AMERICAN ACADEMY *of* ACTUARIES

October 4, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Sir or Madame:

This letter presents the comments of the American Academy of Actuaries'[1] Medicare Steering Committee[2] regarding the Centers for Medicare and Medicaid Services' (CMS's) proposed regulations on the Medicare prescription drug benefit (CMS-4068-P).

In particular, this letter discusses issues related to eligibility and enrollment, benefits and beneficiary protections, submission of bids and monthly beneficiary premiums, payments to prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations, etc. (We provide comments on issues related to actuarial equivalence in a separate letter.)

The proposed rule requires Part D plan sponsors, Medicare Advantage plans, and employers to make a number of certifications and attestations based on prospective actuarial estimates of future prescription drug costs and utilization. As with any other actuarial projection, it is inevitable that actual experience will deviate from projected results—regardless of how carefully they are performed. Such deviations do not, of themselves, indicate that the projections were inappropriate or invalidate attestations based on the projections. The Academy strongly recommends that the standard of reasonableness for prospective actuarial estimates required under the rule be based on conformance with recognized standards of actuarial practice.

[1] The Academy is the public policy organization for actuaries of all specialties within the United States. In addition to setting qualification and practice standards, a major purpose of the Academy is to act as the public information organization for the profession. The Academy is nonpartisan and assists the public policy process through the presentation of objective analysis. The Academy regularly prepares comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

[2] Other Academy groups who played a key role in the development of this letter include: the Actuarial Equivalence Work Group, chaired by John M. Bertko, FSA, MAAA; the Health Practice Financial Reporting Committee, chaired by Darrell D. Knapp, FSA, MAAA; the Medicaid Work Group, chaired by Grady C. Catterall, FSA, MAAA, EA; the Medicare Coordination Work Group, chaired by Cori E. Uccello, FSA, MAAA, FCA; the MedSupp Work Group, chaired by Michael S. Abroe, FSA, MAAA; and the Prescription Drug Work Group, chaired by Thomas S. Tomczyk, ASA, MAAA, FCA.

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We provide comments, where appropriate, based on specific requests from CMS, and we also comment on other issues where we feel our perspective may be useful. The proposed rule presents many issues at a conceptual level, with the detailed mechanics to be worked out later. These details may have a significant impact on beneficiaries, Medicare Advantage plans, and the Medicare program. The Academy would welcome an opportunity to review and comment on the detailed regulations before their final publication.

SUBPART B – ELIGIBILITY AND ENROLLMENT

423.44 Disenrollment by the PDP

Issue: Should a PDP plan disenroll individuals who no longer reside in the PDP service area?
Comment: Experience with Medicare suggests that PDP regions will have a significant number of individuals who spend winter months in one location and summer months in a different location. In contrast to the provider network issues for current MA-HMO enrollees (where the MA-HMO sponsor is unlikely to have network providers in distant areas), many potential PDP contractors with national or multi-regional networks and mail-order pharmacies would likely be able to accommodate such individuals using existing arrangements. CMS should consider whether to allow PDPs to offer travel networks for members who spend many months out of area, without requiring these PDP vendors to contract in those regions. For example, a member who spends most of the year in Michigan might enroll with a Michigan Region PDP, but use the travel network when spending the winter in Arizona, without needing to disenroll. This would greatly reduce the need to transfer prescription drug spending data from plan to plan (e.g., the coverage limit data, etc.).

Such arrangements could be an interim approach pending evaluation of the cost/payment experience that emerges from both the plan and CMS perspectives. The current approach to developing Medicare medical fee-for-service payment rates includes, in the county-level experience that underlies payment rates, the combined in-area and out-of-area usage of beneficiaries relative to their assigned county. Such information does not exist for pharmacy experience. Further, geographic difference in cost/usage will emerge and relativities may be quite different from medical. Making maintenance medications available by mail order may significantly reduce the impact of geographic cost variations, as mail order programs will provide a uniform national price.

