STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION

REPORT TO THE PRESIDENT AND CONGRESS

DECEMBER 20, 2004

A C K N O W L E D G M E N T S

The State Pharmaceutical Assistance Transition Commission (the Commission) would like to acknowledge several organizations and individuals who provided their knowledge, expertise, and support to our work. Kathleen Mason with the New Jersey Department of Health and Senior Services, along with Wade Epps and Cynthia McGettigan of her staff, were instrumental in writing significant portions of this report and providing valuable technical expertise along the way. Thomas M. Snedden, Director of the Bureau of Pharmaceutical Assistance in Pennsylvania and Ellen Kramer Adler, Esq., Executive Director of the Pennsylvania Council on Aging also devoted time to developing the recommendations in this report. Kimberley Fox with the Rutgers University Center for State Health Policy (CSHP) participated in conference calls and offered tireless assistance as a result of the research she, Stephen Crystal, and other colleagues at the CSHP have conducted in the area of State pharmacy assistance programs (SPAP). Ken Majkowski, Pharm.D., VP of Business Development for RxHub presented an overview of the various products and services that his company offers in the pharmacy industry. Rebecca Rabbitt, Director of Clinical Program Development with Express Scripts offered assistance to Commission members by talking through pharmacy network issues. Lynne Gilbertson, Director, Standards Development, National Council for Prescription Drug Programs (NCPDP), Patsy McElroy, Manager, Standards Development, NCPDP, and Margaret Weiker, NCPDP Board of Trustees and Standardization Co-Chair gave an overview of what is included in the NCPDP claims transaction set, how it is used, who uses it, and how it may be helpful to efforts to coordinate not only claims benefits but prior authorization (PA) and denial notifications for appeals purposes. Michael McMullan, Director of the Center for Beneficiary Choices with the Centers for Medicare & Medicaid Services (CMS) shared important information regarding coordination between CMS and the Social Security Administration (SSA) for beneficiary education and outreach under the Medicare prescription drug benefit. George Mills, Aaron Wesolowsky, Ann Marie Vrabel, Brian Johnson, Sabrina Lopez, Harry Gamble, Jennifer Lindstrom, Joan Fowler, Tracy McCutcheon, Robert Donnelly, Sean Creighton, Deirdre Duzor, Katiuscia Potier, and many others at CMS participated in conference calls with the Commission, offering technical expertise and insight into a variety of issues. Lethia Kelly, Senior Conference Manager, AFYA, Inc. provided essential logistical support to the Commission, including all of the

administrative work behind securing meeting space, travel arrangements, and responding to, if not anticipating, our needs during three face-to-face meetings. She worked tirelessly behind the scenes to make our work as smooth as possible.

The Commission thanks CMS for assigning such a competent, knowledgeable, and delightful staff member to work with in the person of Marge Watchorn. Marge was responsive to our requests, provided extensive support for us to complete our work, but most importantly brought substantive knowledge on technical issues to our deliberations. We simply could not have completed this task without her assistance and gentle reminders about deadlines.

The members of the Commission especially want to acknowledge the leadership and energy provided by Joan Henneberry, who served as chairperson. She brought order and direction to the group, and she played a significant role in building consensus on the recommendations contained in this report.

CHARTER OF COMMISSION

The Commission was chartered by the Honorable Tommy G. Thompson, Secretary of Health and Human Services (HHS) on March 1, 2004. The Commission was established by section 106 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The Commission was responsible for developing a proposal to address the unique transitional issues facing SPAPs and SPAP participants due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act, as added by section 101 of the MMA. In addition, the Commission was to submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate, no later than January 1, 2005.

A copy of the Commission's charter is attached to this report at Appendix A.

COMMISSION MEMBERSHIP

The Commission was selected by the Secretary through an open nomination process. On February 27, 2004, a notice was published in the Federal Register to request nominations for individuals to serve on the Commission. The statute called for Commission members to come from a variety of fields, including States with comprehensive, statewide SPAPs; States with other SPAPs; organizations that have an inherent interest in the Medicare program and the beneficiaries served by SPAPs; Medicare Advantage organizations; pharmacy benefit managers; and other private health insurance plans.

Twenty-four members were sworn in by the Secretary during the Commission's first public meeting on July 7, 2004 in Washington, DC. The members included:

Joan Henneberry (Chairperson); Clifford E. Barnes, Esq.; Donna Boswell, Ph.D., J.D.; James Chase (Minnesota); David Clark; Jay D. Currie, Pharm.D.; Barbara Edwards (Ohio); Nora Dowd Eisenhower, J.D. (Pennsylvania); Janice O. Faiks, J.D.; Dewey D. Garner, Ph.D.; Karen Greenrose; Laurie Hines, J.D. (Missouri); Joseph B. Kelley; Mary Liveratti (Nevada); Anne Marie Murphy, Ph.D. (Illinois); Julie A. Naglieri (New York); Dennis O'Dell; Robert P. Power, M.B.A., C.E.B.S.; Susan C. Reinhard, R.N., Ph.D. (New Jersey); Sybil M. Richard, J.D., M.H.A., R.Ph. (Florida); Elizabeth J. Rohn-Nelson; Marc S. Ryan, M.P.A. (Connecticut); Linda J. Schofield, B.S.N., M.P.H.; and Martin Schuh, M.B.A.

A full roster of Commission members, including their affiliations, is attached at Appendix B.

TABLE OF CONTENTS

A P P E N D I C E S

WHERE WE STARTED

The Commission began with its first public meeting on July 7, 2004, in Washington, D.C. After an official welcome by Mark B. McClellan, M.D., Ph.D., Administrator for CMS, and the swearing in by the Honorable Tommy G. Thompson, Secretary of the U.S. Department of Health and Human Services, the Commission wasted no time getting to work. The first open meeting focused on hearing official testimony from researchers, advocates, and state officials with experience in managing outpatient prescription drug benefit programs. On July 8, 2004, the Commission began closed deliberations to develop a workplan for the remainder of the year.

The complexity of the issues that needed to be addressed, along with the size of the group, led the Commission to break into three workgroups, each covering topics that seemed to cluster around four themes; 1) the transitional issues directly affecting beneficiaries of existing SPAPs as they move to Part D, which included education, eligibility, and enrollment; 2) benefit design, or the ability for SPAPs to coordinate benefits with the new Part D program; 3) issues affecting the infrastructure of providers, systems, and data collection and management; and 4) maximizing benefits for Part D-SPAP beneficiaries. Commission members volunteered to serve on workgroups and at least one SPAP representative served on each workgroup. Susan Reinhard chaired the Beneficiary Transitions Workgroup, which included Clifford Barnes, Janice Faiks, Mary Liveratti, Anne Marie Murphy, and Elizabeth Rohn-Nelson. Linda Schofield chaired the Program Design and Benefits Administration Workgroup, which included Donna Boswell, David Clark, Barbara Edwards, Nora Dowd Eisenhower, Laurie Hines, Robert Power, Sybil Richard, and Marc Ryan. Julie Naglieri chaired the Data Systems and Claims Processing Infrastructure Workgroup, which included James Chase, Jay Currie, Dewey Garner, Karen Greenrose, Dennis O'Dell, and Martin Schuh. Joseph Kelley, a member of the Data Systems Workgroup, withdrew from the Commission in late July.

Generally speaking, the workgroups met weekly by telephone between July and November, with the workgroup leaders meeting by phone every few weeks. Workgroups invited outside experts and researchers to join their phone calls when they needed additional technical information or clarification from CMS officials.

The three groups began developing outlines for their sections of the final report immediately, and over the course of the summer drafts of papers began to

circulate among Commission members. We made decisions by consensus and encouraged issues to bubble up from the workgroups. Each workgroup would have discussion around a recommendation or a draft of someone's paper. They would continue to work on a recommendation and refine it until they felt it was ready to present to the members of the other groups. By the time the Commission met for the second time in Baltimore on September 15, there were many preliminary recommendations to be discussed. Because the proposed rules and regulations were released by CMS over the summer, the Commission chose to submit formal comments, many of which were already being considered as recommendations for the report.

The last meeting of the Commission took place in Washington, D.C. on October 13 & 14, 2004. By this time the Commission had reached consensus on recommendations and had drafted most of the sections that would be included in the report to the President and Congress. The last important agenda item for the meeting was to present those draft recommendations to the public and incorporate their feedback in the last draft of the report. The Commission was able to reach consensus on almost every item we identified at the beginning of our deliberations, and on issues that emerged over the summer and fall. Where we could not reach consensus, we have discussed the issue in the report in a section for unresolved questions and issues.

WHERE WE ENDED: OVERARCHING THEMES

As the Commission worked to develop national recommendations, several principles emerged as overarching themes. First and foremost, the Commission believes it is essential to assure that SPAP members have uninterrupted access to medications during the transition into the Medicare drug benefit. There needs to be a framework that makes it easy for SPAPs to coordinate with PDP sponsors in such a way as to maximize benefits for individuals enrolled in Part D, encourage state flexibility and minimize cost shifting to SPAPs. There should be seamless coordination of benefits between providers and payers, which requires real-time information exchange. Ideally, paperwork should be minimized and the use of technology should be maximized to the extent possible. It is important to apply the lessons learned by all parties from the implementation of the Medicare drug discount card. Finally, the Commission acknowledges the enormous challenge of public education and marketing, as well as the role that SPAPs will need to have in outreach to ensure the success of Part D.

Before proceeding, we wish to note for the record the limited role of the Secretary of HHS with respect to this Commission. Activities of the Secretary

and HHS staff with respect to the Commission were limited to those necessary to fulfill the Secretary's obligations under section 106 of MMA and to provide assistance to other Commission members. Neither the Secretary nor any HHS designees took an active role in the development of the recommendations presented in this report. Accordingly, the views and recommendations stated in the report should not be attributed either to the Secretary or to the Administration.

KEY RECOMMENDATIONS

The Commission developed numerous recommendations built around the issues discussed in their workgroups. While all of the recommendations will be discussed in greater detail throughout the body of this report, following are the top six recommendations the Commission wants to emphasize as having primary importance:

- **SPAPs should be considered authorized representatives of their beneficiaries** for the purposes of determining their eligibility for subsidy assistance, enrolling them in one or more preferred PDP sponsors, and paying their Part D premiums.
- To better coordinate benefits, **SPAPs should be allowed to choose preferred PDP sponsors** on behalf of their enrollees.
- **SPAPs should be given authority to appeal on behalf of beneficiaries**, since the SPAPs are at financial risk for formulary denials and high tier copays. Further, **the exceptions and appeals process, as proposed in regulations, should be revised to assure that consumers are given denial and appeal rights notices and to make the process timelines much quicker** for the sake of consumer access and protection.
- **CMS should form an ongoing advisory committee of SPAP representatives** to assist and inform them through the transition of implementing Part D.
- **CMS should establish a Centralized Data System to facilitate data exchange through a single entry point** so that all involved parties have access to timely and accurate data needed for the "real-time" coordination of benefits (COB).
- **Marketing, enrollment, and educational materials should include clear explanations of how the SPAP will coordinate prescription**

benefits with prescription drug plans (PDP) and Medicare Advantage plans with a prescription drug benefit (MA-PD) (collectively, PDP sponsor).

