask CMS to consider elimination of all employer waivers or, at a minimum, to scrutinize employer waivers very carefully. We continually hear from retirees who are moved into MA plans by their employers only to find that the MA plans do not live up to the promises made by the MA organizations and/or their employers. In particular, retirees who are moved to PFFS plans continue to find themselves without access to hospitals and doctors, particularly when they live outside their former employer's work area.</p>

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NSCLC	Section B - Prescription Drug Plan Sections Calendar	46	Submission of applications, bids, formularies	We thank CMS for requiring plans to submit marketing materials earlier than last year. This will provide CMS with additional time to review the materials to ensure that they are accurate and not misleading.
NSCLC	Section B - Prescription Drug Plan Sections I. Bidding/Payment	50, 51, 52	Specialty tier	We thank CMS for taking a strong stand against delayed, incomplete, and inaccurate submissions. When plans fail to comply with these rules, the contracting process becomes delayed and CMS may not be able to provide beneficiaries with the information they need to make accurate choices during the annual enrollment process. Additionally, a plan's inability to provide timely and complete information as part of its application, bid, or formulary calls into question its ability to run a prescription drug plan effectively.
NSCLC	II. Formulary	55		We ask CMS to prohibit the use of specialty tiers as they discriminate against people with disabilities, and in particular people with HIV/AIDS. We commend CMS to the report issued on March 3, 2009 by MedPAC. The report finds that 4 classes of drugs (antineoplastics, immunologics, antivirals, and antibacterials) account for two-thirds of specialty tier drugs. Specialty tier drugs vary greatly from plan to plan, with 40% drugs of such drugs being listed on a specialty tier in fewer than half of all plans. Additionally, specialty tier drugs are subject to utilization management much more frequently than other drugs. <a href="http://www.medpac.gov/documents/Feb09_DrugsonSpecialtyTiers_CONTRACTOR_RS.pdf">http://www.medpac.gov/documents/Feb09_DrugsonSpecialtyTiers_CONTRACTOR_RS.pdf</a> . If CMS does not prohibit specialty tiers, we ask CMS: 1) to issue proposed rules that would allow tiering exceptions from specialty tiers. We believe the exemption violates 42 USC 1395w-104(g)(2), which contains no exemption to the right to request a tiering exception. 2) to continue to monitor specialty tiers closely and to reject any formulary that contains an unreasonable num

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			Transition notices in long-term care settings	(cont'd) 3) to conduct a study to determine whether the VA and state Medicaid programs pay less than \$600 for specialty tier drugs.
NSCLC	II. Formulary	56	Transition across contract years	We ask CMS to require plans that send transition notices to network long term care pharmacies to also send the notices to the resident/resident's surrogate. Residents and their surrogates may need to make a number of decisions regarding the drug in question, in addition to filing an exception. These decisions, none of which can be made by the pharmacy, may include how to pay for the drug if it is not covered or whether to change plans. Residents/surrogates need the information as quickly as possible.
NSCLC	II. Formulary	56	Utilization Management Criteria	We appreciate CMS's clarification that transition requirements also apply to new prior authorization and step therapy restrictions. We ask that the clarification also include new quantity limits.
NSCLC	II. Formulary	56, 57, 58	New website posting requirement	While we agree with the responses proposed by CMS, we ask CMS to take stronger steps against plans that continuously impose unnecessary and burdensome utilization management criteria, including plans that have a disproportion number of formulary drugs subject to such criteria. The use of utilization management tools to restrict access to drugs described as being on a plan's formulary continues to cause confusion for beneficiaries. We ask CMS to clarify that multiple utilization management tools cannot be applied to one drug or, if a beneficiary who seeks an exception for one UM tool should be granted an exception for all UM tools. We also ask CMS to proposed regulations that clarify the relationship between prior authorization and step therapy/quantity limits, and that a request for prior authorization is treated like an exception, so that if the request is granted it remains in effect for the rest of the plan year.

