Congress of the United States
House of Representatives
Washington, DC 20515

October 4, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

As the Ranking Members of the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Government Reform with authority over the Medicare program, we respectfully submit the following comments on the Medicare Prescription Drug Benefit Titles I and II Notice of Proposed Rule Making (NPRM) issued August 3, 2004.

While we continue to oppose the Medicare prescription drug benefit in its current form, we believe it is important for the regulations to address as many flaws in the bill and be as protective as possible of Medicare beneficiaries. In that regard, the proposed rule falls short. A prime example of the proposal's failure to adequately protect beneficiaries in Title I is the unworkable appeals process. In addition, the proposed rule fails to protect against arbitrary limits on prescriptions, ensure broad access to pharmacies, protect beneficiaries against improper marketing, or ensure simple enrollment of the low-income population. Prime examples of Title II failures include weakening of quality, oversight, and consumer protections. In many instances, Title II moves the program backwards, removing the requirements for accountability and consumer protection that currently exist. Medicare was enacted as a program to provide health insurance to the elderly and individuals with disabilities, not to provide government subsidies to insurance companies.

Moreover, we are also concerned that much of the detail necessary to implement Titles I and II is missing from the NPRM. This law is the most complicated change to Medicare in the program's history. Therefore, we strongly recommend that CMS either (1) conduct a second Notice of Proposed Rule Making using a new proposal that incorporates changes based on this first round of comments or (2) issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of input.

While we have chosen to focus our comments on a few important provisions, the lack of comments from us on other provisions should not imply that we support the proposed regulations. We feel strongly that the proposed rule is strongly tilted to favor private insurance

plans instead of beneficiaries -- we urge you to refocus the rule on consumers. Finally, we would like to affiliate ourselves with the comprehensive comments submitted by Families USA, the Center for Medicare Advocacy, the Medicare Rights Center, and other organizations representing beneficiary interests, and hope that you will give great weight to their input as well. Our detailed comments on the NPRM [CMS-4068-P and CMS-4069-P] are attached.

Sincerely,

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Attachment

October 4, 2004

Comments on Proposed Regulations
File Code [CMS-4068-P]

Title I NPRM, Medicare Program; Medicare Prescription Drug Benefit
42 CFR Parts 403, 411, 417, and 423

As the Ranking Members of the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Government Reform, we respectfully submit the following comments on the Medicare Prescription Drug Benefit Title I Notice of Proposed Rule Making (NPRM) issued August 3, 2004.

It is important to note that we continue to oppose the Medicare prescription drug benefit in its current form. The alternative we offered would have established a guaranteed, comprehensive benefit in Medicare and would have avoided many of the pitfalls and complexities in the Medicare Modernization Act (MMA) as well as this proposed rule. Although we oppose this ill-conceived law, in the absence of any current legislative opportunity to fix its flaws, we believe the regulations should address many of these flaws to protect Medicare beneficiaries as much as possible. It would be wrong to use regulatory fine print to essentially take away the promised drug benefit for many seniors.

We are particularly concerned that the Centers for Medicare and Medicaid Services (CMS) failed to take regulatory steps to strengthen the underlying law. Such action is necessary to ensure that the central focus of the Medicare program remains its beneficiaries, and not the profit motives of the health care industry. There are a number of policies in the proposed regulation that make matters worse for beneficiaries, with examples being the appeals process and oversight activities. Additionally, CMS's failure to use its authority to protect against "cost-management" tools, such as limiting the availability of certain drugs or the number of prescriptions, ensuring broad access to pharmacies, protecting beneficiaries against improper marketing, or ensuring simple enrollment of low-income individuals, should be corrected. We highly support the expanded definition of who qualifies for the low-income benefit and the more lenient assets test. Pro-beneficiary provisions, however, were only discussed in the preamble and should be included in the final regulations.

We are also concerned that much of the detail necessary to implement Title I is either too vague or missing from the NPRM. The MMA is the most complicated change to Medicare in the program's history. We strongly recommend that CMS either (1) conduct a second Notice of Proposed Rule Making using a new proposal that incorporates changes based on this first round of comments or (2) issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of input.

Due to the complexity and abundance of provisions in the Title I NPRM, we are focusing our comments on the most important provisions. The lack of comments from us on a specific provision should not assume that we support the proposed regulations. In fact, we wish to affiliate ourselves with the comprehensive comments submitted by Families USA, the Center for Medicare Advocacy, the Medicare Rights Center and other organizations representing beneficiary interests. We urge your careful consideration of the issues and comments raised by these groups. Our detailed comments on the regulations are as follows:

Subpart B – Eligibility and Enrollment

We are very concerned that the proposed enrollment process will result in mass confusion for tens of millions of beneficiaries. We urge CMS to make significant changes to this portion of the rule. In particular, CMS must expand the assistance for low-income beneficiaries and beneficiaries with special needs. Given the confusion that will surround the initial years of implementing this benefit, we urge CMS to delay the instituting of the late enrollment penalty provisions for the first few years. Also, a simpler process as well as additional support for information and counseling are needed to ensure the maximum number of beneficiaries are reached. We urge CMS to use its resources, and to work through Congress, to secure additional resources for beneficiary and provider education on these matters.

The proposed rule falls woefully short on enrollment issues pertaining to dually-eligible beneficiaries, i.e., those enrolled in both Medicare and Medicaid. On January 1, 2006, 6.4 million dual eligible individuals will be transferred from their Medicaid coverage to the new Medicare drug benefit. The rule fails to adequately address the timing and the mechanics of this mammoth transition. Automatic enrollment in the Medicare benefit will not begin until May of 2006, even though Medicaid coverage of these beneficiaries ends in January of that year. Without substantial outreach and education efforts prior to 2006, many dual eligible individuals will in all likelihood have no drug coverage for several months. This is unacceptable and we urge CMS to begin right away working with states to identify and notify dual eligible individuals as quickly as possible. We urge the Administration to protect this population from any temporary loss of coverage by implementing any steps necessary such as delaying the transfer and extending Medicaid coverage for additional months. If legislation is needed to accomplish this, you should act quickly to provide Congress with the necessary legislative language.

In order to best implement automatic enrollment, we believe the states should administer the process. States have readily available data and are already required to perform the low-income subsidy enrollment. Along with this added responsibility the States should receive a transfer of sufficient administrative funds to ensure this implementation is done properly and thoroughly. We believe that states should receive 100 percent federal funding for this activity. In addition, the federal government should work with the states to ensure each has adequate systems and data to accomplish this task expeditiously.