423.50 Approval of marketing materials and enrollment forms

Issue: Is it appropriate to apply MA marketing requirements to PDPs?
Comment: In our opinion, the same prohibitions on enrollment forms being accepted in provider offices that apply to MA plans, should also apply to PDPs. A pharmaceutical provider may have the same ability to persuade an individual to select a plan as any other provider. If there is a concern about possible coercion, with providers steering retirees toward plans that maximize the providers' own financial reimbursement, it applies to pharmaceutical providers as well as to other types of providers.

SUBPART C – BENEFITS AND BENEFICIARY PROTECTIONS

423.104 Requirements Related To Qualified Prescription Drug Coverage

Issue: How should FSAs, HRAs and MSAs be treated relative to the definitions of group health plan, insurance or otherwise, and third-party payment arrangements?
Comment: In the future, many beneficiaries may accumulate significant fund balances under one of the medical savings account options available to employed workers and their spouses. Consistent with the proposed regulation, we do not believe that payments made from an HSA should be considered payments from a health plan. Fund balances will, in many cases, be derived from prior beneficiary contributions, may be used for other purposes than paying for pharmaceuticals, and are intended to affect consumer behavior by substituting out-of-pocket spending for third-party reimbursement. Thus, we believe HSA fund balances are better viewed as beneficiary savings than as insurance benefits. As a result, these payments should count toward meeting the out-of-pocket threshold. Clarification should be provided regarding the treatment of other account-based funds toward satisfying the out-of-pocket threshold, because some types of funding may have been originally classified as employer funding. We would also recommend that similar accounts such as HRAs and FSAs be treated in the same way as HSAs for this purpose only. This would provide an additional incentive to employers to continue to provide these plans, and will provide retirees similar treatment regardless of which type of account-based plan they have.

423.124 Special rules for access to covered Part D drugs at out-of-network pharmacies

Issue: This section requires that a PDP or MA/PDP assure that beneficiaries have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy. Do these proposed access requirements constitute unintended incentives for pharmacies to raise usual and customary prices?
Comment: While we believe section 423.124 is laudable in its attempt to ensure access to needed medicines while protecting the contracting entity and discouraging out of network utilization, we also believe that the current language does not accomplish this goal, nor is it possible.

As written, the section specifies that beneficiaries pay not only their standard cost-sharing amounts, but that they are also responsible for any amounts above the Part D plan's allowed charge for non-participating pharmacies, but below the pharmacies' usual and customary charge. We believe that this will encourage pharmacies to raise their prices for non-negotiated customers to enhance their revenue.

Even though beneficiaries would be responsible for any excess amounts, the excess amounts would apply toward meeting the beneficiaries' out-of-pocket threshold. This would reduce the value of the cost-sharing limits.

Specifically, the section refers to an exemption for Part D enrollees residing in a long-term care facility. In this case, and with a captive population, it would appear likely that these pharmacies would be highly motivated to raise their prices. This would not only enhance their revenue from those customers with the means to pay, but also increase the speed at which beneficiaries would reach the catastrophic benefit threshold and begin receiving higher reimbursement.

SUBPART D – COST CONTROL AND QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste

Issue: This section requires Part D plans to establish a quality assurance program that includes measures and systems to reduce medication errors and adverse drug interactions, and improve medication use. This raises the question of whether there are industry standards for cost effective management of drug utilization and should CMS adopt any of these standards for PDPs and MA-PDs?
Comment: While there are many common approaches among plan sponsors to managing costs, in general tools used to manage pharmacy benefit costs vary from one sponsor to the other. As a result it will be difficult to establish a list of industry standard tools for cost-effective drug utilization management. Further, the application of management tools varies from plan sponsor to plan sponsor, resulting in varying levels of cost management and cost controls. MA/PD plans will be providing coverage for both medical and pharmaceutical, and therefore will likely be able to effect a more integrated approach.