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NSCLC	II. Formulary	58	Beneficiary understanding of Part D benefits	<p>We are pleased that CMS is requiring plan sponsors to post submitted step therapy requirements. We ask that they be required to post the step therapy requirements by October 1, 2009, or the same date that they post their formularies. We also ask that CMS continue to require plans to post information about prior authorization and quantity limits.</p>
NSCLC	III. Part D Benefitis	59, 60	Post enrollment provision of information	<p>Simply by listing the four benefit types and the other variables in Part D benefit structure, CMS explains why beneficiaries have difficulty understanding and comparing Part D plans. The Call Letter does not discuss the additional confusion caused by the large number of Part D plans available to most beneficiaries. More needs to be done to clarify and simplify the variations so that beneficiaries can make more informed choices. We ask CMS to issue proposed regulations to limit the number of plans a sponsor may offer in a region and to develop standardized benefit packages. The gap coverage level description is a first step, but requires the beneficiary to understand what the terms mean or go to another screen to understand the terms. We suggest using just the numbers for each gap coverage category, rather than the descriptors of the numbers, and to require that the plan distinguish between coverage for generic and brand name drugs.</p>
				<p>(cont'd)            Additionally, a plan that covers many drugs in the gap still may not cover the drugs an individual beneficiary requires, which is what the individual cares about. Therefore, any web postings about gap coverage that is less than 100% should also include a link to a list of all the specific drugs that are subject to gap coverage. Similarly, statements in written materials, including marketing materials, should be required to include an attachment listing specific drugs.</p>

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NSCLC	III. Part D Benefitis	60, 61	Medication therapy management	EOBs continue to remain too complicated, particularly for high users of drugs. We do not believe either the plans' websites or electronic communications with plan members can be the primary means of communicating post-enrollment information to members. CMS should increase user fees and increase funding for SHIPs and other beneficiary counselors to expand the availability of individualized counseling.
NSCLC	III. Part D Benefitis	61-65		We continue to find that MTM programs are either non-existent or non-effective. Plans should not be allowed to satisfy the MTM requirement by providing fact sheets to beneficiaries who have been dealing with their chronic condition for many years, particularly when the fact sheet does not provide information about new treatment modalities. The opt-out provision will help ensure greater participation in the programs, however, the programs still need to provide meaningful assistance to the targeted plan enrollees. We also ask CMS to provide additional guidance on how MTM programs relate to requirements concerning monitoring of medication under the Nursing Home Reform law, and suggest CMS monitor how Part D plans and nursing facilities coordinate their statutory obligations. We have concerns that by listing the seven core chronic conditions, CMS may encourage plans to exclude from MTM other enrollees whose multiple chronic conditions are not on the list.
			Reference-based pricing	(cont'd) Furthermore, we do not understand the limited list of diseases mentioned, noting, for example, the absence of cancer, autoimmune diseases, kidney disease, and Alzheimer's disease, to name a few.

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NSCLC	III Part D Benefits	66	Reassignment of LIS-eligible individuals	<p>We thank CMS for eliminating this option which, because of its lack of transparency, made it almost impossible for counselors to give reliable advice to beneficiaries on the true comparative costs of plans and significantly reduced the value of the Medicare plan compare function. We do note that, though this was the most egregious example of the complexity of plan offerings, the process of true comparison is still extremely difficult because of the lack of standardization in plan offerings. Much more needs to be done to standardize and simplify if consumers are to have meaningful choice.</p>
NSCLC	VI Low-income subsidy policy	67-68		<p>Reassignment of LIS-eligible individuals remains a problem. We believe that CMS can reduce the number of reassignments by using the actual cost of the prescription drug benefit offered by an MA-PD, and not the premium as reduced by application of any rebate, in the benchmark calculation. CMS could also reinstate the de minimus policy it has used in prior years to reduce the number of reassignments. We also encourage CMS to engage in intelligent assignment to ensure that beneficiaries are placed in more appropriate plans. To the extent that plans that are no longer benchmark plans are permitted to reach out to their enrollees, the purpose should be to minimize cost to the enrollee, i.e. to state that the plan will waive the premium difference and accept the LIS premium subsidy as full payment for the premium. Allowing plans to call members they are losing to convince them to enroll in other products would seem to violate the MIPPA provision prohibiting outbound calling. The reassignment process is also in need of adjustments.</p>
			Retroactive auto-enrollment	<p>(cont'd)  We recommend that CMS meet with plans and advocates to discuss how the process can be improved. Possible improvements included better notices, notices to all choosers (even those not currently enrolled in a benchmark plan), more data from CMS regarding the enrollment of LIS recipients and more.</p>