The full list of the Commission's recommendations is included at the end of the report at Appendix C.

CURRENT STATE PHARMACY ASSISTANCE PROGRAMS

Common Program Characteristics

Following is information on current SPAP practices as they relate to cost-containment on the clinical side (as opposed to reimbursement and rebates on the financial side). Most of this information is based on a survey of SPAPs conducted by the Rutgers University CSHP in 2000-2003 with funding from The Commonwealth Fund. The survey was completed by 21 of the 22 programs in operation in 2003 and is supplemented by data that was derived from SPAP annual reports in states that have them.

- In 2003, 38 states had some type of drug benefit program for low-income elderly and/or disabled persons.
- In 2003, 22 states had a direct benefit program rather than a discount program. These are the programs that would most likely be integrated with the new Part D benefit. Some of them are Pharmacy Plus states that may seek to give up their waiver authority and become SPAPs. (Regulations still unclear about how this would occur although the preamble suggests that states should consider doing so.) Six states (IL, NJ, NY, PA, VT, and WI) actually have multiple programs, with some having two or more programs that qualify as SPAPs.
- Of 21 states surveyed in 2002 that were SPAPs or Pharmacy Plus states, only ten states had programs that also served the non-elderly disabled.
- Together these 21 states provided benefits to over 1.3 million enrollees in 2002.
- In 2002, income eligibility ranged from 100 percent of the Federal poverty level (FPL) to 500 percent FPL. In two states, higher income persons that meet other eligibility requirements can enroll in the program and pay the full premium without state subsidy.
- In 2002, four of the 21 states had income thresholds at or below the Part D full low-income subsidy threshold of 135 percent and two had income thresholds at or below the 150 percent FPL threshold for Part D partial subsidies. Most states were providing benefits to persons who will not be eligible for the low-income subsidies under Part D.
- In 2003, only two states had enacted any sort of asset test in their SPAPs – MN and MD. This sharply contrasts with the Part D benefit, which

provides for asset restrictions for both full and partially subsidized populations. Thus, asset tests will be a major issue for all but two SPAP states, and will still be of some concern for the two that currently have such tests.

- In 2003, the most prevalent form of cost-sharing for SPAPs is co-insurance. Six states utilize two-tiered co-pays/co-insurance (percentage co-insurance or flat dollar amounts) and four states use multi-tiered co-pays/co-insurance. In 2003, eight programs had deductibles. To some degree, the use of co-insurance and deductibles ties well with the MMA; however, the MMA appears far more complex in certain circumstances and integrating the myriad of different co-insurance requirements in MMA with SPAPs will be challenging for states that wish to contract with a PDP sponsor for supplemental benefits or wrap-around the Part D benefit.
- In 2003, eight programs utilized benefit caps generally by limiting how much a program will pay in a given month or year for a beneficiary; one of these states caps the number of prescriptions per month. (Some states also only cover drugs for certain diseases or specifically exclude certain categories or classes, such as lifestyle drugs.) In contrast, ten programs cap out-of-pocket expenses for beneficiaries with high annual drug costs. The MMA has both features – it has the so-called "donut hole" where drug expenses are not covered for higher income beneficiaries, but it also provides for catastrophic coverage over certain levels.
- Fourteen of 20 states in 2002 did utilize a PBM in their programs. However, most used them in an ASO capacity and only for administering portions of their programs. Thirteen used PBMs for drug utilization review (DUR). Eight used PBMs for rebate collection, while four used them for rebate negotiation. Six used them for eligibility and formulary or PDL administration. Five used them for pharmacy reimbursement.
- In 2003, 18 programs in 14 states had mandatory generic substitution. It appears that a majority of states allowed override by simple declaration of a physician, although some states required a PA process.
- With regard to formularies, 18 of 21 states in 2002 had open or voluntary formularies. Two states had multi-tiered formularies; one state had a closed formulary. In 2002, eleven states had some form of PDL or PA. In 2003, ten states had active PDL programs or had passed legislation to implement such programs. Of the states with active PDLs in 2003, there was a wide variation in the number of classes of drugs covered. Of seven states that released details about their PDLs on their website, four states had in excess of two dozen classes restricted through a PDL, one had

more than a dozen, and two had a minimal number of classes restricted. The resolution of the Pharmaceutical Research and Manufacturers of America (PhRMA) vs. Michigan/Thompson case has clarified the criteria under which CMS may approve states' plans to pursue both PDLs/formularies and supplemental rebates in conjunction with their Medicaid programs. While some states already have a history of using these cost-containment practices separate from their Medicaid programs, it is clear that the MMA contemplates programs with much more restrictive formulary and PDL practices.

- In 2002, SPAPs on average spent $1,367 per enrollee. This was an increase of 53 percent from 1999 to 2002. By FY 2006 (the first state fiscal year when the Part D full benefit is on line), costs per enrollee conservatively will have risen to between $1,800 and $2,000. Overall, this is a fairly generous benefit as data suggests that about 40 percent of all Medicare beneficiaries spend less than $1,000 annually on drugs. CMS estimates that it will spend $1,437 on a beneficiary not eligible for the low-income subsidy and $3,476 for those that are eligible when the program begins.
- In 2002, the average cost per claim in states was $46.82 and ranged from $18.56 to $114.83. In 2002, the number of claims per enrollee averaged between 28.5 and 32.7 prescriptions per year depending on the measures used. In 2002, the average rebate per claim in ten states where information was available was $7.43. Fourteen states report using the Medicaid rebate system for their SPAP rebates.
- At least seven states report that, because their SPAP enrollees can hold other drug coverage, that they already have COB in their programs with various entities, including Medicare and private insurers.
- Twelve states allow some or all prescriptions to be filled for more than a 30-day supply. Some states limit this to mail order. About seven states allow coverage for over-the-counter medications.
- Based on commercial standards, SPAPs generally reimburse pharmacies at higher rates.

A list of states with SPAPs, including the number of Medicare beneficiaries enrolled in those programs, is attached at Appendix D.

PREFERRED PLANS

Overview of Issues

States are considering whether or not to continue, or create, SPAP programs to supplement the new Part D drug benefit in 2006. A major factor in such a decision is the challenge of coordinating benefits between the federal and state programs in a manner that (1) maximizes participation in the Part D program, (2) avoids states covering costs that are the responsibility of the Medicare plan, (3) avoids any disruption in drug benefits received by the elderly and disabled population served, and 4) maximizing benefits for Part D-SPAP enrollees. These major challenges will be exacerbated by the numbers of plans that will be offering Part D benefits.

The challenge of maximizing participation in the voluntary Part D program will be particularly difficult for SPAPs, whose enrollees are typically very satisfied with their SPAP coverage. SPAP benefits are often much more generous than the benefit envisioned by Part D. The Part D premium, deductible, cost-share, "donut hole", and limited formulary will be very unappealing to SPAP members who have previously enjoyed coverage without these additional financial burdens. SPAP enrollees must be convinced that their benefits can easily be coordinated with Part D coverage without compromising their current level of benefits. Yet these beneficiaries will receive information from multiple plans about the different pharmacy networks, formularies, benefit designs, etc. that will not clearly present information about if or how their SPAP coverage will apply or coordinate. They will likely see the higher costs and limited drugs with the Part D coverage, and opt to remain with their SPAP. With multiple options for plans with different cost-sharing, it is likely that SPAP beneficiaries will find it challenging at best to select a plan with which their SPAP coverage can be coordinated for maximum benefits. In addition, the act of enrolling in a plan once the beneficiary has hopefully managed to select a plan, will be a further barrier to participation.

Multiple plans, forms, processing streams, and contacts make it difficult for SPAPs to efficiently and effectively facilitate the enrollment process. Further, it will not be feasible for SPAPs to work with all plans to assure that marketing materials and communications provide clear information to enrollees about coordinated SPAP and Part D benefits.

Based upon the past experience of many SPAPs in coordinating benefits with other coverage, there is significant concern that SPAPs will often bear costs that are the responsibility of the Part D plan. This will require that states monitor and

intervene on behalf of their Part D-SPAP enrollees to ensure that the primary Medicare benefit is fully provided. To do so will be complicated and inefficient given the multiple plans, formularies, networks, and designs with which the SPAP must be sufficiently familiar. The cost management tools utilized by the multiple plans would add to the complexity that SPAPs would face. Communications and messages issued by the plans may also be misleading, misinterpreted, or inaccurate with respect to SPAP enrollees and/or providers. This may result in costs being diverted to SPAPs inappropriately and with multiple plans, it will be difficult to sufficiently address this concern.

The more plans that the SPAP must coordinate with, the greater the risk of a disruption in drug benefits provided to the elderly and disabled population served by the SPAP and Part D. Multiple plans make it impossible for SPAPs to provide clear communication and direction to their enrollees on how to coordinate the two benefits. If enrollees do not understand, they may not receive their full benefit at the pharmacy and therefore may be unable to afford their needed medication. In addition, the more plans there are to coordinate with, the less SPAPs are able to customize their claim processing systems to address the various exceptions and coverage rules that the plan sponsors may have. This will likely result in an increase of inappropriate denials. Questions and inquiries, specific to each of the various plans, are difficult to coordinate through and between different customer service centers. Clear communications with pharmacies are critical in avoiding any disruption of benefits at the pharmacy.

Recommendation and Rationale

SPAPs should be allowed to endorse one or more preferred Part D plans for their enrollees. We understand the MMA provision that prohibits SPAPs from discriminating by limiting SPAP eligibility or the amount of financial assistance available from the SPAP on the basis of a beneficiary's Part D Plan selection, and do not interpret it to mean that SPAPs cannot encourage or assist beneficiaries to enroll in a plan that the SPAP has determined to be favorable. SPAPs must be allowed to select a preferred plan or plans in order to maximize enrollment and ensure the smooth coordination of benefits of their enrollees. This still gives the beneficiary the option to select a different plan, with no diminishment in their eligibility for the SPAP or in the amount the SPAP contributes towards their benefits.