On the other hand, the competitive bidding and the premium-setting process will inherently require plan sponsors to employ various cost management tools and to maximize cost savings. Therefore, CMS will achieve the desired end of including cost management tools in the administration of prescription drug plans without having to recommend or require specific standards for cost management.

SUBPART F – SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

General comment:
In evaluating the detailed regulations governing bid submissions, approvals, and payment mechanisms, it is important to bear in mind the impact they will have on the willingness of private organizations to participate in the system. Organizations considering whether to bid to be a Part D plan sponsor will weigh the administrative difficulty involved, the insurance risk involved, and the business risk involved. Private plans will be more likely to participate if the rules are clearly established, and they are confident that there will be no significant rule changes affecting their operations or payments over the next several years. Private plans will also be looking for rules that treat all participating organizations equally; the fear of competing with another organization, which may be advantaged by the market rules, is a significant barrier against participation. It is critical that private plans be able to predict, in advance, the estimated costs and reimbursements associated with the program. Any uncertainty about the ability to

recoup costs and achieve a reasonable return on capital will discourage private plan participation. Similarly, the lower the initial capital investment required, the easier it is for a private organization to decide to bid, and the lower the profit margin required for participation to make financial sense. Timing of payments is crucial. Retroactive payments have the potential to increase the uncertainty of the financial results, and increase the short-term capital required. In reviewing these issues, it is important to evaluate the cumulative effect of all the rules; the aggregate administrative burden and business risk will likely be more important than any one specific provision.

423.286 Rules regarding premiums

Issue: How does the proposed 1 percent per month delayed enrollment penalty perform as a measure of the additional costs incurred due to late enrollment?
Comment: A late enrollment penalty can serve a number of purposes: (i) to provide premiums sufficient to cover the expected (higher) cost of care for those beneficiaries who enroll after their initial period of eligibility, (ii) to make up for any lost cross-subsidies between the age cohorts because of late enrollment, and (iii) to provide an incentive to enroll when first eligible, or as a disincentive for deferring enrollment.

A cost-neutral amount would require that the net present value (NPV) of the benefits for late enrollees would have to equal that of the penalty amounts. In NPV calculations, the rate used to discount the benefits and penalties would be a critical assumption. In most situations involving voluntary open enrollments, however, there may be no penalty amount that will fully compensate for the anti-selection that can be anticipated due to late enrollments. Whatever the additional premium, the average additional expected lifetime cost for those who elect to enroll late would be expected to be still higher. This is especially the case for a stand-alone prescription drug benefit such as Part D, for which enrollees can compare premium rates with their current and projected prescription outlays.

In the context of a new, very complex program such as Part D, however, factors other than calculated selection are likely to be more important causes of late enrollments, and the presence of a significant penalty can be expected to improve overall participation by discouraging delayed decisions. Further, the higher the original enrollment, the less potential there will be for the anti-selection by late enrollments to constitute a significant financial drain. Accordingly, the Academy suggests addressing the question primarily from the perspective of the additional premium that will maximize the first-year enrollment, rather than making each population self-supporting.

The most comparable experience is Part B of Medicare, for which the 10 percent per year additional premium has resulted in a relatively low overall level of additional costs associated with delayed enrollments (although the cost of anti-selection at high penalty levels is apparently significant). If Part D enrolls a similar proportion of the eligible population, we would expect the anti-selection costs to demonstrate a similar pattern.

CMS's intentions of imposing the 1 percent per month penalty and analyzing emerging data from the program to assess its adequacy appears reasonable. A potential exception, however, may

apply to MA-PD plans. Premiums under these plans may be minimal, in which case CMS may wish to consider a minimum dollar amount for penalty.