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NSCLC	VI Low-income subsidy policy	68		<p>We are concerned that the proposed demonstration will increase confusion for beneficiaries. Beneficiaries who use the POS or are retroactively auto-enrolled will get information from two different plans covering two distinct periods of time. In order to avoid confusion, significant outreach explaining the new process must be conducted and notices must be extremely clear and simple.</p> <p>The proposed demonstration will address only one of the problems involving retroactive auto-enrollment, the problem related to assuring coverage by a prescription drug plan. It does not address issues of retroactive LIS coverage for those already in Part D plans when they become entitled to retroactive LIS. Beneficiaries continue to encounter problems because plans do not comply with federal requirements to reimburse beneficiaries for premiums or co-payments that would have been covered by LIS, even though the plans themselves are reimbursed retroactively for these amounts.</p>
				<p>(cont'd)</p> <p>Federal regulations provide that a person with the Low-Income Subsidy (LIS) is entitled to reimbursement from his or her Part D plan of any non-LIS amounts paid out during the period between the first of the month the beneficiary applies for the benefit—or between the start of his or her retroactive eligibility for Medicaid or an MSP, through which he or she is deemed eligible for LIS—and the date the plan recognizes the enrollee's LIS status. This includes reimbursement of any premiums (or portions of premiums beyond the LIS subsidy) and any co-payment amounts that would have been covered by LIS. Medicare guidance further states that failure by a Part D plan to reimburse an enrollee for these amounts is considered "fraud, waste, and abuse." While plans are paid by Medicare to automatically reimburse their members, plans regularly fail to do so.</p>

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				<p>(cont'd)</p> <p>To ensure that plans are aware of their responsibility and to ensure that they conduct the reimbursement process correctly, we urge CMS to add to the Call Letter the following requirements concerning retroactive reimbursements:</p> <ol style="list-style-type: none"> <li>1. Clearly state that the LIS reimbursement process must be automatic in all situations except when the LIS status change and the PDP enrollment are both retroactive, since the PDP will not have claims information for the retroactive period.</li> <li>2. Reiterate that when a reimbursement is not made automatically and a request for reimbursement must be made, that request must be treated as a coverage determination, which requires plans to make a determination within 72 hours of receiving the request and issue payment within 30 days.</li> <li>3. State that reimbursement, whether automatic or requested, must be made within 30 days, not quarterly or annually.</li> </ol>

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				<p>(cont'd)</p> <p>4. Affirm that the obligation to reimburse falls to the plan irrespective of problems with the plan's contracted PBM. Plans have delegated the responsibility to reimburse beneficiary cost-sharing to PBMs, which is permissible. However, even after plans have been notified of the PBMs failure to reimburse the beneficiary, the plan continues to defer to the PBM and state that the plan is unable to take any action. Plans may delegate this responsibility, but the ultimate responsibility to reimburse falls to the plan.</p> <p>5. Reiterate that plans cannot require beneficiaries to use particular claim forms when requesting a LIS reimbursement.</p> <p>6. Clearly state that plans have the obligation to have in place a process to determine when an SPAP or other third party payer is owed money and reimburse the beneficiary and third party payer accordingly.</p>
			Compliance with process	<p>(cont'd)</p> <p>Plans regularly fail to provide reimbursement properly and instead reimburse beneficiaries money that is owed to a SPAP or other third party payer in violation of guidance issued by CMS, which states: "CMS expects that plans will develop standard operating procedures to address the research and determinations of liability for cost sharing reimbursements, and will not adopt a "one size fits all" approach, such as always cutting checks to the beneficiary."</p> <p>7. Require plans to provide an accounting, written in a consumer friendly manner, with any reimbursements that clearly indicates what the reimbursement is for.</p> <p>8. Include information about the new Best Available Evidence process and plan responsibilities under the new BAE policy.</p>