By working with one or few plans, SPAPs will be better able to promote and facilitate the enrollment of their participants into the plan(s). The confusion and complexity of multiple plans to choose from, which will surely deter participation, will be eliminated. SPAP enrollees trust their SPAP. The preferred plan(s) will gain name recognition by SPAP enrollees and providers, further reducing the confusion and complexity. Working with limited plans will make it more practical

to achieve simpler, clearer communications and messages coordinated between the SPAP and plan(s). Marketing materials distributed by the SPAP and the preferred plan(s) can be coordinated to provide clearer information on how benefits are coordinated. These communications can be developed and scheduled as mutually agreed. With sufficient legal authority, SPAPs can even apply on behalf of the participant for a plan through a coordinated process, or at a minimum facilitate the enrollment that will require coordinated processing and shared information.

Not only will it be important for SPAPs to convince their enrollees to join the Part D benefit in coordination with SPAP coverage in 2006, SPAPs must ensure the experience is a positive one for continued participation. This will not happen if SPAP enrollees join a Part D benefit which does not include their SPAP pharmacy in the network, or does not allow the same dispensing limits as their SPAP coverage, or does not cover their particular drugs and strengths previously covered by their SPAP. SPAPs should be allowed to select a plan(s) based on criteria designed to ensure smooth coordinated benefits, which is most likely to yield the best experience and benefit by individuals.

A significant administrative burden would be placed on SPAPs by not allowing them to select a preferred plan with which to streamline enrollment and coordination of benefits. Having to work with multiple plans, establish legal agreements as needed, develop coordinated communications and processes, maintain a detailed knowledge base on each plan's benefit design and formulary, and maintain connections will impose a tremendous administrative burden and inefficiency on SPAPs.

In addition, allowing an SPAP to choose a preferred plan is consistent with the market oriented direction of the MMA. The competition between plan sponsors to become a preferred plan will likely generate better benefits for beneficiaries and will maximize the benefits purchased with Part D dollars. This can only benefit the Part D program.

The Medicare drug discount card provided valuable experience in clear support of this recommendation. SPAPs that endorsed a single card sponsor for enrollment of their participants into the low-income Transitional Assistance Program were immensely successful in maximizing participation and streamlined coordination with the discount card. The following quotes are common examples of the satisfaction SPAP enrollees expressed regarding this issue:

> "I would love to thank you and EPIC for handling my Medicare Drug Card. That was great. You can't imagine how much I appreciated what you did. I have always been happy with your service. Thanks again & God Bless You"

"Thank you for your recent update on the Medicare Drug Discount Cards. I'm sure I am not the only one confused about them. I am so thankful for the EPIC coverage, & hope there will be no interruption of that coverage. Thank you again. Mrs. E."

"Thank you so much for offering to help me decide if I should choose Medicare discount card or not. I have been in a quandary not knowing what to do. I appreciate your help. Yours truly, Mrs. S."

Further discussion of this recommendation follows in later sections, since it permeates throughout the various issues facing SPAPs as they transition enrollees to Part D.

BENEFICIARIES

Overview of Issues

SPAP beneficiaries value the prescription coverage they receive from their State-funded programs and appreciate the ease with which the programs enable them to obtain prescribed medications at a low cost. Consequently, it will be difficult to persuade SPAP beneficiaries to voluntarily enroll in a Medicare Drug Plan with premiums, deductibles, and gaps in coverage that they will have to understand and pay. Enrollment in Medicare Part D will be further inhibited for lower-income Americans by the proposed two-step process people will encounter to apply for the subsidy and to actually enroll in a drug plan.

Furthermore, most beneficiaries will be overwhelmed by the marketing materials they will receive from various PDP sponsors. This will be a very significant change for SPAP and Medicaid beneficiaries who have previously not had to choose from an array of prescription drug plans. Many will have concerns about whether the specific prescription drugs they need will be covered by a particular plan's formularies and whether their pharmacies will participate in the plan's network. Most SPAP beneficiaries have never had to decide which prescription plan to choose to best meet their needs. They will have legitimate concerns that making a wrong choice could diminish the comprehensive coverage they have enjoyed through their SPAP. Confusion in selecting a plan has resulted in many beneficiaries not enrolling for the current discount card coverage.

The experience SPAPs have had with the Medicare-approved Drug Discount Card program has proven that automatic enrollment with one or more preferred plan(s) is the most efficient and effective way for SPAPs to coordinate prescription drug benefits for their beneficiaries with Medicare. This approach has proven popular with beneficiaries and has ensured their coverage far more effectively than any other strategy used to date. Therefore, the Commission strongly recommends that automatic enrollment of SPAP beneficiaries with one or more preferred plan(s) be permitted under Medicare Part D to ensure that SPAP beneficiaries enroll in a Medicare Drug Plan and maximize their benefits. Auto-enrollment would alleviate an SPAP beneficiary's anxiety about comparing plan options and would drastically reduce their paperwork to enroll in a plan. It would also allow the SPAP to negotiate with the plans to ensure the most comprehensive and seamless coverage for beneficiaries. While auto-enrollment may be an effective enrollment strategy for many, others may opt-out if they prefer a different plan.

Many SPAP beneficiaries will be eligible for the low-income subsidy assistance provided in Medicare Part D. Most SPAPs' coverage includes Medicare

beneficiaries with incomes below 150 percent FPL. These beneficiaries have already provided the SPAP with financial eligibility information. Therefore, the paperwork and confusion about eligibility for low-income subsidy assistance can be substantially reduced by allowing SPAPs to determine eligibility of their beneficiaries for subsidy assistance and then automatically enrolling them with a preferred PDP sponsor. It should be noted, however, that some SPAPs will choose to accept applications for the low-income subsidy but may decide to have the eligibility determination administered by the SSA.

Overview of the Problems

Automatic Enrollment

The automatic enrollment process for SPAPs was tested and proven successful in the Medicare-approved Drug Discount Card program. SPAPs that automatically enrolled beneficiaries in a discount card simplified the application process for their beneficiaries and eliminated confusion and unnecessary paperwork associated with comparing and choosing a discount card, by contracting with a card sponsor and submitting applications on behalf of enrollees utilizing existing information from the SPAP application. Feedback from SPAP beneficiaries has been favorable about the simplified process. Beneficiaries were given a choice to opt out of the automatic enrollment process and to enroll in a different card of their choice through the "opt-out" process. While given the choice to opt-out, very few elected to do so, implying that enrollees are comfortable with the State acting on their behalf in selecting a card or plan.

In contrast, Medicare beneficiaries who are not SPAP beneficiaries have found the Medicare discount card enrollment process complex and the many choices overwhelming. Most of those who could have benefited from transitional assistance under the Medicare discount cards have chosen simply not to enroll in one. In fact, of those enrolled in Transitional Assistance, more than 80 percent were automatically enrolled through either SPAPs or MA organizations, suggesting that, even with extensive education and outreach campaigns, low-income beneficiaries are unlikely to enroll on their own. Part D will be more confusing than the Medicare Discount Card (due to premiums, deductibles, gaps in coverage, and varying copayments); therefore, it is expected that seniors will be exponentially overwhelmed. In addition, the two-step enrollment process for low-income beneficiaries is likely to only further dissuade people from enrolling.

The automatic enrollment process in the discount card program also minimized administrative costs and burden for SPAPs by eliminating the need to hire additional staff or pay the card sponsor for the labor-intensive process of following up with eligible beneficiaries to encourage them to enroll. Further, the process clarified the coordination of benefits process for pharmacies because the

SPAPs' Preferred Medicare Discount eligibility cards included the logo of the SPAP and instructions for the pharmacist on how to submit the claims. This was a significant benefit to beneficiaries.

Therefore, the Commission recommends that CMS allow SPAPs to be considered authorized representatives of their beneficiaries for the purposes of determining their eligibility for subsidy assistance, enrolling them in one or more preferred PDP sponsors, and paying their Part D premiums.

Eligibility for Subsidy Assistance for Low-income Beneficiaries

Under the proposed rules for Medicare Part D, each individual decides whether to apply for financial assistance for Part D in an SSA office or in a location designated by a State agency to receive Medicaid applications. Each individual must then separately enroll in a prescription drug plan directly with the PDP sponsors in their area. PDP sponsors will be provided information as to which enrollees are eligible for subsidies. However, there currently is no mechanism to permit a beneficiary to apply for the low-income subsidy at the time of enrollment with a PDP sponsor. PDP sponsors are not required to inform beneficiaries that a subsidy may be available, but if an enrollee inquires about eligibility for low-income subsidies, they are to be referred to the State or an SSA office.

For one set of the Part D-eligible population – full benefit dual eligibles – a process of deeming or auto-enrollment in the low-income subsidy combined with an auto-assignment to a plan sponsor if a beneficiary does not choose a plan by themselves should ensure that these beneficiaries receive prescription drug coverage. In contrast, the population traditionally served by SPAPs – low-income persons who are not eligible for Medicaid – may very well fall through the cracks of the new system if they have to navigate two separate enrollment processes (financial and benefit) without the benefit of deeming for the low-income subsidy or auto-assignment for PDP/MA-PDPs. To add to the confusion, financial eligibility determination is split between two agencies. This will undoubtedly produce confusion in communicating to SPAP beneficiaries about how they can go about applying and appealing a denial of financial assistance. Under the MMA, if a beneficiary is determined eligible by the state Medicaid agency, then re-determinations and appeals are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. If a beneficiary is determined eligible by SSA, then the Commissioner of the SSA (the Commissioner) will decide how to conduct re-determinations and appeals for such individuals.

The SSA has many programs under its jurisdiction, but because of its similarity to Part D assistance, we assume that it will build on its Supplemental Security Income (SSI) eligibility process. SSI determinations are made by State agencies that

contract with the Commissioner to make determinations, or by the Commissioner in States that do not enter into contracts to make SSI determinations. The State agency's decision is considered to be the decision of the Commissioner, unless the applicant appeals that decision. There are a series of levels of appeals, and beneficiaries may appeal to a federal court after the reconsideration process is completed by the State agency.

Although an argument can be made that the intent of the MMA was to permit Medicare beneficiaries to apply for the subsidy in SSA offices, an argument also can be made that the SSA could contract with the SPAP to make determinations of eligibility for financial assistance in accord with its procedures, as occurs in SSI eligibility. Under the Medicaid program, States are required to provide notice and fair hearing if Medicaid benefits are denied. Ultimately beneficiaries may appeal state decisions to State or federal courts. A State must make eligibility determinations "in the same manner" as made for Medicaid applicants. Under federal law, States are prohibited from contracting with private organizations to make eligibility determinations.

Where an SPAP is administered by the State, arguably there is no legal impediment to a State's designation of its SPAP as the State enrollment agency, as long as eligibility determinations and re-determinations are made in the same manner as for Medicaid recipients. In fact, there currently is a precedent for this practice. New Jersey presently has an interagency agreement between the State Medicaid agency and the SPAP where the SPAP determines eligibility in the Medicare Savings programs (MSP), including Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), and Qualified Individual-1 (QI-1) programs. These programs are administered by the New Jersey Medicaid agency and include an asset test. Illinois also has an interagency agreement between the Medicaid agency and the Department on Aging, whereby the Department on Aging does the eligibility determination and re-determination for both the SPAP and the Illinois Pharmacy waiver.