SUBPART G – PAYMENTS TO PDP SPONSORS AND MA ORGANIZATIONS OFFERING MA-PD PLANS FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

423.322 Requirement for disclosure of information

Issue: What is the appropriate content and format, and the optimal frequency of data needs? In particular, what is the nature and format of data needed for: risk adjustment, reinsurance payments, risk sharing, and program audits?
Comment: It is important to balance the need for information and accuracy with the administrative burden on plans providing the information and on CMS, which processes the information. Unless plans can provide all information electronically, weekly data cycles would be too burdensome and would likely pose a processing problem for CMS. Monthly or quarterly data submissions are more in line with other plan financial processes and thus minimize the administrative burden of compliance. The cash flow impact of monthly versus weekly data submission to enable reinsurance adjustments as soon as individuals reach their out-of-pocket (OOP) limits would seem to be minimal, particularly early in a year. If cash flow were materially improved, the extra administrative effort of weekly data submission might be justified. Frequent data submission to enable identification and resolution of data issues could be beneficial in the early months of the program, but the administrative burden to support the review of weekly data is unlikely justified by the improved accuracy of results. Once the program is well established, quarterly data submission and review should be sufficient to appropriately address both data issues and cash flow concerns but monthly submission may still be appropriate if preferred by plans.

The data elements described in the proposed regulation appear to be detailed and comprehensive, which would be appropriate and necessary for proper administration of all aspects of the program (risk adjustment, reinsurance payments, risk sharing, and program audits). Submission of data on a subset of participants or submission of a limited set of data elements may provide sufficient information to properly administer a certain aspect of the program. For example, data on participants with costs that exceed the OOP that does not include details on specific drug agents may be sufficient for administration of the reinsurance payments. However, submission of only partial details on all participants would be insufficient to allow proper administration of all aspects of the program.

Issue: "Allowable costs" for purposes of reinsurance and risk corridor payments are net of discounts, chargebacks, average percentage rebates, and administrative costs. What methodologies and data sources can be used to make these adjustments? What effect on costs would such adjustments have?
Comment: Financial arrangements among health plans, pharmacy benefit managers (PBMs), and drug manufacturers take many forms that will likely change over time. This means that full reporting of financial arrangements and the process the plans have used to allocate price concessions by line of business, subject to CMS audit, will be necessary. The intent of the

proposed regulation seems clear but the lack of a standard for these financial arrangements will make it difficult to administer. Certain discounts and rebates cannot be directly related to a specific incurred drug purchase or claimant, and some may take more than three months to "settle." There will likely be a substantial lag between the time a prescription drug claim is incurred and the time full price concession information (i.e., rebates) is available.

Assuming CMS receives accurate information that quantifies the aggregate amount attributable to price concessions, allocated appropriately by line of business (Part D, commercial, Medicaid, etc.) and class of drug or category (generic vs. brand), a discounted unit price can be developed. Incurred costs can be restated using the discounted unit price and the restated cost used as the basis for reinsurance and risk corridor payments. The timing lag described above will likely make it necessary for CMS to provide a settlement based on preliminary information with later reconciliation.

To simplify administration, we suggest CMS consider establishing a benchmark discount—including all typical price concessions—that would be used for evaluating plan cost results, thus rewarding plans that negotiate more substantial discounts and penalizing plans that minimize the importance of the negotiated discount. Annual reporting of aggregate discount information could still be required and reviewed to update the benchmark for the following year (using some percentile threshold of plans by their average discount obtained and neutralizing in some way the negotiating clout of larger plans). Use of a benchmark discount should enable more timely processing of reinsurance and risk sharing payments.

Issue: A 3-month claim close-out window is proposed in the regulation, as opposed to 18 months for FFS Medicare medical claims. What share of claims would be excluded with a 3-month close-out window?
Comment: Due to the benefit structure (i.e., copay per script) and the heavy reliance on electronic processing, prescription drug claims are typically submitted on a more timely basis than medical claims. Based on observed claim patterns, at least 98 percent of prescription drug claims (dollars) are paid within 3 months. Claims that fall outside of this 3-month window are typically those that are filed on paper rather than electronically. These may include out-of-network claims and claims with coordination of benefit issues.