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NSCLC	VII Grievance, Coverage Determinations, and Appeals	68	Plan Reporting Requirements	We ask CMS to issue proposed regulations to improve the grievance, coverage determination and appeals process for beneficiaries. We ask CMS to: 1) require that notice given at the pharmacy constitute the coverage determination; 2) require plans to submit unfavorable redeterminations directly to the IRE as is required under Part C; and 3) establish shortened time frames for ALJs to issue decisions in Part D claims. We also ask CMS to include in the Call Letter a reminder that plans must comply with the regulatory time frames, and that the time frames represent hours and calendar days, not business hours and business days. We further ask CMS to take swift enforcement action against plans that continue to ignore the rules.
NSCLC	XI. Quality and Performance Measures	70	Compliance with requirements for processing out-of-network reimbursement requests	In order to address health disparities CMS must being to require plan to collect racial, ethnic and language preference data of beneficiaries.
NSCLC	X. Compliance/Monitoring	73-74		Compliance problems related to reimbursement for out-of-network claims are broader than CMS describes. Beneficiaries report difficulty in getting reimbursement requests processed at all; they sometimes do not even get an unfavorable coverage determination. Plans need to be held out of compliance in these situations, particularly when, as CMS indicates, the problem stems in part from an inability to process mail properly and quickly. We ask CMS to require plans to include more prominently in their ANOC a statement that requests for reimbursement for out-of-network pharmacies are coverage determinations and the plan process for making the request. If CMS believes that giving plans additional time to process this kind of coverage determination will prompt plans to issue coverage determinations, then we believe that CMS needs to issue a notice of proposed rule-making to change the time frame in its current regulation.

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			Auto-Enrollment Readiness Audits	(cont'd) We are concerned about the legal precedent of modifying existing rules that went through notice and comment rulemaking through contract provisions.
			Mid-Year enrollment by SPAPs	We applaud CMS for continuing with these audits. We do, however, recommend the following changes in policy. First, CMS must do more to ensure that ALL benchmark plans are complying with BAE policy requirements. We repeatedly hear stories from beneficiaries and advocates who have contacted plans only to find that the plan representatives are not familiar with the BAE policy. Second, CMS should share the results of the readiness audit with the public before the start of the Annual Enrollment Period. Last year, CMS waited until the start of the new plan year to reveal that WellPoint had not been approved to receive reassignments in the Fall of 2008. The fact that WellPoint had problems with its enrollment systems that were serious enough for CMS to suspend auto-enrollment privileges is information that beneficiaries who were choosing plans may have found useful. Unfortunately, they did not have access to this information until after all WellPoint enrollments were suspended in January.

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NSCLC	XI SPAP Guidance	74, 75	Waivers	We object to any attempt to limit SPAPs from making mid-year enrollment changes. SPAPs change Part D enrollment for their SPAP enrollees during the plan year because the Part D plan does not cover the drugs needed by the individuals or because the Part D plan is failing in its obligation to coordinate with the SPAP. Our experience has been that such changes are rare. The CMS proposal undermines the effectiveness of SPAP programs to ensure that beneficiaries with limited means get the prescription drugs they need. We ask CMS, instead, to determine the plan non-compliance issues that lead SPAP programs to make enrollment changes. We do share CMS's view that plan changes can be disruptive when not done with the needs of the beneficiary in mind. That is why we encourage CMS to take more action to address the problem of annual reassignment.
NSCLC	XII Licensure and solvency	75, 76	Contract termination	We appreciate that CMS will take strong action to ensure that all PDPs meet the state licensing requirements.
NSCLC	XIV. Employer and Union-Sponsored Group Health Plans	76	Marketing Requirements Oversight	We ask that CMS ensure that retirees enrolled in these plans receive the proper protections, including notice and SEPs.

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NSCLC	Section C Marketing	77-82		<p>As the Call Letter indicates, marketing violations continue despite the additional regulation and oversight by CMS. We thank CMS for your continued vigilance over marketing activities and ask that you take the following additional steps to prevent abuses: 1) Preclude marketing after the end of the Annual Enrollment Period on December 31. After that time period enrollment changes may only be made in limited circumstances, and no change of PDPs is permitted. Agents use this time period to target PDP members who are unhappy with their drug coverage to enroll them in an MA plan, often unwittingly. At a minimum, marketing should end by March 31. Any enrollments after March 31 are due to a special enrollment period not geared toward the general population. It is during this time period that agents target dual eligibles, and enroll others in C-SNPs who may not meet the eligibility requirements. 2) As indicated above, we believe the ANOC and EOC should be separate documents.</p>