If the SPAP uses a private contractor for eligibility determination, some might argue that such an arrangement would violate the requirement that Medicaid not contract out enrollment. But CMS arguably has authority to encourage States to make such arrangements based on the fact that this outreach is similar to Medicaid "outstationing" eligibility workers in disproportionate share hospitals and federally-qualified health centers to enroll pregnant women and children.

The Commission, therefore, recommends that CMS ensure that SPAPs (through interagency agreement with State Medicaid offices and the SSA) have the option to accept applications and make eligibility determinations for subsidy assistance to low-income Medicare Part D beneficiaries at the discretion of the state. Again,

the Commission notes that some SPAPS may choose to accept applications but also choose to have SSA determine eligibility.

Asset Determinations

Medicare Part D includes an asset test in the determination of eligibility for subsidy assistance. It is unclear at this point how those assets will be defined. Because most SPAPs do not have asset tests, SPAPs will need to collect this information from current and future beneficiaries to establish eligibility for Part D subsidies. Collecting asset information may deter SPAP beneficiaries from enrolling in a Medicare Drug Plan because they have not previously been required to provide this information.

To ensure the most seamless transition for SPAP beneficiaries into Medicare Drug Plans, it would be preferable to allow States considerable latitude in defining what counts as an asset, even allowing them to disregard all assets. Precedent for this flexibility can be found in the MSP programs, which include an asset test. While the federal minimum MSP resource standard is twice the SSI rate, states are given latitude in what resources are counted and what level of verification is required. According to 2001 data from an October, 2002 report authored by Laura Summers for the Commonwealth Fund titled*, The Role of the Asset Test in Targeting Benefits for Medicare Savings Programs*, twenty-one states in total, (14 of which have SPAPs), have more liberal asset disregards in their QMB, SLMB, or QI-1 programs than SSI rules.[1] For example, the states of Delaware (SPAP), Alabama, Arizona and Mississippi disregard all assets for all MSP programs and the states of Connecticut and New York that both have SPAPs disregard all assets in the QI-1 and/or Qualified Individual 2 (QI-2) programs. According to Summers' report, other states that also have SPAPs disregarded one or more of any of the following:

- the value of one or more vehicles (1 – FL, KS, MO, SC; 2+ ME, VT)
- household goods and personal effects (SC, VT)
- the higher value of burial funds (FL)
- the higher value of life insurance (FL)
- lowest asset value for the month (KS, ME, MO, SC)
- income producing property (FL, IN, KS, VT)
- resources necessary for self-support (FL, IL)

[1] (Summer, l and Friedland, R, The Role of the Asset Test in Targeting Benefits for Medicare Savings Programs, The Commonwealth Fund, October 2002)

- resources to pay certain medical, legal, guardianship, or tax assessment fees (ME, RI)
- property that the applicant has made an effort to sell (IN, KS, ME, VT)
- some portion of assets (FL, ME, MN)

This is not a comprehensive list. Many states also allow self-declaration of assets rather than requiring applicants to provide supporting documentation. It would appear that SSA's application will allow for self declaration of assets. The decision to allow self-declaration will certainly improve the ease of administration of the program.

The MMA gives the Secretary discretion to permit States to use the same asset or resource methodologies that are used with respect to determining eligibility for a QMB individual so long as the methodology does not result in any significant differences in the number of individuals determined to be subsidy eligible under Part D. In fact, most states that have disregarded all or a portion of assets have determined that liberalizing the asset tests is budget neutral and is primarily intended to reduce administrative burden. Based on interviews with officials in seven of these states, none had experienced a significant increase in enrollment after liberalizing the asset test.

To facilitate enrollment of low-income beneficiaries in the Medicare Part D program, the Commission recommends that the MMA be amended to eliminate the asset test for determining eligibility for low-income subsidies. Until an amendment is signed into law, the asset determination should be liberalized, as several states have done to facilitate enrollment in MSP programs.

Marketing Materials to Encourage Enrollment

Many SPAP beneficiaries will be confused and will decline enrollment in Medicare Part D if the Part D plan marketing materials discuss premiums, deductibles, and coverage gaps that SPAP beneficiaries may not be accustomed to. A PDP sponsor's marketing materials and enrollment forms should include information and an explanation about coordination of benefits with SPAPs. The SPAP and the PDP sponsor should work together to provide such information.

Similarly, the SSA's marketing materials and subsidy application forms also should specifically address how the PDP sponsors will coordinate with SPAPs. In addition, the SSA should notify SPAPs when it does a mass mailing so the SPAPs can prepare for questions/inquiries from their beneficiaries regarding the SSA mailings.

The coordination of marketing materials and beneficiary education and outreach can be substantially simplified if SPAPs can work with one or more preferred

plan(s). In this way, marketing materials can be specifically tailored to the wrap-around coverage provisions of the SPAP.

Patient Need for Professional Assistance in Plan Selection

As was observed with the discount card system, it is anticipated that many beneficiaries will seek assistance from their pharmacists to help them assess individual plans, a process that was sometimes burdensome and poorly supported by CMS. Implementation of Part D is expected to create the same result. Pharmacists who have knowledge of beneficiaries' medication needs, a working relationship with the beneficiaries' prescribers and experience working with third party payers should be seen as an asset in assisting individuals in making plan selection choices and facilitating enrollment. However, pharmacist assistance to beneficiaries in this process could be viewed as having the potential for conflict of interest. This is particularly true if a pharmacy is only in-network for a subset of PDP plans. CMS should establish rules to ensure that beneficiaries are not steered toward particular plans by those who only participate in a subset of plans. The Commission recognizes though, that pharmacists will have direct business consequences if they mislead the beneficiaries who trusted them for assistance. If the beneficiaries think they did not get a good deal or got bad advice, they will be reminded about it each time they purchase prescriptions, and they will go to another practice at the next opportunity. The pharmacists are at direct financial/business risk if they do a poor job. The pharmacists would also be at risk of negative effects on their business from any bad publicity or government agency concerns about not putting the beneficiary needs first. However, this does not eliminate the need for CMS involvement to assure the best interests of the beneficiary and adequate preparation of pharmacists and others who may play such an advisory role. (It should be noted that some pharmacists who could be involved in this assistance might not have a connection with a retail pharmacy outlet.)

CMS should ensure that all providers of information to assist beneficiaries in making enrollment decisions receive adequate training to assure proper provision of this service. CMS, working with provider associations, could implement training to allow interested providers and in particular pharmacists to assist beneficiaries, especially those with added SPAP coverage, to make these often-difficult decisions regarding their medication-related health care.

Disenrollments

Under the Notice of Proposed Rule Making (NPRM) issued by CMS on August 3, 2004 for implementation of MMA, a PDP sponsor may disenroll an individual from

its plan if the person's behavior is disruptive, unruly, abusive, uncooperative or threatening or if premiums are not paid timely. Many commission members question whether CMS has authority to allow such disenrollment. While the law allows such disenrollment for those in MA-PDs, it is questionable as to whether the law really allows for disenrollment from PDPs. In the rest of the Medicare program (parts A,B, and C), a beneficiary may be disenrolled from a Medicare Advantage plan for such behavior but in that instance the person reverts to Medicare Fee-for-Service. There is no provision allowing Medicare Fee-for-Service to disenroll beneficiaries from the Medicare entitlement based on their behavior. Therefore, the Commission recommends that CMS remove this provision from the Medicare part D rules.

In the absence of CMS removing this provision, we suggest that CMS clarify the definition of disruptive behavior and the details on disenrollment for non-payment of premium. Many of the clients that Medicare Part D has been designed to fully serve (i.e., Medicaid clients) are deemed disabled and may have qualified for Medicaid because of mental illness. The symptoms of certain mental illnesses may include behavior that could be categorized as "disruptive, unruly, abusive, uncooperative or threatening." These behaviors may be a direct result of their illness. Often the best way to control these behaviors is through pharmaceutical management. The symptoms of the disease should not inadvertently result in the discontinuation of treatment.

Similarly, there may be occasions where the safety of others may be at risk. In these instances, every effort to secure proper treatment or placement should be utilized prior to disenrollment. The competency and ability of the person to control their own behavior should be emphasized when determining whether to disenroll a beneficiary. Moreover, it is possible that clients in crisis will not be capable of representing themselves during the review and may not be able to submit necessary information to CMS. CMS should include safeguards for mentally impaired or incapacitated clients. A physician with experience in the treatment of mental illness should be involved in the determination of disenrollment for those clients receiving treatment for mental illness.

SPAPs should be notified by the PDP sponsor or CMS that a person has been disenrolled at the point that CMS is notified of the intent to disenroll by the PDP sponsor and the reason for disenrollment. SPAPs claims processing systems will require pharmacists to bill Medicare Part D prior to billing the SPAP. If a beneficiary is disenrolled, the SPAPs claims processing system will need to reflect this change in coverage.

Premium Payments

Some SPAPs have expressed an interest in paying premium costs on behalf of their beneficiaries as provided for in the MMA. If SPAPs will be paying the premiums, they do not want their beneficiaries to have to incur the costs and be reimbursed by the State. If SPAPs pay the premiums upfront on behalf of their beneficiaries they can be sure that their beneficiaries maintain their Medicare Part D coverage. SPAPs have beneficiaries in each of the three premium groups: less than 135 percent of the FPL; 135-150 percent of the FPL; over 150 percent of the FPL. For the group in the sliding scale category (135 percent-150 percent FPL), each person in that group could have a different premium cost. If the SPAP is going to pay these costs, there will need to be a coordinated effort between CMS and the SPAP on these payments because in some categories, CMS would be paying all or part of the premium costs and, in other cases, the SPAP would be paying full premium costs.

Therefore, the Commission recommends that prior to January 1, 2006, there be an automated premium buy-in system in place, similar to the process whereby States pay Medicare Part B premiums on behalf of Medicaid beneficiaries.

Late Enrollment Penalties

Medicare Part D will include a late enrollment penalty under certain conditions for a Part D eligible individual. The penalty will occur if there is a continuous period of 63 days or longer at any time after termination of the individual's initial enrollment period during which the individual meets all of the following conditions: (1) the individual was eligible to enroll in a PDP sponsor's plan; (2) the individual was not covered under any creditable prescription drug coverage; and (3) the individual was not enrolled in a PDP sponsor's plan. To avoid the late enrollment penalty, Medicare beneficiaries will have to enroll in a Part D plan as soon as they become eligible.