A 3-month claim closeout window may be reasonable for claim reporting assuming all administrative, payment, and information systems are functioning efficiently. Achievement of that level of efficiency may not be practical from the beginning. CMS should monitor payments made during the first year of program operation, and adjust the 3-month claim closeout period, if appropriate. Until more information is available regarding actual claim lag patterns under the program, CMS should err on the side of flexibility and allow retrospective adjustment based on complete claims data or inclusion in the calculation of subsequent years. As noted in the comment above, full information on all forms of price concession may not become available until much later.

423.329 Determination of payments

Issue: The proposed rule states that CMS will publish an appropriate methodology for adjusting for variation in costs of prescription drug coverage based on differences in the actuarial risk of

the beneficiaries served. CMS is particularly concerned that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy payments for premiums to amounts at or below the average, could systematically underpay plans with many low-income subsidy enrollees. Is this concern valid, and how might CMS address the potential problem?
Comment: Based on the explanation of the statutory limitation provided, the concern regarding impact on plans that enroll a disproportionate share of low-income subsidy enrollees appears valid. Accumulated neglect, pent-up demand, and reduced cost-sharing requirements all have the potential to affect drug utilization. It also seems reasonable that the risk adjustment process be used to correct any understatement caused by statutory limitations on low-income subsidy direct payments. This will likely require an additional step in the development of risk adjustments to properly analyze this and create appropriate allowance for low-income beneficiaries in the proposed risk adjustment factors. We would encourage CMS to expose the risk adjustment methodologies for comment.

Issue: There is a requirement that the risk adjustment methodology be implemented in a budget-neutral manner. Since there is no group of beneficiaries outside the system (as there is under Part C), should risk adjustment, as applied to part D, be inherently budget neutral with respect to the risk of the individuals who actually enroll without additional adjustments?
Comment: It will take several years of Part D coverage to develop a credible overall "budget," given the many unknowns associated with the new program. If risk adjustment factors appropriately reflect the relative risk of individual beneficiaries, an additional budget neutrality adjustment does not seem to be appropriate or necessary.

Issue: How will reinsurance payments be made to the plan sponsors?
Comment: The level of reinsurance payment for each plan can be determined only after submission of data for the full calendar year. This places a cash flow strain on plans if such payments prove to be significant. The proposal to make interim monthly payments to plans during the year in anticipation of the appropriate final reinsurance settlement seems reasonable, reflecting appropriate lags in discounts and rebates as mentioned earlier. Providing equal monthly payments (or adjustments) should be sufficient, rather than trying to anticipate how reinsurance costs will actually emerge, provided the reconciliation at the end of the year reflects the timing difference as well as the absolute value of the cost difference.

Issue: The statute provides that the reinsurance subsidy would be paid only for the plan's share of individual expenses in excess of an enrollee's true out-of-pocket (TROOP) threshold. How will the TROOP threshold be calculated and administered?
Comment: Careful consideration should be given to the administration of the TROOP provisions. While pharmacy claims are routinely submitted to PBMs and health plans electronically, the TROOP threshold is to be adjusted to remove the cost of enhanced alternative coverage, supplemental benefits, and cost sharing paid or reimbursed by secondary insurance or otherwise. It is unlikely that such information will be available at the point of sale, so pharmacies and PBMs cannot monitor this, nor can they appropriately adjust the beneficiary's cost-sharing at that time. Proper administration will likely require that beneficiaries collect drug receipts and explanations of benefits (EOBs) and submit them to their health plan once they believe they have reached the TROOP threshold. This introduces an additional timing consideration that will complicate the mathematical calculations required. Ultimately, electronic

claim records have to be created to capture this additional information to enable processes such as establishing proper incurred-but-not-reported (IBNR) estimates, developing proper adjustments for price concessions and enhanced or supplemental benefits, and risk adjustment. This may become an overwhelming burden for plans and CMS if the program is as successful as it is hoped (i.e., enrollment at 90 percent or higher).