It is our view that dual eligible individuals should have special enrollment periods and they should be exempt from the late enrollment penalty should this complex process result in a

coverage gap of more than 63 days. Based upon the experiences of beneficiaries under the current plan participation, we expect these beneficiaries will have coverage gaps resulting in frequent changes from one plan to another. An ongoing commitment by CMS and the Administration is essential to ensure no loss or disruption of coverage during the annual open enrollment cycle. All of these protections should extend as well to those eligible for full or partial low-income subsidies.

We have grave concerns as to the effect of the new Medicare benefit on continuity of care for dual eligible individuals. The proposed rule would require dual eligible individuals to enroll in the "benchmark" or average plan without regard to whether that beneficiary's drugs are covered or whether the plan's coverage is appropriate for that individual. In addition, because the Medicare subsidy will only pay enough to cover the average plan, a beneficiary may be unable to afford a different plan that meets their individual needs. Plan formularies are expected to be less comprehensive than current Medicaid coverage, and this could force beneficiaries to switch medications. Not only would such a change be disruptive, but also very difficult for those with complex or serious medical conditions such as mental illness. We believe that CMS should retain coverage of medications for dual eligible individuals and other especially vulnerable populations. Plans should offer special formulary protections for these beneficiaries as well.

Disenrollment

We oppose CMS making it easier for plans to involuntarily disenroll beneficiaries from their plan. We also oppose CMS's new policy on disruptive behavior, and fear the resulting negative consequences for those with mental illnesses. CMS should clearly outline the requirements for plans seeking to involuntarily disenroll a beneficiary. These requirements should include notice requirements, reasonable efforts to resolve the situation prior to disenrollment, and documentation of the process. Involuntary disenrollment should not be permitted simply because an enrollee chooses not to comply with a treatment regimen cannot afford the cost sharing or decides to seek treatment which the plan does not support , including the decision of receiving no treatment. Moreover, if there is no other plan in a geographical area, a plan that involuntarily disenrolls a beneficiary must be required to readmit that person. To fail to do so would be contrary to the entitlement nature of this benefit.

Plan Information

We recommend CMS strengthen the section pertaining to information that plans must provide to beneficiaries. Merely issuing guidance on this is insufficient; CMS needs to issue regulations that are binding and enforceable. In order for beneficiaries to make an informed choice about their drug plan, they must have all the necessary information to evaluate the plan. Written plan information should be provided annually, including premium information (including portion, if any, applicable for low-income individuals), benefits and formulary structure, coinsurance or copayments for each drug, negotiated prices (so that individuals know how much they will pay in the coverage gap), participating pharmacies, comparative value of the plan, out-of-service options (and charges), appeals and grievance procedures, and general information on plan

performance (including quality measures, information on grievance and appeals rates, and so forth).

Marketing Protections

CMS must ensure final regulations are thoroughly protective of beneficiaries, who are frequently victimized by marketing abuses and scams. CMS must detail the specific information it will require plans to include in their marketing materials, including which drugs are on the formulary, pricing, and premium information. Plans should be expressly prohibited from telemarketing (either by phone or e-mail). There have already been numerous reports of telemarketing fraud under the Medicare discount card and we do not want this perpetuated under the Medicare drug benefit. To further protect beneficiaries, plans should not be allowed to market "other" services to beneficiaries. Having these plans offer additional non-Medicare services would be confusing for beneficiaries, who might believe that CMS had approved these services. This would also make the task of comparing plans more difficult for beneficiaries. CMS must also limit provider or pharmacy-based marketing, as this has the potential for those with a financial stake in a plan to inappropriately steer beneficiaries to that plan. Finally, any organization that has a primary purpose other than improving the health of beneficiaries should not be permitted to act as a drug plan. In particular, financial institutions, which are exempt from the HIPAA privacy rule, should not be permitted to participate in the program.

Privacy

CMS should include in the regulation plans are prohibited from using enrollee and applicant information obtained in the Medicare drug card program during the marketing of prescription drug benefit drug plans. In addition, CMS must specify in the final rule how it will disclose any personally-identifiable information to plans. The disclosure of a beneficiary's personal information should be limited to the minimal amount necessary. Certainly no health or financial information should be disclosed. Nor should telephone numbers or e-mail addresses be disclosed because plans do not need this information and telemarketing is objectionable. Beneficiaries should be given the choice of whether they want this information disclosed. CMS should also make clear that if beneficiaries opt-out of having this information disclosed, they can still enroll in a plan and will still receive information from CMS, rather than the plans, about the benefit.

Creditable Coverage

CMS must establish specific requirements for what it means to have "creditable coverage." Creditable coverage is a determination of the whether a beneficiary's current level of prescription drug coverage is comprehensive enough that the beneficiary may decide to stay with that coverage rather than switch to the Medicare Part D drug plan without incurring adverse consequences. If CMS decides a beneficiary's current prescription drug plan does not qualify as creditable coverage and the beneficiary still decides to retain current coverage instead of joining the Medicare Part D coverage, and then later changes their mind and decides to enroll in Medicare Part D, that beneficiary will be subject to a late enrollment penalty. Thus, failure to

properly set out the creditable coverage requirements and notify beneficiaries will result in permanently higher premiums for beneficiaries. CMS must develop standard notices for beneficiaries so that they will know when they are losing coverage, and should provide notice through as many avenues as possible, including retiree statements, medical billing correspondence, etc. Any changes in an individual's coverage status must trigger immediate beneficiary notification. Individuals who are not appropriately notified must be allowed special enrollment exceptions and must not be penalized financially.

Subpart C – Benefits and Beneficiary Protections

Definition of Person

Throughout the debate on this legislation we expressed concern over the inability of third parties to assist with a beneficiary's out-of-pocket drug costs without penalizing the beneficiary. We believe the regulation should re-define "person" so that family members can pay for covered Part D cost sharing.

Treatment of HSAs

Regardless of our opposition to Health Savings Accounts (HSAs) and similar plans, we believe the final rule should not give preferential treatment towards contributions from these plans in order to reach catastrophic coverage by counting them as incurred costs toward coverage during the coverage gap. This is particularly true when contributions from employer-sponsored group health coverage are not counted as an incurred cost.

Treatment of ADAP and SPAP Subsidies

We not only believe that employer sponsored group coverage should be counted as incurred costs, we also believe cost-sharing subsidies from AIDS Drug Assistance Programs (ADAP) should be counted as incurred costs. Not counting these costs will make it nearly impossible for many individuals with HIV/AIDS to attain catastrophic protection under the law. Forcing beneficiaries to forgo these subsidies could be a significant barrier to their obtaining needed medications and would pose a substantial financial burden on these individuals, many of whom are low-income. We support the provision in the rule allowing State Pharmaceutical Assistance Program (SPAP) expenditures to count as incurred costs. ADAP assistance should also be treated this way.