For those SPAPs who elect to pay a beneficiary's premium, the late enrollment penalty will likely have a financial impact. It should be noted that SPAP beneficiaries do not necessarily enroll in the SPAP when they turn 65. For example, New Jersey's participation numbers would suggest that people actually enroll in the state pharmaceutical assistance program at ages older than 65 due to a variety of reasons, including the simple fact that a person may have been relatively healthy at age 65 and did not need prescription drug coverage until he/she became older and perhaps more sickly. Based on the assumption that a smaller percentage of elderly beneficiaries enroll in a SPAP at the age of 65, it will be crucial to have people enroll in Medicare Part D, whether or not they enroll simultaneously in an SPAP, upon their 65th birthday. If the person waits to enroll in Part D, he/she will incur a late enrollment penalty. If he/she then chooses to

enroll in a SPAP at an older age, the SPAP may incur the late enrollment penalty for coordinating benefits with Part D on behalf of that person.

In addition, there are beneficiaries who do not renew their benefits on time and become inactive in the SPAP, thus experiencing a lapse in coverage. SPAPs would not cover such individuals' Part D premium during this lapse. This may mean that the SPAPs could incur a late enrollment penalty for enrolling a beneficiary whose coverage has lapsed back into the State program and back into Part D.

A broad and comprehensive outreach effort to get people to enroll in a Part D plan as soon as they are eligible will be critical to avoiding late fee penalties that either the individual beneficiary or the SPAP that enrolls beneficiaries may have to assume. Given the enormous confusion that is likely to be experienced by beneficiaries at the beginning of this new program, which is very different from other programs that beneficiaries are enrolled in, it seems appropriate that CMS delay the imposition of penalties for at least a year. Many beneficiaries are likely to fail to sign up purely because they do not understand the program. They should not be penalized for the complexity of the program. Neither should SPAPs who provide a benefit to a state's residents be penalized for assisting beneficiaries with their premiums.

Recommendations

Automatic Enrollment

CMS should establish an enrollment process that permits the following:

- **SPAPs should be authorized representatives**. A definition of "authorized representative" should be added to Subpart B that would **enable SPAPs, as authorized representatives of their beneficiaries, to choose to: 1) determine eligibility for Medicare Part D and low income subsidies for SPAP beneficiaries; 2) enroll their SPAP beneficiaries in a Medicare Part D plan; and 3) pay premiums on behalf of SPAP enrollees.** This will allow SPAPs to act on their beneficiaries' behalf to enroll them in a PDP under Medicare Part D. It also will benefit enrollees by eliminating their administrative burden and facilitating enrollment in the program.

The Commission received two legal analyses demonstrating the legal basis that gives the Secretary authority to permit SPAPs to auto-enroll their beneficiaries into a Part D plan. The Covington and Burling opinion indicates that language in Section 1860D-23 of the MMA permits an SPAP that is an "authorized representative" of its beneficiaries under state law to select one or more preferred PDP sponsors in which to enroll its beneficiaries. Such an

interpretation, the opinion states, is consistent with the statutory intent to establish effective coordination mechanisms between SPAPs and PDP sponsors.

The opinion by Hogan and Hartson indicates that the MMA does not prohibit the Secretary of HHS from allowing states to establish processes for auto-enrolling their SPAP beneficiaries in plans that are co-branded, endorsed or otherwise selected by the SPAP, so long as there is an opt-out process to protect the individual's choice by selecting a plan other than that preferred by the SPAP, and so long as the State will meet the non-discrimination requirement by allowing the amount of the per person benefit provided through its preferred Part D plan to be paid to a plan selected by the individual in the form of a premium subsidy and/or toward a reduction in cost-sharing imposed on the individual by the Part D plan. Moreover, the opinion states that it is clear that Congress recognized that low-income persons who depend on government subsidies may need special assistance in ensuring that the plan selected is appropriate to their ability pay any excess premium or cost-sharing over the government subsidy. According to Hogan and Hartson, the best interpretation of the MMA, therefore, would be for HHS to expressly permit States to carry out activities that will maximally ensure that individuals are enrolled in appropriate Part D plans, including their auto-enrollment in plans evaluated by the SPAP for purposes of effective coordination of benefits and payment of coverage on behalf of the individual. In light of these legal opinions, the Commission makes the following recommendations:

- **SPAPs should be permitted to select one or more preferred PDP sponsors.** This will enhance benefits to enrollees, encourage enrollment, and promote coordination between Medicare Part D and SPAPs.
- CMS should interpret Section 1860D-23 (b)(2) of the MMA to **permit SPAPs to determine the scope of wrap-around benefits**. If the beneficiary chooses to enroll in another PDP sponsor's plan, the SPAP should not be held responsible for a level of coverage above the benchmark level of coverage of the SPAP's preferred PDP sponsor(s). SPAPs should not be required to provide wrap-around coverage over a standard benefit or for costs higher than those of the preferred PDP sponsor, thus providing the same coverage across all plans.
- CMS should **require SPAPs to provide an opt-out provision**. An opt-out provision would permit the beneficiary to have the option of choosing another PDP sponsor's plan. Opt-out addresses CMS's concerns about discrimination toward preferred plans. As long as the SPAP gives each enrollee ample opportunity to select a different plan and gives that enrollee the same wrap-around benefits, the SPAP has not in any way changed the enrollee's eligibility nor reduced the level of SPAP

benefits to which they are entitled as required by Section 1860D-23 (b)(2) of the MMA.

To review the entire legal opinions by Covington and Burling and Hogan and Hartson, please see Appendices E and F.

Eligibility Determinations

The Commission opposes the two-step process in Medicare Part D, whereby a person applies for the subsidy assistance, if eligible, in a Social Security office or in a location designated by a State agency to receive Medicaid applications, and then enrolls separately in a drug plan. **Allowing SPAPs to determine eligibility and automatically enroll its beneficiaries in a preferred drug plan would eliminate the confusing two-step eligibility and enrollment process** for many who are not eligible for deemed eligibility for the low-income subsidy and would also simplify enrollment for those who are not eligible for the low-income subsidy but who would benefit from maximization of their drug benefit between Medicare part D coverage and SPAP coverage.

CMS should clarify in Section 423.774 of the regulations and in guidance that **State Medicaid programs should have the option to permit SPAPs to take applications and make the initial eligibility determinations and re-determinations for subsidies for low-income persons who apply for benefits through the SPAP**. The clear intention of the MMA is to have a single set of eligibility criteria with multiple locations and opportunities for an individual to apply for financial assistance with Part D.

Where an SPAP has an arrangement with a State Medicaid program for determining eligibility for Part D financial assistance, the Commissioner should deem the SPAP to be eligible for contracting to perform the same activity for the SSA.

The SSA should allow coordination of the eligibility determination and re-determination process, including use of SPAPs as contractors of the SSA for initial eligibility determinations and re-determinations as an option for States.

In all cases, whether the SPAP or SSA is responsible for determining eligibility, **CMS should strongly encourage SSA to share appropriate information with SPAPs to ensure a seamless determination process for the beneficiary.**

CMS should **ensure that State Medicaid arrangements with SPAPs for initial eligibility determinations and re-determinations are eligible for federal matching funds** to the same extent that such activities are matched when performed by the State Medicaid agency.

The Commissioner should arrange for compensation of the SPAP for initial enrollment and re-enrollment in accord with applicable law.

CMS should specifically **authorize SPAPs to use the funds available to them under the statute to establish and publicize a preferred point of contact – one-stop shopping – for Part D eligible individuals** to find out about PDP sponsor's plans in their area, as well as to obtain financial assistance to which they are entitled.

To facilitate the SPAP's ability to determine a person's eligibility for Part D benefits, the SPAP should have **direct online access to the State Verification Exchange System (SVES) provided by the Social Security Administration and the Income Verification System (IVS), the reporting system provided by the Internal Revenue Service.** Once Medicaid and the SSA have developed the uniform application process and forms, SPAPs can readily implement eligibility determination and re-determinations in the same manner that Medicaid currently arranges for outreach and enrollment.

Asset Determination

In evaluating the asset criteria for these programs , the Commission makes the following recommendations for efficiently determining assets and coordinating benefits with SPAPs under Medicare Part D:

- **Eliminate the asset test**. The asset test information is not currently collected by SPAPs and will result in additional administrative burden for both enrollees and state programs. Its removal will have little effect on the number of individuals found eligible for the low-income subsidy. Elimination of the asset test provides for the most seamless transition of SPAP enrollees to Medicare Part D. This recommendation will require an amendment to the federal law.
- Until an amendment is signed into law, the Secretary **should permit states that have more liberal asset or resource disregards in their Medicaid or MSPs to use the same methodology in establishing eligibility for Part D low-income subsidies.** Beneficiaries of MSPs are automatically deemed eligible for full premium subsidies. If States are not allowed to use the same asset criteria for Medicare Part D as for their MSPs, then this will result in having two different asset limits for qualifying for Medicare Part D within the same State (one asset test for those automatically deemed eligible based on participation in an MSP and a different asset test for those who meet the asset test of the MMA but do not participate in an MSP).

If neither of the above recommendations are accepted, and for States that use the SSI asset test, the following modifications to Section 423.772 of the regulations are recommended:

- **Eliminate life insurance policies as an asset.** Currently, this is the most complicated determination for Medicaid and the MSPs. The face value, cash surrender, and dividends of such policies must all be documented, creating an administrative burden and barrier for beneficiaries.
- **Confirm that vehicles will not be as an asset** in the regulations. Including this specific exclusion in the regulation itself, and not just the preamble, will provide more clarity for SPAPs and beneficiaries.

Marketing/Educational Materials

A PDP sponsor's marketing materials and enrollment forms should include information and an explanation about coordination of benefits with SPAPs. The SPAP and the PDP sponsor should work together to provide such information. If SPAPs will be paying premiums, deductibles, and/or doughnut hole costs, CMS should require that this information be explained clearly in all appropriate sections in marketing and enrollment materials of PDP sponsors operating in those States. These marketing materials should also be available in Spanish and other languages where appropriate in a given state.

Similarly, the **SSA's marketing materials and subsidy application forms also should specifically address how the PDP sponsors will coordinate with SPAPs.** In addition, the SSA should notify SPAPs when it does a mass mailing so the SPAPs can prepare for questions/inquiries from their beneficiaries regarding the SSA mailings.

Educational materials from CMS for Medicare beneficiaries enrolled in an SPAP will be necessary to differentiate between Part D and an SPAP. Such materials must be written in simple language, preferably in short bullets. Book-length materials are overwhelming and will not be read by beneficiaries. The CMS "Issue of the Day" publication should be produced for beneficiaries and published regularly in local newspapers.

Patient Need for Professional Assistance in Plan Selection

Education Funds – CMS should dedicate funds for grants to community organizations and providers who assist beneficiaries with assessing PDP sponsors.