Issue: How will low-income subsidy payments be made to the plan sponsors?
Comment: The level of low-income subsidy payment for each plan can be determined only after submission of data for the full calendar year. As with the reinsurance payments, this places a cash flow strain on plans if such payments prove to be significant. The proposal to make monthly interim payments to plans during the year in anticipation of the appropriate final low-income subsidy settlement seems reasonable. Establishing a reasonable monthly advance payment with later reconciliation and adjustment seems appropriate and should add a minimal amount of administration.

423.336 Risk-sharing arrangements

Issue: The risk corridors are based on costs actually paid by the plan, net of chargebacks, discounts, or average percentage rebates. Allowable cost also excludes administrative expense and any amount paid by the enrollee or through other CMS subsidy (low-income subsidy payments and reinsurance payments). Should the subsidy exclusion be non-premium components of the low-income subsidy payments only?
Comment: Any premium component of the low-income subsidy payments should be counted by plans as revenue and therefore appropriately ignored in the calculation of allowable costs for risk-sharing arrangements. This would be consistent with the treatment of premiums for other beneficiaries.

423.343 Retroactive adjustments and reconciliations

Issue: There will be a retroactive adjustment to the aggregate monthly payments to a PDP or MA-PD for any difference between the actual number and characteristics of enrollees and the number and characteristics on which the advanced monthly payments were based. What is an appropriate remedy for plans that do not provide adequate information to CMS for proper reconciliation?
Comment: It would defeat the purpose of a retroactive adjustment if a remedy is based on an assumption that could potentially provide a financial benefit to plans that provide insufficient information to CMS. A remedy that is unrealistically optimistic seems appropriate to provide a solid incentive for plans to collect and provide sufficient data. The proposed approach that assumes adjusted allowable risk corridor costs are 50 percent of the target amount appears consistent with this view. In the first program year, it may be appropriate to include an arbitration or appeals process for plans that have made a good faith effort to collect and provide sufficient information and also believe they can provide other acceptable documentation that supports the use of something other than the default assumption. Such arbitration or appeal relief should be limited to the first program year unless it can be proved that the information system requirements pose an unrealistic burden on a participating organization. Presumably, this will not be the case for any organization that elects to become a PDP or MA-PD.

SUBPART I – ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

423.410 Waiver of certain requirements in order to expand choice

Issue: Proper establishment of solvency requirements for PDPs as pertains to the conditional waiver of the state licensure requirements.
Comment: We believe that the proper establishment of this solvency requirement is very important for the following reasons:

- Too high a requirement will discourage PDPs from participating or require additional capital hurdles that will ultimately lead to an increased product cost.
- Too low a requirement will increase the probability of PDPs either becoming insolvent or withdrawing from the program due to inadequate capitalization.

Either of these actions adversely reflects on the program by either requiring a need to fund losses from an insolvent PDP or requiring the members to change programs and coverages from a withdrawing PDP.

The National Association of Insurance Commissioners (NAIC) risk-based capital requirements were not necessarily developed with a granularity to be specific to PDPs. The requirements were also not created to handle how PDPs are to operate under the CMS proposed regulations on Medicare Part D. In addition, the NAIC risk-based capital requirements are generally retrospective in nature, focusing on the level of risk reflected in the most recently filed financial statements. The specific reinsurance and risk-sharing provisions of the Part D program and the potential volume available in the initial year of operations require specific consideration in the development of solvency requirements.