Tiered Cost Sharing Limits

The MMA permits tiered cost sharing to encourage the use of preferred drugs when it is clinically appropriate. We are concerned about the provision in the proposed rule that would allow Part D plans to apply tiered cost sharing without any limits. We strongly recommend CMS set a limit for the number of cost sharing tiers plans can use. Otherwise, plans could effectively eliminate coverage of a medicine by placing it in an extremely high cost sharing tier, undermining beneficiary access. Allowing plans to have unlimited flexibility in cost sharing would provide yet another opportunity to discriminate against beneficiaries who need costly or multiple medications. Unlimited tiers would also further complicate the ability of beneficiaries to compare plans.

Enhanced Alternative Coverage

Similarly, we are opposed to the provision in the proposed rule for "enhanced alternative coverage." The law already provides for standard prescription drug coverage and alternative coverage with at least actuarially-equivalent benefits and access to negotiated prices. Having yet another level of coverage would further complicate plan comparison and make it impossible for beneficiaries to make informed choices.

Negotiated Savings

We believe the final rule should require that plans pass along all of their negotiated savings to beneficiaries.

Access to Pharmacies

We believe that the regulations should require that pharmacy access standards must be met in each service area; plans should not be permitted to apply the standards across a multi-region or national service area thus limiting pharmacies to which a beneficiary can have access. Plans should not be allowed to count providers not physically located in the service area toward meeting these requirements.

In the interest of encouraging provider participation to improve beneficiary access, we recommend CMS develop a standard model contract and require plans to use it with pharmacies. The final rule also must ensure pharmacy access standards for Native American populations, those in long-term care facilities, and those that use federally qualified health centers and rural health centers. Plans should not be allowed to discriminate through cost sharing or otherwise against beneficiaries that use these pharmacies.

Therapeutic Classes, Formularies, Prior-Authorization, and Cost Sharing

We believe CMS must be as aggressive as possible in using its authority under section 1860D-11(e)(2)(D) to review plan designs as part of the negotiation process to ensure they do not discriminate. We have commented separately to U.S. Pharmacopia (USP) on the need for a therapeutic classification system that is solidly protective of beneficiaries to ensure broad access to needed medicines. The USP draft guidelines were deficient in that regard. We believe CMS should set the highest bar possible in analyzing plan formularies, cost sharing tiers and levels and how they are applied to assure beneficiaries who need multiple or costly prescriptions, or whose use of certain drugs predicts expensive health conditions, are not discriminated against. The current rule does not do that and CMS must develop and publish standards that are legally enforceable regulations, not merely guidelines.

CMS should also publish in the final rule guidelines for plans regarding prior-authorization and step therapies which require a patient to try lower costs or preferred medicines first. CMS should publish a list of conditions for which it is clinically inappropriate to require step therapies. Many state Medicaid programs exempt certain conditions from such requirements, including mental illness and HIV/AIDS. In addition, we strongly support the provision in the proposed rule that requires plans to provide special treatment to certain populations due to their unique needs. These populations should be exempted as well from formulary restrictions and protected against tiered cost sharing and other barriers that could limit access to medically appropriate medications. At a minimum, these protections should extend to dual eligible individuals, persons with life-threatening conditions, pharmacologically complex conditions, individuals in institutions, and other vulnerable populations.

Pharmacy and Therapeutic Committees (P&T) are the first step in the process of obtaining access to needed medicines. As these committees determine which drugs are covered, they must be unbiased and independent and the final rule should have stronger protections to assure this. Those who serve on the committees should have appropriate expertise in the care and treatment of the elderly and individuals with disabilities. The committee process should be transparent and open to the public and must provide for consumer input and involvement.

Beneficiaries must be properly informed, in advance of any plan changes to covered medicine, including cost sharing changes. We believe CMS should limit the ability of plans to make mid-year formulary changes that would restrict coverage. Beneficiaries should be provided advance notice of any formulary changes and, at a minimum, those directly affected by the change must be notified in writing. Written notice should extend beyond changes in covered medication, and should also be sent when the plan changes procedures for accessing a particular medicine. Plans must be required to provide beneficiaries needed information in the explanation of benefits. The final rule must be strengthened to require a description of appeal rights and processes in the explanation of benefits. Plans must provide formulary information to all Part D eligible beneficiaries, not just plan enrollees. This information is necessary for potential enrollees to assess the ability of a plan to meet their needs and should be available. This formulary information should include not only covered drugs, but which tier and the amount of co-payment required.

Healthcare needs are not restricted to business hours. The final rule should require plans to offer 24-hour/7 days per week toll-free call centers for beneficiaries and providers may call for informationIn addition, the final rule should strengthen emergency access standards, including requiring plans to cover a temporary supply of medicine and allow medicines to be filled at non-network pharmacies in the event of an emergency or other urgent situation. As with other emergency care, beneficiaries should not be penalized in these instances.

Subpart D – Cost Control and Quality

Prescription Drug Plans (PDPs) should be prohibited from using restrictive cost-containment tools such as dispensing limits, requiring prior authorization, or offering therapeutic substitution without constraint. These types of management and cost containment tools will only create an access barrier for Medicare beneficiaries in reasonable need, and attempting to obtain a prescription medication that their physician prescribes. Overall, this will result in more costs for the entire Medicare system in the form of sicker beneficiaries and increased hospital visits. Administrator McClellan testified before the Senate Committee on Finance that beneficiaries would not be subject to dispensing limits, prescription limits or limits on maximum daily dosages. He should be held to this commitment because such cost containment strategies could fully undermine a beneficiary's ability to stay healthy and independent. Similarly, as the Preamble indicates, therapeutic substitution should be prohibited unless there is physician approval. And, any process for prior authorization that does not minimize the burden on beneficiaries and physicians and does not provide emergency supplies of medications will result in denials of needed prescription medications and harm to Medicare beneficiaries. Prior authorization requirements are most harmful to individuals with conditions requiring complex pharmaceutical protocols such as mental illness, epilepsy, HIV/AIDs, and cancer. All such populations should be exempt from prior authorization.

We believe the draft regulations provide excessively broad authority for the private Prescription Drug Plans to employ strategies that could potentially impair clinical quality and harm beneficiaries. There should be specific language included in the regulations that prohibits or limits the use of such potentially harmful strategies, for example placing overly restrictive limits on dispensing quantities or number of refills, engaging in therapeutic substitution without the advance knowledge and written concurrence of the treating physician, or employing prior authorization procedures that impose excessive burdens on beneficiaries and physicians. The approval and oversight of these cost-containment strategies should be the responsibility of the Pharmacy and Therapeutics Committee of each plan to ensure the clinical needs of the beneficiaries are the primary consideration. It is unfortunate that cost-containment mechanisms in the MMA and the NPRM appear to rely solely on utilization controls that could negatively affect access to needed prescriptions, rather than on efforts to reduce prices.