Counseling services - CMS should work with national provider associations, in particular pharmacist organizations and other appropriate entities to develop a process to:

- Prepare providers and others to assist beneficiaries in assessing PDP sponsors,
- Document the provision of those services, and
- Compensate the service provider.

Disenrollments

If CMS does not remove proposed regulatory provisions pertaining to disruptive behavior for beneficiaries enrolled in PDPs, then CMS should **clarify the definition of disruptive behavior and the details on disenrollment for non-payment of premium**. Many of the clients that Medicare Part D has been designed to fully serve (i.e., Medicaid clients) are deemed disabled and some have qualified for Medicaid because of mental illness that may have as one of its symptoms behavior that might be described as "destructive."

CMS should **include safeguards for mentally impaired or incapacitated clients who may not be capable of representing themselves during the review and may not be able to submit necessary information to CMS**. A physician with experience in the treatment of mental illness should be involved in the determination of disenrollment for those clients receiving treatment for mental illness.

SPAPs should be notified by the PDP sponsor or CMS that a person has been disenrolled at the point that CMS is notified of the intent to disenroll by the PDP sponsor and the reason for disenrollment. SPAPs claims processing systems will require pharmacists to bill Medicare Part D prior to billing the SPAP. If a beneficiary is disenrolled, the SPAP's claims processing system will need to reflect this change in coverage.

Premium Payments

Section 423.293 of the regulations should be revised to **include a process similar to the Medicare Part B buy-in process for states to pay Medicare Part D premiums on behalf of SPAP beneficiaries**. This would avoid the need to bill SPAP beneficiaries individually for monthly premiums. This coordinated process must be in place prior to January 1, 2006**.**

Late Fee Penalties

SPAPs that pay premium costs, including late fee penalties, on behalf of their beneficiaries should be covered under Section 423.780 (c) of the regulations, which allows full-subsidy eligible beneficiaries to enroll late with a minimal late enrollment penalty. This inclusion will minimize the late fee penalties paid by such SPAPs, which cover low-income Medicare beneficiaries.

Additionally, **the Commission recommends that late penalties not be imposed for at least the first year of operation** of the new Medicare part D program.

PROGRAM DESIGN AND BENEFITS ADMINISTRATION

Overview of Issues

This section of the report addresses issues related to how the enrolled beneficiary, and their SPAP, will experience their Part D drug benefit plan. Once enrolled, a beneficiary will need to work with an in-network PDP sponsor's pharmacy, consume formulary drugs, and appeal for non-formulary drugs and lower cost-sharing. Depending upon how an SPAP designs its future program, it will bear the financial impact of decisions made by beneficiaries as they navigate through these Medicare drug benefit plan design features. Therefore beneficiary education is critical to assuring that beneficiaries obtain the medications and rights to which they are entitled and that SPAPs are not bearing costs that Part D plans could or should pay. In addition, it is imperative that the Part D program and its component parts (PDP sponsors, SPAPs, etc) be evaluated and that continuous quality improvement initiatives be based on the evaluation results.

Pharmacy Network and Access Issues

Network Design

Brief Summary of the Problem

Most SPAPs in existence today serve their membership by offering access to any pharmacy in the state that is willing and interested in participating. Pharmacies are critical stakeholders in any pharmacy assistance program. Particularly for senior citizens, pharmacies are often the only touchstone they may have on a regular basis, in their neighborhood, for questions and concerns about their health and their medications.

SPAPs have long recognized this, and have well-established working partnerships with the pharmacies throughout their state. SPAPs do not want their membership to experience a diminution in services and access when Part D is implemented.

The areas of pharmacy access and network configuration as they are currently proposed in the MMA and the CMS regulations present numerous challenges to SPAPs that do not exist in the current relationship between SPAPs and the seniors they serve.

For SPAPs considering wrapping around Part D benefits, there are coordination and cost issues that arise from whether a pharmacy is in-network or out of network; preferred or non-preferred, notwithstanding whether the networks between the SPAP and the PDP sponsor are equivalent. Mismatches between networks and network policies will result in confusion and expense for seniors that they do not have today, and ultimately will result in SPAPs assuming more financial risk.

There are five scenarios that raise issues of cost, training, and access for SPAPs and their members, depending on how they decide to coordinate with Part D providers. These scenarios can result in confusion for the beneficiary, denied claims, and questions of who pays or how much is paid at the pharmacy level and beyond.

- Pharmacies that are in the SPAP network, but are not in one, some or all of the PDP sponsor's pharmacy networks available for SPAP members.
- Pharmacies that are in the PDP sponsor's networks, but not in the SPAP network.
- Pharmacy is in both the SPAP and PDP sponsor's networks. (Ideal situation)
- Pharmacy is not in either the SPAP or PDP sponsor's network.
- Pharmacies that are in the SPAP but are non-preferred in the PDP sponsor's network.

There are also pharmacy-related issues that raise concerns for SPAPs. They include allowances for mail order and extended supply purchases and residency issues, all of which will be addressed in this section.

SPAP Practices

SPAPs generally have large and inclusive pharmacy networks that incorporate almost all licensed pharmacies in their state. This is because they are state-funded programs whose sole mission is to serve their state's seniors in need. Most SPAPs offer generous benefits, without some of the strict cost controls in place for would-be Part D providers, such as restricted pharmacy networks. However, most SPAPs also have state laws that restrict membership and pharmacy participation to within state boundaries, with few exceptions.

SPAPs and state policy-makers will need to decide how they intend to coordinate or wrap-around Part D benefits, if at all. Depending on the type and scope of coordination chosen by the state and SPAP, the strategy and recommendations for how to deal with out-of-sync networks will be different.

Relevant Statutory and Regulatory Language

The following MMA and proposed regulatory references all relate to the overall issues of pharmacy networks and access.

Section 1860D-4(b)(1)(C) of the MMA requires that the PDP sponsor must permit any pharmacy willing to meet the plan's terms and conditions to participate, though the plan may set up a more restrictive pharmacy network and use reduced cost-sharing to steer enrollees to preferred in-network pharmacies. Any such reduced cost sharing cannot increase federal government subsidies to plans.

The plan's network must include a sufficient number and range of retail pharmacies to provide enrollees with convenient access and emergency access. The network must be at least as comprehensive as the network required in the 2003 TRICARE retail pharmacy solicitation: In urban areas, at least 90 percent of Medicare beneficiaries in the plan's service area, on average, live within two miles of a retail pharmacy in a PDP sponsor's network, in suburban areas, at least 90 percent living within five miles, and in rural areas, at least 70 percent living within 15 miles.

CMS' NPRM goes on to define urban, suburban and rural areas as characterized by population per square mile for a zip code. Plans are required to meet or exceed these standards across each region in which they operate.

CMS has interpreted the federal law's 'any willing provider' clause to allow distinctions between preferred and non-preferred pharmacies while allowing both to be counted as within-network for purposes of meeting the access standard. (Section 423.120(a)(5)). It is clear under the proposed rule that a non-preferred pharmacy is intended as a network pharmacy wherein enrollees pay higher cost sharing for covered Part D drugs as compared to a preferred pharmacy. As noted by CMS in the preamble, cost sharing can vary not only based on the type of drug or formulary tier, but also on a particular status of a pharmacy in the plan's network.

The proposed regulations, Section 423.124, also require that PDP sponsors ensure that enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain Part D drugs at a network pharmacy. (Discussed at II.C.5 of the Preamble.) CMS offered some potential exceptions to when an enrollee could appropriately use an out-of-network pharmacy for extenuating circumstances.

CMS' proposed regulations, preamble, and background attempt to address access to Part D benefits for Medicare enrollees in long term care facilities (LTC). These facilities generally contract with a single LTC pharmacy. If the LTC pharmacy

associated with a beneficiary's institution was not in the PDP sponsor's network that was selected by the beneficiary, the beneficiary's only option would be to obtain their Part D drugs from another pharmacy. This is clearly not practical for residents of LTC facilities. Section II.C.5 of the Preamble, and pages 46656-7 of the Background propose two alternative approaches. CMS could use its authority to require plans to contract with some or all of the LTC pharmacies in their service area. This requirement could prove to be too burdensome for plans to meet. Also, LTC pharmacies will be concerned about appropriate reimbursement for ancillary services they provide now (e.g., specialized packaging for intravenous (IV) therapy). CMS recognizes the need to balance the need for access to LTC pharmacies, with the concern of reasonable payment to LTC pharmacies for services. The second option is for CMS to strongly encourage plans to negotiate with and include LTC pharmacies in their network plans. Related to the issue of LTC pharmacies is the definition of LTC facility. CMS narrowly defined LTC facility to include only nursing facilities and skilled nursing facilities. On page 46649 of the NPRM, CMS requested comment on whether intermediate care facilities for the mentally retarded (ICF/MR) and other types of facilities (supportive living facilities or assisted living facilities) should be included in this definition, such that individuals in these facilities are assured access to Part D drugs through all appropriate pharmacies.

PBM Practices

Today, when someone covered by a plan managed by a PBM goes to an out-of-network pharmacy, the PBM sends the pharmacy a reject message of invalid NCPDP number. The pharmacy would typically explain to the customer that they do not participate in this plan, and the customer will have to pay retail price, or go to a pharmacy in-network. There is restrictive access today among plans, and there is disruption. However, plans have developed various ways to assist members when they encounter a non-network pharmacy. Most plans provide a toll free number for members to call for pharmacy locator service.

However, the typical pharmacy network does not contain both preferred and non-preferred in-network pharmacies. The CMS proposal to allow plans to have non-preferred pharmacies in their network, with higher cost sharing, would be a new and potentially very confusing experience for most consumers.

Issues of Concern

SPAPs are deeply concerned with the CMS interpretation of "any willing provider," allowing a PDP sponsor to submit a pharmacy access plan that includes higher cost non-preferred in-network pharmacies. Even CMS acknowledges that this allowance presents risks of certain geographic areas and certain low-income seniors being priced out of participation. The distinction between preferred-in-

network and non-preferred-in-network is one of cost and creates two-tiered in-network access that can lead to discrimination. SPAPs are concerned, a concern shared by CMS and acknowledged in the Preamble (Page 46659), that plans could limit access in certain less lucrative service areas by proposing a cost-differential at preferred versus non-preferred pharmacies that discourages enrollment for seniors in those areas. SPAPs serve many low-income, high-utilization seniors who desperately need inexpensive access to Part D drugs and therefore, are particularly concerned about this provision.