We believe any solvency requirements should contemplate the following:

- *Anticipated enrollment volume.* CMS may wish to consider a solvency-based enrollment cap as part of the approval process.
- *Quality, liquidity, and interest rate sensitivity of assets.* The program will likely minimize positive cash flow. As such, any assets utilized to support solvency should be very liquid and not subject to substantial temporary devaluation.
- *Possibility of losses*. The potential loss analysis should reflect specifics to the Part D program including reinsurance and risk sharing. In addition, the potential losses can vary significantly from organization to organization, based on the ability to contract for set prices for certain drug classes, thus avoiding a portion of the unit cost variability risk.
- *Additional risk at program initiation.* Much of the pricing and product development for PDPs will be based on theory rather than prior experience, so the initial risk is greatly increased. Futhermore, the initial enrollment is also a significant uncertainty. As such, solvency requirements should reflect these additional levels of risk in the early durations of the program.

We also believe that it is important to have a member of the American Academy of Actuaries provide an opinion in the waiver process, which is consistent with the PSO waiver application process. This opinion should include:

- Projections that are developed in accordance with sound actuarial principles and according to Actuarial Standards of Practice;
- Projections that reflect anticipated enrollment, anticipated contracting with pharmacies and drug manufacturers, and other assumptions as deemed appropriate; and
- Projections that show that the PDP meets the minimum capital requirements established by CMS.

The Academy would be willing to assist CMS in developing solvency standards for the PDP waiver process through either primary analysis or by reviewing CMS analysis.

Issue: Limiting language in Section 423.410(c)3.ii: A waiver will be considered "if [the] state has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different than the standards CMS establishes…"
Comment: This language is quite limiting and we believe that most, if not all, states will establish requirements that differ from CMS. CMS may wish to consider language that addresses material differences.

Issue: Lack of a provision with regard to withdrawing a waiver before expiration.
Comment: There is currently no provision for withdrawing a waiver before expiration. A provision of this type would seem especially appropriate for a waiver granted in accordance with 423.410(e) where the PDP had filed an application with the state and the state subsequently disapproves. If the state disapproves, CMS may want to consider withdrawing the waiver.

SUBPART J – COORDINATION UNDER PART D WITH OTHER PRESCRIPTION DRUG COVERAGE

423.464 Coordination of benefits with other providers of prescription drug coverage

Issue: How can CMS ensure that wraparound coverage offered by state pharmaceutical assistance programs (SPAPs) and other insurers does not undermine or eliminate the cost management tools established by Part D plans?
Comment: While the cost-sharing requirements that fall either within the initial coverage provisions or within the catastrophic coverage provisions of the Part D benefit (i.e., the initial deductible and the copayment or coinsurance amounts a beneficiary is required to pay) are properly described as cost management tools, the coverage gap or "donut hole" should not be considered a cost management tool. Instead, this coverage gap is a result of the federal budgetary constraints that were considered during the drafting of the MMA. Thus, wraparound coverage that pays for some of the beneficiary's costs related to the "donut hole" should not be viewed as undermining or eliminating the Part D plans' cost management tools.

SUBPART P – PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

423.782 Cost-sharing subsidy

Issue: The proposed regulation does not say whether, in the case of a beneficiary who is unable to pay the required copayment amount (even the reduced amount as described in section 423.782), the pharmaceutical provider could withhold the prescribed drug from that beneficiary.
Comment: In general, current practice enables a qualified beneficiary (such as a dual eligible) to receive a prescribed drug from a participating provider even if the beneficiary is unable to pay the normally required copayment amount. Is a participating pharmaceutical provider required to dispense the prescribed drug in such a case, or may the provider withhold the drug from the beneficiary until the copayment is paid? Even if the participating provider is not required by law to dispense the prescribed drug if it does not receive the required copayment, may a PDP require the participating provider with whom it contracts to dispense the prescribed drug in such a case?