We recommend that the requirements be strengthened in the regulation for the Quality Assurance programs provided by the PDP and Medicare Advantage (MA-PD) plans. Specifically, we request that all plans, at a minimum, be required to include in their quality assurance systems specific elements that are current or recommended standards of practice (e.g.,

electronic prescribing, clinical decision support systems, adverse event reports, and educational interventions). We urge the collection of quality evaluative data that includes plan error rates and the results of the standardized consumer satisfaction survey. These data should be comparable among all plans and be available in a form that the public can easily understand. Finally, we request that any regulation established to provide incentive payments to a plan be based primarily on measures of quality or improved overall health of beneficiaries rather than their ability to reduce costs through reduced utilization.

Subpart F – Submission of Bids and Monthly Beneficiary Premium; Plan Approval

Given the instances of collusion between drug manufacturers and pharmaceutical benefits managers or other plans that have been documented in the press and recent lawsuits, we believe the final rule must clearly prevent such abuses in the Medicare program. Groups affiliated with drug manufacturers and manufacturers themselves should be prohibited from providing the Part D benefit. CMS must stringently regulate the financial relationships between entities offering the Medicare prescription drug benefit and drug manufacturers, and this must be spelled out in the rule.

As stated earlier, we have many concerns about formulary issues and have provided separate comments on the U.S. Pharmacopeia model guidelines. We hope those guidelines will be strengthened to better protect beneficiaries. For plans that do not use those guidelines, we urge CMS to make clear in the final rule that CMS will not approve plans which develop its own formulary using fewer classes than what we hope CMS will allow and that those will be better than the USP guidelines. In addition, the proposed rule states that CMS will not approve plans that are likely to "substantially discourage enrollment of certain Part D eligible individuals." The word "substantially" only adds confusion and potential for legal action. We urge CMS to drop the word "substantially" from the rule. Cherry picking is an abuse that should not be tolerated; it should not have to rise to the subjective level of "substantial" before CMS will act. The Preamble suggests that CMS will only consider discrimination based on health status, not on other factors. We urge CMS to include a broader list of factors that could potentially discriminate against beneficiaries and to clearly state these factors in the final rule, not only in the Preamble.

Subpart I – Organization Compliance with State Law and Preemption by Federal Law

We support the view in the Preamble that the federal preemption language should be applied narrowly and should not preempt state law where CMS does not have specific authority to regulate.

Subpart K – Application Procedures and Contracts with PDP Sponsors

We strongly support the anti-fraud provisions in this Subpart. We urge CMS to be as aggressive as possible in protecting beneficiaries and program funds from unscrupulous activities. We request that CMS clarify that annual audits must be conducted (not "may") and urge CMS to allocate appropriate resources to do so. We urge CMS to submit any additional legislative authority or resource requests to Congress quickly. We have already requested that the Appropriators provide a $25 million increase in the budget of the HHS Inspector General, in part to ensure adequate funding for new responsibilities brought on by the MMA.

Also in this Subpart, we ask CMS to reconsider the minimum enrollment requirements for plans. Plans with a very small enrollment base cannot adequately leverage discounts on drugs for beneficiaries or efficiently operate to meet the other plan sponsor requirements.

Subpart M – Grievances, Coverage Determinations, and Appeals

We believe that the NPRM fails to provide sufficient due process protections for Part D beneficiaries. These rules should not be less protective of beneficiaries than Medicaid or Medicare, yet they are as drafted. CMS must strengthen these provisions in the final rule to ensure appropriate due process for beneficiaries. As currently proposed, the rules are overly complicated and will not provide timely redress for beneficiaries, many of whom will be forced to go without necessary medications during the appeals process. Congress, on a bipartisan basis, supported strong appeals protections in the versions of the Patients' Bill of Rights that passed the Senate and the House in 2001. Medicare beneficiaries should be afforded equally stringent protections for their prescription drug benefits. To the greatest extent possible, the process should mirror the existing Medicare appeals process. Furthermore, in the settlement of *Grijalva v. Shalala*, CMS established a fast-track, pre-termination review by an independent entity. The proposed rule fails to incorporate such a process. We believe it must.

The review processes in Subpart M must be substantially simplified with revised timeframes that ensure beneficiaries do not go without necessary drugs during the review process. The proposed rule sets an exceptionally high bar for receiving an "exception." Plans should not be allowed to require additional criteria beyond what CMS outlines for receiving an exception. The regulations leave plans too much discretion in this area. The burden placed on physicians to produce clinical evidence is excessive and the level of evidence required may not be available in all instances. The weight of clinical evidence or the physician's experience must be considered and should suffice particularly where clinical evidence is lacking or contradictory. The burden should fall on the plan to show why the doctor's decision is not definitive.

The timeframes for exceptions and redeterminations for appeals are too long. To this end we suggest all reviews be handled on an expedited basis, allowing 72 hours each for re-determinations and independent review entity (IRE) consideration, and access to an Administrative Law Judge within seven days after IRE review. Extensions must only be allowed at the request of a beneficiary, not a plan sponsor. Plans should be required to make determinations regarding exceptions and notify the beneficiary within 24 hours, as required under Medicaid for determinations regarding prior-authorization requests. At the initiation of the review process beneficiaries must be provided a 14-day supply of the requested prescription(s)

and receive immediate notice of their review rights. Most medications are prescribed for immediate use and delay in obtaining the medicine could have disastrous health consequences.

CMS must clarify in the final rule that the role of the IRE is to provide independent, de novo review, especially in regard to the exceptions process. If the IRE does not review the evidence and make recommendations based on its own analysis, enrollees are denied independent review and thus due process. Denials should be automatically sent to the IRE for review as they are in Medicare Advantage. Beneficiaries should be allowed to aggregate prescriptions in order to meet the monetary threshold for higher level review.

Enrollees should be able to initiate review orally and should be able to have an authorized representative submit appeals on their behalf. CMS must improve upon the notice requirement and content of the notice. Beneficiaries must be presented notice immediately upon denial. This notice should explain why coverage was denied, rights to appeal (and any limitation on filing an appeal), and rights to obtain an interim supply of medication. The notice should also include the clinical or scientific basis for denial.

Subpart O – Intermediate Sanctions

Under the MMA prescription drug plans are created to administer the Part D benefit to seniors and individual with disabilities. While Medicare provides guidance, the PDPs have the authority to set formularies, set their cost sharing, set their process and standards for appeals, set drug prices, and attest that they are complying with Medicare rules. We have commented more specifically on these deficiencies in other parts of the letter; however, it is imperative that Congress and HHS provide strict oversight to ensure that PDPs act in a manner consistent with the goals of Medicare and in accordance with the rules and regulations eventually finalized by CMS, particularly given the latitude that plans currently have under the regulations.