The distinction between preferred and non-preferred also adds to confusion and complexity for beneficiaries trying to enroll and understand the rules of a plan. This interpretation provides no advantages to beneficiaries or SPAPs and lends itself to potential discrimination and to access problems for enrollees. According to the MMA, PDP sponsors must, at a minimum, comply with the TRICARE pharmacy access standards belonging to the Department of Defense. This program uses only the criteria of "in-network" pharmacies and "non-network" pharmacies. All in-network pharmacies in TRICARE have uniform cost sharing. CMS has thus established an exception by allowing PDP sponsors to distinguish between preferred and non-preferred in-network pharmacies, resulting in inconsistency, confusion, potential unevenness of service, and possible discrimination.

SPAPs are also concerned about the significant cost shifting that can result from non-preferred pharmacies. SPAPs have no control over the pharmacy network contracts, costs, or geography – and yet SPAPs will experience greater costs because of these designs. If an enrollee decides to purchase Part D drugs at a non-preferred pharmacy, the SPAP has two choices, neither of which is palatable. The SPAP can pay for the drug at the higher cost, or they can deny the coverage and force the senior to pay 100 percent. If the SPAP pays for the drug, the beneficiary has no reason not to continue to use this non-preferred pharmacy. By denying the coverage, the beneficiary is out-of-pocket unnecessarily. Because most SPAPs today offer wide-ranging access with standard cost sharing, our members do not have these confusing choices.

With regard to the proposed allowance for enrollees to access out of network pharmacies on an exception basis, SPAPs are concerned that the larger problem of access is being addressed in an exception process, rather than full support of the 'any willing pharmacy' statutory language.

Recommendations

PDP sponsors should be required to submit network plans that offer the same cost-sharing requirements for all in-network pharmacies. CMS

should not permit plans to create lower or different cost sharing requirements among in-network pharmacies.

If CMS insists on allowing PDP sponsors to submit access plans that include non-preferred pharmacies, SPAPs urge CMS to only approve those pharmacy networks that meet the TRICARE access standards with their preferred pharmacies. This will ensure that all enrollees will have access to the best cost-sharing rates at a pharmacy in their area.

CMS should clarify that the geographic standards for access apply in each zip code, not just on average across all urban, suburban, rural areas in the defined region.

SPAPs strongly support the ability to select (whether formally or informally) one or more preferred PDP sponsors. Because of the variety of pharmacy network designs, SPAPs will have a much harder time coordinating benefits with Plans. SPAPs must be given maximum flexibility when it comes to coordination and options for partnering with PDP sponsors. This would resolve many of the network challenges described in this section. An SPAP who wants to coordinate or wrap-around must have the ability to limit its financial liability. The proposed regulations recognize this risk for PDP sponsors, but not for SPAPs. SPAPs having some control over the terms and conditions of coordination by selecting a preferred PDP sponsor will allow SPAPs to limit their exposure and protect the policies, laws and regulations that reflect sovereign state decisions made while developing strong senior pharmacy programs.

PDPs should be required to approach any willing LTC pharmacies in the service area for participation in a plan's network. With regard to LTC pharmacies, SPAPs share the CMS concern that seniors in LTC facilities continue to have access to their drugs through the LTC pharmacy associated with their facility. See the Formulary sub-section for more detailed discussion and recommendations regarding residents of LTC facilities.

The definition of LTC facility should be broadened to include ICFs/MR, intermediate care facilities for the developmentally disabled (ICF/DD), assisted living and other supportive housing facilities, including group homes under 1915(c) home and community based waivers. This will ensure that enrollees in these settings are not put in a position of being unable to receive their medications from the pharmacy that routinely services their facility, because the pharmacy was not offered to participate in PDP sponsor's networks in that region.

There are a number of reasons why these facilities should be designated LTC facilities. First, many of these residents have similar health conditions and needs for pharmaceuticals as those in skilled nursing facilities. Contracting arrangements

are very similar to nursing facilities because of the unique needs of the residents. Finally, CMS has indicated that it may exempt special needs populations from cost-sharing and formulary restrictions. Residents in LTC facilities as described above should be included in special needs categories for purposes of these exemptions.

CMS should establish a standard policy and set of procedures for all PDP sponsors addressing the acceptable grounds for using an out-of-network pharmacy, and how the claims will work. In response to the CMS proposal that enrollees must be able to obtain covered Part D drugs at out-of-network pharmacies under "certain conditions", we recommend that CMS include in those "certain conditions" instances when SPAP members use a pharmacy that is in the SPAP network but not in the PDP sponsor network. However, we do have concerns about encouraging the use of out-of-network pharmacies. The confusion, paper work (no real time point-of-sale (POS) adjudication), and reconciliation that results when an enrollee purchases a covered drug from a pharmacy that does not have a contract with the enrollee's plan does not seem worth the potential benefit.

Mail Order

Brief Summary of the Problem

PDP sponsors will be allowed to offer mail order services. The MMA (see below) will allow for extended supplies at retail pharmacies, at additional cost. This cost difference could result in more enrollees switching to mail order, or choosing the extended supply at a retail pharmacy and the SPAP and the enrollee paying more.

Relevant Statutory and Regulatory Language

The Secretary has discretion to require PDP sponsors to permit members to receive a 90-day supply of their medication through a retail pharmacy. The MMA states that the member pays any 'difference in charge' between retail and mail order. CMS codified this discretion in its proposed regulations at 423.120(a)(6), which requires plans to offer a 90-day supply at a retail pharmacy (instead of mail order) as long as the enrollee pays for "any differential in the negotiated price for the covered Part D drug at the network retail pharmacy and mail order pharmacy." Negotiated price is defined in the NPRM as taking into account any price concessions, such as discounts, etc. and including any dispensing fees. This means that the cost difference to the enrollee, and thus the SPAP, should only reflect the net cost to the plan of paying for the prescription through retail rather than mail order.

SPAP Practices

Mail order can involve out-of-state providers (locations) and up to a 90-day supply. SPAPs for the most part require pharmacies to be located in-state as a

prerequisite to participation in the SPAP. If the mail order pharmacy is not located in the state, the SPAP most likely does not include it in their existing network. Some SPAPs may even prohibit mail order access for their members. Most mail order is for an extended fill period (90 days). Many SPAPs do not cover more than a one-month fill.

PBM Practices

Many PDP sponsors will probably offer mail order as an option. Express Scripts (one of the nation's largest PBMs) offers their retail pharmacies the option to fill a mail order supply as long as they accept the mail order reimbursement rate.

Issues of Concern

Plans will have the ability to market the cost differential and other benefits of mail order. If the member decides against mail order, but insists on extended supply at retail, the member will be agreeing to an increased cost, without any accompanying agreement by the SPAP to pay the cost. The SPAP may experience a cost differential that it did not choose, and one that it cannot avoid.

Mail order is problematic for many SPAPs. Most SPAPs require a participating pharmacy to be located in the state. Mail order is also a concern for some beneficiaries . There is substantial evidence that beneficiaries, particularly low-income beneficiaries, are victims of theft from their mailboxes. Encouraging beneficiaries to receive their medications by mail to an unsecured mailbox may put the beneficiary at risk. The financial incentive of mail order could be undermined by mail loss. Also, with regard to mail order, certain beneficiaries do benefit from a visit to their pharmacy more so than others. They often reveal things to the pharmacist that result in intervention by the pharmacist. Mail order does not offer this face-to-face interaction.

With regard to allowing a 90-day supply at a retail pharmacy, the SPAP that chooses to coordinate will be subject to a cost-differential that is unknown until after the fact. The only way an SPAP could avoid this is to restrict paying for extended supply. While providing maximum flexibility and options for PDP sponsors and enrollees, these regulations are forcing SPAPs to restrict how they coordinate due to this kind of risk for unexpected costs.

Adopting the mail order option, or the extended supply at retail pharmacy would be policy changes for most SPAPs, that they may not be desirous of making, simply to accommodate the PDP sponsor. In some cases, state legislatures will need to amend existing laws. State policy decisions will be made based on the benefit to the senior and the cost to the state program.

Recommendations

The final regulations should make it clear that any price differential, paid for retail versus mail order, would count as an incurred cost toward the out-of-pocket threshold (TrOOP) for the enrollee, whether paid by the enrollee or the SPAP. The Commission also recommends that the regulations require PDP sponsors to report on the comparative cost data for retail versus mail order to the SPAPs. This cumulative data can support SPAPs in their policy and legislative decisions as to how to address mail order and extended supplies. The final regulations should clarify that the differential in negotiated price between retail and mail order paid for by the enrollee or SPAP must reflect the net direct cost to the plan for the medication purchased at a retail pharmacy versus mail order. It is important that enrollees not be steered to mail order and away from their local pharmacy by inflated cost savings at mail order. States with SPAPs may need to make policy, regulatory or statutory changes to accommodate mail order, or to strictly prohibit mail order for its members. This analysis will require that states have reliable data from the plans. CMS points out on page 46793 of the NPRM that there is currently limited publicly available data related to mail order utilization.

CMS should also include some exception in their regulation that requires plans to recognize the risk of mail order for beneficiaries by allowing the beneficiary to pay mail order prices at a retail pharmacy when they can demonstrate that their mailbox is not secure or if they do not have a mailing address at all. We do recognize that making this exception could be a slippery slope, but we urge CMS and PDP sponsors to be mindful of the risk of mail order. We do not have specific recommendations for how to allow for the exception; it may be as simple as requiring the senior to file a complaint of stolen mail with the United States Postal Service.

Snow Birds/Residency

Brief Summary of the Problem

SPAPs currently only offer benefits to state residents. Because the Part D regions may not respect state boundaries, SPAPs will be challenged to track membership in relation to the plan's region, pharmacy network, and policies regarding travel and residency.

SPAP Practices

SPAPs are offered to state residents only because state funds are used to fund the programs. Residency is typically attested to, or proof is required. Many states have experience with residents who move back and forth between states, summering in

one state and wintering in another. Some SPAPs allow a vacation supply for traveling members.

PBM Practices

Current practices regarding traveling and members' participation based on residency and geography are not known. PDP sponsors' policies will be dictated by the final CMS regulations on these issues.

Relevant Statutory and Regulatory Language

Prescription drug plans will serve regional areas, with the regions being determined by the CMS. Service areas must consist of at least one entire PDP region or multiple PDP regions. To the extent practicable, the drug plan regions will be consistent with regions established for the new regional preferred provider organization plans in Title II, though the Secretary may establish different regions for drug plans if it would improve access for eligible individuals**.** A drug plan may offer a benefit nationally by bidding on all regions.