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				<p>(cont'd)</p> <p>3) Develop standardized marketing forms and standardized language, including standardized definitions. The use of such standards would help beneficiaries make meaningful comparisons and simplify CMS review. The forms could be developed and reviewed through the Paperwork Reduction Act process, which requires publication in the Federal Register and opportunity for comment. 4) Restrict the File &amp; Use process to marketing materials that use language/format developed by CMS. 5) Preclude generalized ads that could be misleading. Ex.: HMOs, PPOs, and PFFS plans all have different networks and cost-sharing requirements. Plans should not be allowed to advertise them together with a statement that says their plans provide wide access to doctors and hospitals. 6) Include in the Call Letter and in the Marketing Guidance that plan sponsors must follow Federal Trade Commission standards with regard to celebrity endorsements.</p>
			<p>Payment of Referral Fees to Agents</p>	<p>(cont'd)</p> <p>7) Include in the Call Letter that plans must make marketing materials available in languages other than English for limited English speaking populations. This includes ensuring that plan call centers have a process and understand the process for assisting non-English speaking callers.</p>
NSCLC	Section C Marketing	77	Multiple organization marketing pieces created by agents	We appreciate the strong reminders concerning improper referral fee arrangements.
NSCLC	Section C Marketing	78	Standardization of plan name type	We would also add a reminder that materials developed by any entity, including materials developed for MA plans by state entities concerning SNPS, are subject to review by CMS and must comply with CMS marketing guidelines.

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NSCLC	Section C Marketing	78, 79	Part D marketing materials	<p>We note that the list devised by CMS contains 18 distinct plan name types. There are benefit package variations within each of these types of plans. While we recognize that not all beneficiaries are eligible to enroll in all plan types, and that not all plan types will be available in every part of the country, the potential number of variations makes meaningful comparison and choice difficult. At a minimum, CMS needs to limit the number of plans each sponsor may offer and develop standardized benefit packages to allow beneficiaries the opportunity to make informed choices.</p>
NSCLC	Section C Marketing	80	Part D marketing materials-mail order	<p>The changes to the marketing materials will provide increased transparency for beneficiaries about plan benefit structures and practices. We ask CMS to require the use of the model notices that it is developing in this regard. The use of standardized, mandatory notices will ensure that CMS ensures that beneficiaries receive the information they require.</p>
		80	Part D marketing materials-general	<p>We do not think that CMS should allow plans to move beneficiary prescriptions to mail order status without express permission from the beneficiary. Providing after-the-fact notice is insufficient. The Part D benefit is supposed to give beneficiaries choices, including choices of pharmacies. Moving them without prior consent creates barriers to that choice. We are particularly concerned because such moves, though almost always benefiting the plans, do not always benefit the enrollees. Advocates have heard of cases where, though a co-pay at a mail order pharmacy may be the same as or lower than the co-pay at a retail pharmacy, the full pharmacy price is higher with the result that using the mail order pharmacy moves the enrollee into the doughnut hole faster. Without research and careful comparisons of EOBs, enrollees cannot figure out which route is most cost effective for them. Because in many cases mail order pharmacies are operated by the plans, this issue of transparency is of particular concern and one that we hope that CMS will carefully monitor.</p>

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		80	CMS surveillance of marketing activities	<p>Beneficiaries are confused by the flood of materials that they receive from CMS, plans, and SSA, some of which contains important information about their benefits (e.g., the ANOC) and some of which are pure marketing. We urge CMS to develop some requirements for mailings to help beneficiaries more easily distinguish mailings. For example, CMS could require plans to print "MARKETING" or some similar language on ALL mailed materials that are for marketing purposes only. These indicators, combined with an informational campaign about them, would help beneficiaries sort through the mass amounts of paperwork they are mailed each fall. CMS would need to monitor plans to make sure they follow the rules.</p>
NSCLC	Section C Marketing	81-81		<p>We thank CMS again for your increased efforts in this regard, including imposing more substantial sanctions against violators. We believe that CMS should review its oversight activities and consider not renewing contracts of organizations that continue to violate marketing and other rules.</p>