Although the proposed rules establish four types of sanctions and six bases for imposing the sanctions, they do not provide guidance on which sanctions should be applied when. In addition, the sanctions are all permissive. To protect Medicare beneficiaries and the taxpayers against fraud, waste, and abuse, sanctions should be administered through a clear process and methodology and should be mandatory.

Additionally, CMS needs to ensure that it has the ability and data necessary to determine when a specific PDP is not in compliance with stated rules and regulations. CMS should not farm out to accreditation organizations or any other entity the role of overseeing plans. It should not rely on outside entities to review the work of PDPs or information that a PDP may submit. CMS should have a direct survey process to review PDPs to ensure that Medicare beneficiaries' trust in their Medicare coverage is not undermined by a few rogue private PDPs and lack of oversight.

Subpart P – Premium and Cost Sharing Subsidies For Low Income Individuals and S – Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

Special attention needs to be given to ensure that Medicare's low-income population and Medicare individuals with disabilities will not be made worse off than they are today. This is a vulnerable population and all protections afforded them today should be guaranteed through the regulations. Moreover, it is very important that dual eligible individuals, those that were previously on Medicaid and are now going to be covered under Medicare's Part D program not be harmed by the transition from Medicaid to Medicare. We applaud CMS for choosing to define Medicare Savings Program (MSP) beneficiaries, those not fully qualified for Medicaid but low-income enough to receive some benefits under Medicaid, as full subsidy eligible individuals under the statute.

First, institutionalized individuals should be defined to include all those receiving home and community-based services under a Medicaid waiver and receive all the benefits of an institutionalized individual under the MMA. Individuals receiving services under a Medicaid home and community-based waiver have already met the criteria for being in a nursing home and were just lucky enough to live in state that affords them the option of living at home and receiving services there to maintain them. Their continuity of care should not be disrupted because these individuals took advantage of a program alternative that Congress, the Administration, and States support.

Second, information and outreach is imperative to ensure that the low-income population and individuals with disabilities that were receiving Medicaid or were Qualified Medicare Beneficiaries are enrolled in a Part D prescription drug plan before 2006 when Medicaid stops providing prescription drug services to them. The regulations needs to clarify explicitly that states are required to notify all deemed subsidy eligible individuals of their status by July 1, 2005. The notice should have next steps, sources for information, counseling and assistance information in choosing a Part D plan and what that will mean for them. Each individual should

also be told of their right to appeal the subsidy level to which they are entitled. CMS should have learned a valuable lesson about information and outreach from the Medicare Prescription Drug Cards. Information and program enrollment processes must be simple, timely, and clear or else beneficiaries will not enroll. Low participation will not only signal another failure for Medicare, but it will put 6.4 million low-income individuals and individuals with disabilities at risk as today each of these persons is cared for under Medicaid.

Third, we applaud the Administration's belated recognition of the benefits of automatic enrollment in the Medicare prescription drug program. MSP beneficiaries should be automatically eligible for the low-income subsidy as reflected in the proposed legislation.

Fourth, individuals applying for the low-income subsidy should be automatically screened for other important benefits by SSA or Medicaid, wherever the individual applies. For example, individuals should be screened for Medicaid, the Medicare Savings Program within Medicaid, food stamps, etc. It is important as we spend money on outreach and education that CMS be prepared to reap the benefits in other programs, specifically for programs we have been concerned about low participation, such as MSP. The joint applications should be straightforward and streamlined and as much as possible require no additional documentation or forms for screening of additional programs. CMS can act on our concerns by making enrollment straightforward and easy and working with the U.S. Department of Agriculture and the Social Security Administration to ensure they too are screening people for all programs for which they may be eligible.

Within this joint application process, however, CMS should ensure that, with regard to MSP screening, applicants will be given the choice of opting-out of the subsidies. Because of complex income calculations under different assistance programs such as food stamps or Section 8 Housing, the low-income Medicare benefits could endanger an individual's ability to enroll in the other assistance programs. Some Medicare beneficiaries signing up for drug discount cards early on were later disqualified from housing and food stamps qualification because of the drug card's discounts and subsidies.

Fifth, once screened for benefits, CMS should require states and SSA to notify individuals of determinations within 24 hours of making them.

Sixth, it is imperative that MSP eligibility requirements be applied in a standardized manner within each state regardless of who is screening the individuals for MSP and thus automatically for the low-income subsidy. Under the regulations, it is likely that the Social Security Administration would apply a more restrictive assets and income test than a state for MSP eligibility and thus fewer people would be deemed eligible for the low-income subsidy. Such confusion and unfairness will undermine the low-income subsidy.

Seventh, low-income beneficiaries must be protected from excessive co-payments and premiums during the time it takes for plans to be notified that an enrollee is a subsidy eligible individual. The regulations affirm that low-income Medicare beneficiaries should be protected from the excess co-payments and premiums, but as written a plan only protects the beneficiaries

once they have been notified to do so. The regulations should extend the protection to beneficiaries who present their notice of approval for the subsidy to their pharmacies.

Subpart Q – Guaranteeing Access to a Choice of Coverage (Fallback Plans)

We are opposed to the overall framework of the drug benefit in its reliance solely on private insurance plans. We believe that a fallback plan will be critical for many beneficiaries in Medicare. We continue to maintain that in the absence of a private Medicare drug plan, every area should have a continuously operating "fall back" plan that is available to all beneficiaries. The Administration's aggressive attempt to limit the fallback option is disconcerting. We believe that CMS should interpret the statute as liberally as possible to ensure continual operation of fallback plans and minimal disruption for beneficiaries. CMS should ensure there is a level playing field for fallback plans as well. The Preamble states that CMS is contemplating tying performance payments to fallback entities to average discounts they are able to negotiate. This is a higher requirement than for non-fallback plans. CMS also discusses examining bidders' pricing structure and the nature of their arrangements with manufacturers to ensure there is no conflict of interest leading to higher bids. This requirement should also be imposed on private plans, as they too could engage in collusion. The Medicare Advantage program could benefit from CMS's thorough review of plan costs and payments like CMS is proposing for the fallback plans. Finally, barring fallback organizations from acting as a risk plan for 4 years is unacceptable and will be a significant dampening factor on any entity's willingness to bid for such a contract.

Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

We strongly believe the retiree provisions in MMA do not go far enough to retain current levels of retiree coverage. Currently, one in four Medicare beneficiaries receives prescription drug coverage from their former employers. CMS needs to draft regulations that mitigate, and not exacerbate, these provisions in the law.