SUBPART T – PART D PROVISIONS AFFECTING PHYSICIAN SELF-REFERRAL, COST-BASED HMO, PACE, AND MEDIGAP REQUIREMENTS

Proposed revision to the definition of a Medigap policy (Section 403.205)

Issue: Revising the definition of a Medigap policy (currently codified at 42 CFR 403.205)
Comment: We believe the proposed definition of Medigap would extend far beyond its current definition to include types of coverage that Congress did not intended to regulate as Medigap policies. There are several types of policies, many of which are considered limited benefit plans, that could possibly be redefined as Medigap under the proposed regulation: cancer, long-term care, stand alone prescription drug plans, property & casualty plans, major medical plans (not cancelable due to HIPAA), and hospital indemnity plans.

The redefinition of these types of policies presents significant challenges due to what the Medigap regulation entails:

- *Standardized benefit designs.* These policies by their very nature don't comply since they are not designed to supplement Medicare and do not fill Medicare's major gaps as a Medicare Supplement is designed to do.
- *Annual filing and state-by-state review of rates*. Many of the aforementioned coverages are not filed in every state in which they are sold, nor do all states subject them to annual rate review.
- *Underwriting limitations and guaranteed issue requirements*. Medigap rules are likely not consistent for these products.
- *Annual filing of benchmark loss ratio calculations to demonstrate compliance with minimum loss ratio standards (and determine refunds due) for existing and new business*. Medigap loss ratio standards and refund requirements were not considered in the pricing of the other products.

The scope of the current definition of a Medicare Supplemental policy at Section 403.205 is restricted by Section 1882(g) of the Social Security Act. The NAIC Medigap Model Regulation

clearly distinguishes between Medicare supplement policies and limited benefit policies. Since 1995, Appendix C of the "Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act," has contained seven disclosure notices that must be provided with specified types of health insurance policies that could be classified as "limited benefit" insurance. In bold lettering at the top of each disclosure notice is the phrase "**This is not Medicare Supplement Insurance**." The seven general types of policies identified are:

1. Benefits for accidental injury only
2. Benefits for specified limited services
3. Reimbursement for expenses incurred for specified diseases or other specified impairments
4. Payment of fixed dollar amounts for specified diseases or other specified impairments
5. Indemnity policies and other policies that pay a fixed dollar amount per day (excluding long-term care policies)
6. Policies that provide benefits upon both an expense-incurred and fixed indemnity basis
7. Policies not specifically identified above

We recommend several possible remedies:

- Delete the proposed clause (c)(4) from the definition;
- Include in part (e) an exclusion for the types of policies referenced in the disclosure notices in appendix C of the NAIC model regulation;
- Modify (c)(4) to be consistent with 4 b on page 46758 of the federal register, 69FR;
- Specifically exclude products such as disability income, long-term care, cancer or other products that may contain incidental prescription drug benefits.

Members of the Academy are available to work with you as you finalize the proposed Medicare prescription drug benefit and Medicare Advantage regulations. If you would like to discuss these issues further, please contact Academy senior health fellow Cori Uccello (Uccello@actuary.org or 202-223-8196), or senior health policy analyst (federal) Holly Kwiatkowski (Kwiatkowski@actuary.org or 202-223-8196).

Sincerely,

Thomas F. Wildsmith, FSA, MAAA
Chairperson, Medicare Steering Committee
American Academy of Actuaries

Members of the Medicare Steering Committee include: Michael S. Abroe, FSA, MAAA; Stuart H. Alden, FSA, MAAA, FCA; David V. Axene, FSA, MAAA, FCA; David J. Bahn, FSA, MAAA; Alan D. Ford, FSA, MAAA, EA; P. Anthony Hammond, ASA, MAAA; Dennis J. Hulet, FSA, MAAA, FCA; Kent E. Levihn, FSA, MAAA, FCA, EA; James J. Murphy, FSA, MAAA, FCA; Donna C. Novak, ASA, MAAA, FCA; John J. Schubert, ASA, MAAA, FCA; Michael J. Thompson, FSA, MAAA; Gordon R. Trapnell, FSA, MAAA; Lynette L. Trygstad, FSA, MAAA; and George B. Wagoner, FSA, MAAA, FCA.