We urge CMS to adopt and enforce an actuarial equivalence test that assess both design and practice and has strong retiree protections. The regulations did not propose an actuarial equivalence test, but offered a few options of how CMS could approach the definition. Although we agree that this is a complex issue and appreciate the opportunity to comment on three options that CMS proffered, it is precisely because this is an important and complex issue that we will need time to review any final formula which CMS adopts as well. However, we tend to believe that the "two-prong" test in which the employer would also have to show it is paying for at least a specific minimum share of the total benefit is a good starting point to prevent cost shifting to beneficiaries. In implementing the test, the employer plans should be limited to the extent possible from making mid-year changes to their formularies or cost sharing unless they certify that the benefit value continues to meet the actuarial equivalence test in order to continue to get the subsidy. Retirees should receive notification when they are offered a drug benefit that is inferior to the Medicare Part D benefit. Any material changes should be noticed 90 days prior to the effective date of the change. Retirees who are misinformed or improperly informed about the employers level of coverage (or when the employer's attestation was not filed in a timely manner) should not incur penalty for late enrollment.

To ensure oversight in this area, subsidies given to employers should be transparent and reporting in disclosure should be made public. In addition, employees should be permitted to challenge an employer's attestation that its plan is actuarially equivalent.

Subpart T – Changes to Parts 403, 411, 417, 460, and 442

The disclosure notice concerning Medigap H, I, and J policies must be concise and easily readable. As proposed by CMS, the notice contains unnecessary information that may be confusing for beneficiaries, in particular the information about Medicare Part D and the value of Part D benefits. We object to the subjective editorializing on the overall drug benefit contained in the CMS proposal. We would note that the National Association of Insurance Commissioners (NAIC) provided CMS with a model notice as required under the law, which CMS apparently chose to ignore. Given NAIC's expertise in Medigap issues, and the fact that the NAIC notice was developed in an open public process, we believe CMS should work more closely with NAIC on this matter and build off the NAIC draft. Finally, CMS should develop a separate notice for those who have creditable coverage that counts towards their drug benefit; their options will be different than those who do not.

We also support the extension of the physician self-referral rules to Part D drugs.

Comments on Proposed Regulations
File Code [CMS-4069-P]

Title II NPRM, Establishment of the Medicare Advantage Program
42 CFR Parts 417 and 422

The Ranking Members of the Committee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Government Reform respectfully submit the following comments to the Establishment of the Medicare Advantage Program Title II Notice of Proposed Rule Making (NPRM) issued August 3, 2004.

We remain opposed to the underlying premise of the Medicare Advantage (MA) program – excessive spending to expand private health plans in Medicare in order to undermine traditional Medicare. While we have historically supported giving Medicare beneficiaries the *option* of enrolling in managed care plans – an option that has existed since the mid-1970s – we feel strongly, however, that the government should not pay these options more than traditional Medicare. Our experience with Medicare+Choice (M+C) and HMOs that preceded the M+C program has consistently shown that private plans cost significantly more relative to the traditional fee-for-service program. In addition, numerous studies and data show lower quality of care, or care that is comparable to the traditional Medicare program. The Medicare Advantage program essentially codifies this past waste and guarantees that private plans will always be paid higher rates than the traditional fee-for-service program. Data from the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary and Medicare Payment Advisory Commission (MedPAC) show that payments to Medicare Advantage plans will average 115 percent of fee-for-service expenditures – 107 percent for the formula and an additional eight percent to reflect the healthier, less expensive population enrolled in the private plans. This year plans will get an additional $552 per beneficiary per month, for a total of $2.75 billion in excess of fee-for-service in 2004 alone.

Indeed, we find it ironic that the NPRM's Executive Summary asserts that the MA program will "advance the goal of improving quality and increasing efficiency in the overall health system." Yet the MMA and the NPRM appear to point us in precisely the opposite direction. Paying the private plans more than traditional Medicare gives the HMOs and other plans a financial advantage to lure certain beneficiaries out of traditional Medicare, while funneling scarce taxpayer dollars into the pockets of managed care stockholders and industry executives. Such practice will ultimately decimate the traditional Medicare program and limit beneficiaries' choice of providers, while increasing costs to the government and undermining access to care. Indeed, given the recent experience of the PPO demonstration project, we remain very concerned about the willingness and ability of the CMS to oversee plan behavior and even to enforce the law.

The winners and losers associated with this harmful policy are clearly reflected in the data in the NPRM. The Medicare Advantage program will cost taxpayers an additional $50

billion over the next ten years relative to what would otherwise be spent in traditional Medicare. Table 4 on page 46930 of the *Federal Register* projects that the administrative costs will total nearly $2.5 billion over the next six years (the narrative description of Table 4 just above incorrectly states the administrative costs to be $1.2 billion, but this total appears to leave out the $1.3 billion administrative cost to local plans). Averaged across the 145 plans that currently participate in Medicare Advantage, this means that each plan will be paid about $3 million annually just to administer the Medicare benefit. These administrative costs are very high relative to the traditional fee-for-service program; other data have shown private plans operate on an overhead of about 5 to 25 percent compared to approximately 2 percent for Medicare fee-for-service.

Beneficiaries do not receive such a generous windfall. Despite claims that Medicare Advantage plans will result in generous extra benefits to enrollees, Table 2 on page 46928 of the Federal Register projects that only $1.4 billion will be spent on extra benefits. When divided among the 4.6 million people currently enrolled in Medicare Advantage plans, this amounts to a little more than $50 per enrollee per year. If enrollment in Medicare Advantage grows as anticipated, this paltry amount will be greatly reduced.

Our overall objection having been stated, we offer the following comments on the NPRM to guide implementation of the Medicare Advantage program. It should be the agency's role to act as necessary through the regulatory structure to ensure that taxpayer funds are wisely spent and that the central focus of the Medicare program remains its beneficiaries, and not the profit motives of the health insurance industry. We recognize the enormously difficult task of writing regulations to implement this hopelessly and unnecessarily complex law. However, we are particularly concerned that CMS has not taken regulatory steps where possible to strengthen the underlying law; for example, we were discouraged that the MMA eliminated the requirement that health plans make a special effort to reduce racial and ethnic disparities in treatment. The Secretary should use his authority to reinstate this requirement in the regulations, especially in light of the controversy surrounding the initial issuance of a "sanitized" National Health Care Disparities Report last December. Left unchecked, the quality chasm that exists for people of color in our health system will only grow wider. In other cases, it appears that the Administration has weakened current beneficiary protections beyond the damage done in the MMA.

Due to the complexity and abundance of provisions in the NPRM and the fact that many provisions of interest are absent, we have chosen to focus our comments on selected provisions. The absence of a specific provision from our comments should not automatically imply support. We would like to affiliate ourselves with the comprehensive comments submitted by the Medicare Consumers Working Group and urge your careful consideration of the specific issues raised by these groups.

We are very concerned that much of the detail necessary to implement Title II of the Medicare Modernization Act (MMA) is either too vague or missing from the NPRM.

For example, the lack of information on the regions that will be used for the MA regional plan make it difficult to envision precisely how the proposed regulations would be implemented. We also note with interest your decision to omit any detail on the "Comparative Cost Adjustment

program" – otherwise known as Premium Support. While we acknowledge that it is not slated to take effect for several years, we remain interested in the Administration's thoughts on implementation of this controversial section of the MMA to which we remain strongly opposed. Absent details, it is impossible for us to thoughtfully critique your proposals or offer constructive suggestions while adhering to the spirit of the Administrative Procedures Act. The MMA is the most complicated change to Medicare in the program's history. There are many interactions with the existing law that need to be taken into consideration. Therefore, we strongly recommend that CMS conduct a second Notice of Proposed Rule Making, incorporating changes from this first round of comments and allowing for public comment on the additional details that are currently under development or issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of input.

Subpart A

Definitions

We note that you have reminded the public of the requirement that the PPO "provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers." Given the recent findings in the Government Accountability Office's (GAO) evaluation of the PPO demonstration, we are concerned that the agency is not effectively enforcing current law. The lack of oversight in today's more limited private plan environment does not bode well for the future as envisioned by the Administration and other proponents of the MMA.

User Fees

We support your efforts to increase user fees upon the plans in order to support beneficiary education, and urge you to collect the entire $200,000 and work with the Congress to either index it or otherwise lift the cap if needed to adequately inform beneficiaries about the new complexities associated with private plans. However, we remain concerned that there is still neither adequate nor guaranteed funding for the State Health Insurance Programs (SHIPs), and urge you to consider dedicating a portion of the MA and PDP user fee revenues in support of SHIPs. We also think it is important to provide beneficiaries with comparative information on plan quality and access, in addition to cost-sharing and other benefit differences. Finally, in light of GAO's finding earlier this year that some of the Administration's materials constituted "propaganda" and others had serious problems (including "notable omissions"), we urge you to share future beneficiary education materials with the Committees of jurisdiction prior to finalizing them for release.

Subpart B

Disenrollment

We are very concerned about provisions under Section 422.74, which will make it easier for plans to disenroll individuals for disruptive behavior. These provisions should be removed. It is easy to imagine people with Alzheimer's, highly disturbed individuals (e.g., a patient undergoing a severe episode of psychiatric illness) and others who will be at risk of benefit termination. In addition, the NPRM asks for comment on whether plans should be able to involuntarily disenroll beneficiaries for non-payment of cost-sharing. While the NPRM asserts that care would be taken to protect "low-income" individuals and limit the authorization of this only to "significant" amounts, neither term is defined and the entire concept is problematic. This proposal should be rejected from additional consideration. Not doing so would place beneficiaries with high medical costs who may be temporarily unable to pay their cost-sharing at high risk of termination of plan benefits; unless the disenrollment occurred shortly after initial enrollment, most may be unable to find other supplemental coverage. Taken together, these new terminations would allow MA plans to dump the most expensive cases by transferring sicker, more costly patients into the traditional Medicare program. Of equal concern, these newly facilitated terminations would also cause unnecessary disruptions in beneficiaries' clinical care. We urge you to drop the provision in the NPRM that makes it easier for HMOs, PPOs and other private plans to stop serving people with mental illness or other complex conditions, and to stop pursuing additional opportunities to help private insurers at the expense of beneficiaries with high medical bills.

Marketing materials

We strongly oppose the decision by CMS in the NPRM to expand the "File and Use" program for MA plan marketing materials. Giving CMS just five days in which to "review" the materials abrogates important agency oversight and enforcement responsibilities, leaving the agency no choice but to rubber stamp all materials. This timeframe is wholly insufficient to ensure that prospective and current beneficiaries receive accurate, clear materials from MA plans. All MA plan marketing materials should be thoroughly reviewed by CMS to ensure plans are not using misleading tactics to cherry-pick or otherwise attract only the healthiest individuals. Marketing requirements should be strengthened, not weakened. Given both the track record of the private insurance industry with this population and the unique circumstances surrounding marketing to an older population, it is critically important that materials be straightforward and useful to prevent widespread abuses. We suggest MA plans present all marketing materials at least 30 days before proposed distribution, and that plans are in no circumstances allowed to distribute materials without the express written approval from CMS.

Subpart C

Basic Benefits

It is unfortunate that the NPRM fails to provide guidance regarding acceptable levels for the single deductible and catastrophic coverage levels required by the regional MA plans. Lack of guidance implies that the agency is willing to accept any level for these triggers. Relying on the ability of the agency to deny a plan only if it "substantially" discriminates in setting these

levels is an unrealistic response. We urge you to include additional detail or suggestions on these new requirements when the next regulation is published.

We are pleased that you intend to require that plans track the beneficiary cost-sharing in order to trigger the unspecified deductible and catastrophic coverage, and we hope that the notification requirements will be clear, promptly issued, and enforced. It is not clear how you intend to differentiate between "incurred" and "paid," but we urge you to choose a definition which ensures that all cost-sharing paid by or on behalf of a beneficiary is counted and tracked.

Disclosure Requirements

Beneficiaries must have ready access to current lists of contracting providers – both as prospective enrollees and once enrolled – with a clear distinction for which providers are preferred versus non-preferred, as applicable. Plans should provide information to current and prospective enrollees without any subjective judgment about those who are "reasonably expected" to enroll.

We do not object to requiring MA plans to establish Internet sites, but want to reiterate that such actions should supplement, not supplant, requirements to provide information in other forms and forums (e.g., written information via mailing, toll-free help lines, etc.). Data indicate that the vast majority of beneficiaries do not have access to or have working knowledge of the Internet.

Access to Services

We oppose the elimination of Section 422.112(b), "Rules to Ensure Continuity of Care." Among other things, these provisions guarantee that beneficiaries are receiving at least minimal levels of care from Medicare Advantage plans, such as providing enrollees with an ongoing source of primary care, ensuring that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health, and providing beneficiaries with an initial assessment of enrollees' health care needs. These are not "unnecessary" or "overly burdensome" provisions, as implied in the NPRM. In fact, continuity of care is what managed care plans allegedly *do.* And since Medicare pays the Medicare Advantage plans its fees each month regardless of whether a beneficiary receives care, maintaining these minimal requirements is imperative. While MA plans are required to cover all Medicare-covered services, even if provided out-of-network (OON), we are not sure what is meant by requiring all plans to offer beneficiaries "reasonable access to in-network cost-sharing" under certain circumstances. It appears that this is a nod in the right direction toward protecting beneficiaries from higher cost sharing, but we are not certain how that would be defined and what its practical effect would be. We urge you to elaborate on this proposal in the next publication on these regulations. In addition, we are concerned about the proposals to relax network adequacy and its potentially negative effect on beneficiaries in rural areas.

The proposal in the rule to tie allowable cost-sharing levels to the "robustness" of an HMO's provider network raises a number of issues. Beneficiaries need to be both protected in terms of access to *and* affordability of benefits. We are also concerned with how these trade-offs will be conveyed to beneficiaries in a manner to allow effective comparison among options. We

urge you to take a position that protects beneficiary access to care and minimizes cost-sharing. We are paying too much for these plans to allow beneficiary overcharges, too. Given the recent GAO report on PPO overpayments, we hope that CMS will strengthen beneficiary protections to ensure that beneficiaries are not overcharged by plans (relative to fee-for-service) for benefits, either in-network or out-of-network, and that access to covered benefits is not restricted by private insurance companies.

Subpart D

We strongly recommend that the requirements for MA plans to engage in quality improvement efforts be significantly improved. More specifically, we request that all plans be required, rather than encouraged, to participate in CMS and HHS quality improvement initiatives, that currently required (e.g. HEDIS) and any newly developed quality reporting data be collected in a manner that would allow comparisons among all programs, and that all quality data be available in easily understandable form to the public.

Quality Improvement

We object to efforts to undermine quality improvement activities by limiting the agency's ability to require data or otherwise weakening current activities. While the MMA appears to reduce the agency's ability to oversee these efforts, we support the agency's statement in the preamble that HEDIS and other tools can still be modified and improved as needed. We hope that this statement translates into the regulation itself.

You ask for comments on whether plan data should facilitate comparisons among all plans or just similar plans or plan types. We strongly urge you to require that data be compiled, analyzed and reported in a fashion to allow beneficiaries to compare across all plans. For those who have choices, it will be important for them to make an apples-to-apples comparison among their various options. Providing information by type of plan will make this task more difficult.

The NPRM's proposal to eliminate requirements relating to minimum performance levels and those that address clinical and non-clinical areas is deeply troubling; we urge you to reconsider.

Given the high level of payment provided to MA plans and claims that private plans provide superior care (relative to traditional Medicare), we believe it is important for the regulations to be as aggressive as possible in requiring the plans to prove their worth. Sadly, it appears that many provisions do the reverse. By allowing plans to pick their quality projects, manipulate samples for those projects, and rely on data from non-Medicare enrollees, it will be more difficult than ever to accurately and adequately assess plan quality.

We urge you to define what constitutes "measurable and sustained improvement" for quality, and to reject the NPRM's decision to gauge success by a "we know it when we see it" standard. If the MMA's efforts to dramatically increase enrollment in MA plans is successful, oversight and enforcement of quality measures could mean the difference between life and death for millions of beneficiaries.

Finally, we are very concerned about the possibility that the agency would further outsource its oversight to private accrediting bodies. We have seen problematic trends in other provider categories (e.g., JCAHO) and strongly believe that CMS should be doing more, not delegating more.

Preferred Provider Organizations (PPOs)

Generally speaking, all standards should apply to all plans – local, regional, HMO or PPO. With few exceptions, there is no supportable rationale for holding local and regional plans to different standards for performance, quality, data collection, reporting or other important activities. PPOs and HMOs are both serving beneficiaries, and as such, should be held to the same standards.

Subpart E

The MMA essentially eliminated requirements that limited the ability of plans to threaten or bribe physicians to provide less care (called "physician incentive plans" or PIPs). Last August, prior to the MMA's passage, CMS significantly weakened the regulations by eliminating routine reporting and replacing it with a requirement merely that the information be made available on request. Now, MA plans need only "assure" CMS that they aren't engaging in abusive behavior. Unfortunately, the NPRM fails to address the statutory requirement that plans provide sufficient assurance providers are not paid or otherwise financially rewarded to withhold needed care; we strongly suggest that the final rule explicitly require plans to attest their compliance with the physician incentive plan law. This will make the "assurances" meaningful, with virtually no additional regulatory burden, as false certifications will fall under the False Claims Act. CMS should monitor compliance during audits, and expressly state that non-compliant plans will be fined or dropped from the MA program.

Subpart F

This section needs much greater detail before interested parties can provide useful comment. That said, we are concerned about the lack of discussion around the certification process and whether this will hamper the government's ability to conduct proper oversight.

Beneficiary Premiums

On page 46898, there is discussion around premium payment options for beneficiaries. We think it is very important that plans and CMS make it clear that additional charges may apply if beneficiaries do not choose to have their premiums deducted from their Social Security checks. This need to be conveyed clearly and in writing before another option is exercised; plans should be required to state the precise charges that will apply for any other options.

Risk Adjustment

You ask for comment on whether risk adjustment should be done on a plan-specific basis or state-specific. We believe it is important to focus on the actual enrollment in the plan and employ a plan-specific approach. This is especially important given the issues resulting from service areas that cross state borders and the desire that a risk adjuster accurately reflect the health of actual enrollees (and adjust the plan's payments accordingly).

Subpart G

Risk Adjustment Data

We strongly object to the NPRM's proposal to move from the current practice of encounter-level data to targeted risk-adjustment data. It is imperative that sufficient and representational data be provided by the plans so that appropriate risk adjustment mechanisms can be designed and implemented. We are well aware of the historical risk adjustment problems and resulting overpayments that occurred with both Medicare+Choice and precursor plans. It is possible, if not likely, that the risk adjustment mechanism may change over time; without broad access to encounter-level data, however, such a change may be impossible, even if it may lead to a better approach. Among alternatives that should be considered are requirements to ensure that the submitted abbreviated samples are representational of the plan's population, or, even better, that the plans submit clinical severity data for the entire population.

Subpart J

This section deals with rules for regional managed care plans. We note again here that the lack of specificity in the proposed rule that makes it difficult to envision this new system regional plans. However, we would note that we are concerned in establishing regional plans with any waiver of state licensing requirements in the states that they are operating. We urge you to be as conservative as possible in deciding how long to waive state licensing requirements as described on page 46907. Knowing that health insurance industry is aggressively objecting to multi-state certification, even though they may be serving beneficiaries in multiple states, we are keenly interested in making sure that these plans are held accountable under the state laws in which they are operating.

Subpart M

We are very concerned that beneficiary grievance and appeals rights be protected and, if possible, improved in light of the expected increase in private plan enrollment. Unfortunately, this NPRM raises a number of issues with respect to obtaining and enforcing these rights. We write to specifically align ourselves with the detailed comments provided by the Center for Medicare Advocacy.

Advanced Beneficiary Notices

We appreciate your solicitation of comments with respect to whether providers (both network and non-network) should provide advanced beneficiary notices (ABNs) for non-Medicare services. We believe these notices should be provided, as they would be for beneficiaries in traditional Medicare. We also strongly support inclusion of a requirement that MA plans provide ABN-like notices to alert beneficiaries to the higher charges that may result by using non-network providers.