It is CMS' interpretation that Section 423.120(a) (1) of the proposed rule would not in any way preclude PDP sponsors from contracting with pharmacies outside their plans' service areas, provided that the plans meet the pharmacy access requirements within their service areas. According to CMS, such a feature would be of particular benefit to beneficiaries who spend significant amounts of time outside their PDP sponsor's service area (for example, "snowbirds") and could make a particular PDP sponsor's plan more attractive to them. In addition, the fact that beneficiaries would have access to network pharmacies outside their plan's service area would obviate the need for out-of-network access to covered Part D drugs in many cases. Thus, contracting with pharmacies outside a plan's service area could ultimately represent a cost-savings both to plans and beneficiaries, particularly if a plan enrolls a high proportion of beneficiaries who regularly travel outside the plan's service area. (Page 46656)

With regard to disenrollment, the preamble language states that CMS is particularly interested in receiving comments about the requirement to disenroll individuals from a PDP sponsor's plan if they no longer reside in the service area. Section 423.44 requires that a PDP sponsor disenroll individuals who no longer reside in the PDP service area. The MMA at 1860D-1(b)(1)(B) directs CMS to use disenrollment rules established in section 1851. This section allows that MA plans disenroll individuals who are out of the service area for more than 6 months. CMS recognizes that this limit may not be necessary when applied to Part D benefits, as long as the enrollee has access while out of the service area. A regional PDP may either have a corporate or other relationship with a PDP sponsor in another region or have a network of pharmacies in other regions (or nationwide) that would provide access to prescription drugs outside of the region on the same

basis as in-network pharmacies within the enrollee's region of residence. CMS specifically requested comments on this area.

Issues of Concern

Having membership in a PDP sponsor's plan that fluctuates based upon a residency rule within the service area makes it much harder for SPAPs to offer coordination. At the same time, it appears that PDP sponsors can offer a plan that allows members to function outside the service area. While states understand the need for plans with maximum flexibility for members, this increases the challenges and difficulty for coordination of benefits. Most states restrict state funded benefits to state residents. If beneficiaries are allowed to access drug coverage outside of the region for 6 months or longer, SPAPs may not be legally authorized to offer any benefits. SPAPs will need to consider whether to cover beneficiaries who move in and out of the state/region. This will be a training and education issue for members.

Recommendations

SPAPs will need to consider how they will handle snowbirds and establish appropriate policy on a state by state basis. Some SPAPs have specific policies that address snowbirds, or vacation supplies in their current design. State policy makers will need to consider to whom wrap-around coverage will be offered, and what rules will be in place for ensuring that wrap-around benefits are only provided for that specific population.

The regulations should require PDP sponsors or CMS to notify SPAPs of any disenrollments or enrollment changes in order to allow the SPAP to discontinue its wrap-around coverage, if appropriate. **The regulations should also require the PDP sponsors to detail their visitor/traveler benefits to members and SPAPs.**

We support the proposal that PDP sponsors contract with pharmacies outside their service area to provide access to Part D drugs for those enrollees who must travel, or who have residence in more than one service area. These pharmacies would become part of the network, but should not count toward meeting the access standards.

Formularies and Clinical Integration Issues

Brief Summary of the Problem

Most SPAPs exist as free-standing fee-for-service (FFS) drug assistance plans. While many use PBMs or other like entities, the services they provide are usually on an "administrative-services-only" basis, are not all-encompassing and are not

usually commercially oriented. Some SPAPs do use some of the cost-containment tools used by the private sector such as the use of a preferred drug list (PDL), mandatory generic substitution, and use of step therapy. However, access to non-preferred drugs is generally available in such instances through PA within 24 hours. Therefore, formularies are not considered closed. In contrast, the MMA contemplates PDP sponsors entering Part D with a vigorous commercial orientation, including full-scale closed formularies, tiered copays, step therapies and other aggressive cost-containment measures on the clinical side. Access to non-formulary drugs under Part D may be more limited than in typical state Medicaid PDLs due to the proposed complex, lengthy exceptions process, as described later in this report..

The challenge is to find ways to integrate the fairly liberal, FFS SPAP benefits into this new market-driven Medicare Part D benefit. The challenge is even more daunting because SPAP programs are long-standing and state Legislatures and plan beneficiaries have grown accustomed to the relatively open access environments. Integrating these benefits with those of the Medicare Part D plan will be complex and require education. The goal will be to ensure continuity of care and as little disruption as possible for the client as any integration occurs.

Issues surrounding continuity of care and disruption cannot be taken lightly. SPAP states need the financial relief from funding the entirety of drug costs for lower income elderly. The MMA gives the opportunity to achieve this goal. However, as states look to continue to provide a state benefit in tandem with the national benefit, it is important that careful thought be given to the relationship between SPAP plans and PDP sponsors. Dialogue, data sharing, the possible integration of exception procedures must be an important underpinning of the implementation of the drug program – from issues of step therapies, generic substitution, formularies, PDLs, and PA. During implementation of the program, SPAPs should be recognized as important and vested partners in the implementation of the MMA drug benefit and given a voice on behalf of their existing clients regarding continuity of care and disruption issues.

PBM/PDP Sponsor Practices

Based on the existing practices of the SPAPs, it is clear that the Part D PDP sponsors will put in place more aggressive cost-containment clinical management tools in the Part D benefit. Current industry practices are much more restrictive and the increasing trends are for:

- Generally, fairly aggressive utilization management techniques that go well beyond the DUR programs in most SPAP states.
- Mandatory generic substitution or, in the alternative, much higher cost sharing for a brand name drug when a generic exists.

- Step therapies to dissuade or rule out the use of more expensive medications for a condition when a cheaper alternative is available for treatment.
- Restrictive formularies or, in the alternative, much higher co-pays for non-preferred drugs.
- The use of restricted pharmacy networks or, in the alternative, higher co-pays when utilizing a non-preferred or out-of-network pharmacy.
- PA is used aggressively for any type of drug substitution.
- Most private plans limit a beneficiary to a 30-day supply for each co-pay, although they may incentivize beneficiaries to utilize mail order for a lower co-pay or greater supply of their maintenance drugs.

It should be noted that while the MMA and its proposed regulations do not specifically outline what cost containment tools must be used, section 423.153 of the proposed regulation states that a PDP sponsor must establish a cost-effective drug-utilization management program that reduces costs when medically appropriate. Pages 46661 and 46666-46667 of the regulation's preamble list a number of vehicles for cost containment: use of PA, therapeutic interchange, step therapy, tiered cost-sharing, differential dispensing fees to encourage use of multiple source drugs rather than single source drugs, and use of mail order.

Page 46661 of the preamble states that a PDP sponsor "could develop a formulary that employs a number of strategies – for example, financial incentives to encourage use of generics, tiered cost-sharing and other mechanisms that create strong incentives for manufacturers to negotiate favorable prices for covered Part D drugs, PA procedures, therapeutic interchange, step therapy, and use of mail order – to produce cost savings both for plans and for Medicare." On page 46666 of the preamble, CMS points to PDP sponsors using different dispensing fees to encourage use of multiple source drugs. CMS also states on page 46779 of the preamble that it expects drug plans to achieve on average a 15 percent cost management savings in 2006, which it notes will increase over time and also yield beneficiaries additional out-of-pocket savings. Thus, the law and regulation endorse such mechanisms and plans will probably be required to use such tools to live within the constraints of the financing and the reinsurance and risk-sharing outlined in the law and proposed regulation.

Issues of Concern

Minimum Disruption and Ensuring Continuity of Care

Given the significant difference in the relatively open formulary FFS SPAP programs and the expected private-sector cost-containment model of the Part D PDP sponsors, the fear that many SPAP states have is that the continuity of

patient care could be undermined. This will be especially true during the transition to new Part D plans, especially for dual eligibles and SPAP beneficiaries who are accustomed to access to a wide or more open formulary. This low-income population is an especially vulnerable population. For example, only 8 percent of duals have no chronic illnesses. Therefore, we know that the vast majority of this population will be on chronic use medications for serious illnesses. Stabilizing them on appropriate medications takes time and should not be lightly compromised. Many drug switches require titration and monitoring until the patient is restabilized, thus adding to medical expenses for physician visits and lab tests. Not only can switching result in new side effects or other discomforts for patients, but it can also result in a loss of symptom control than can result in the need for acute care services. States are especially concerned that sudden loss of access to psychotropic medications for persons with severe and persistent mental illness will result in their re-entry into state psychiatric hospitals.

The rule's preamble does recognize that cost-saving strategies could negatively impact vulnerable populations, such as skilled nursing facility residents (see page 46661). Also, page 46670 of the preamble notes that: "One area of concern is inappropriate switching of prescriptions by a PDP sponsor without consulting a prescribing physician. For instance, switching from brand to generic may be appropriate, but switching brands, e.g. Lipitor to Zocor, may not, without consultation." Many SPAP beneficiaries have spent years on a given maintenance drug and without proper planning and coordination between PDP sponsors and SPAPs these beneficiaries' health might be compromised.

To protect the health of the patient and ensure minimal disruption and continuity of care, setting up a retrospective medical necessity review framework should be investigated, whereby a drug is authorized in favor of continuity of care for the beneficiary and the clinical review occurs afterward. This assures continued coverage of a medication until an exception or appeal can be completed. Both PDP sponsors and SPAPs would have to be willing to take on the possible financial liabilities incumbent in such a system. The system could be similar to a recent Medicare-Medicaid home care demonstration set up in several states. SPAPs would have to have standing to appeal for their clients through this process.

Clinical Data Sharing Between SPAPs and PDP Sponsors

From a continuity of care and minimal disruption standpoint, it is important that SPAPs and PDP sponsors share clinical data. While section 423.464 of the regulation dictates that PDP sponsors must coordinate with SPAPs, the detail is insufficient to address the significant continuity of care concerns raised by SPAP plans on behalf of their beneficiaries. The regulation needs to be stronger on the requirements of PDP sponsors to share data and enter into agreements regarding continuity of care and coordination of such things as PA, generic substitution and

formulary changes. States would also argue that some deference should be given to the previous PA and generic substitution decisions made by SPAPs.

To protect continuity of care, procedures should be put in place before January 2006 to mandate dialogue concerning SPAP clients that have already been prior authorized for certain brand drugs. For example, in Connecticut, atypical antipsychotic drugs are exempt from PA for clients currently on them – only newly prescribed atypical antipsychotics that have at least three A-rated generics available for substitution will be required to get PA, for initial scripts only.

A PDP sponsor may have a step therapy or PA requirement, while the SPAP has claims history that shows that the formulary drug was previously tried unsuccessfully. This data, if exchanged in advance, can prevent an unnecessary denial and possible interruption of medically necessary care. Clearly, SPAPs will have the longest and most complete history. Of important note is the fact that people may change PDP sponsors every year, but the SPAP will remain consistent. Thus, it is essential that SPAPs and PDP sponsors coordinate or at least share clinical criteria for PA, step therapies, and generic substitution. This will likely require the development of business associate relationships between PDP sponsors and SPAPs so as to comply with HIPAA requirements.

Without data sharing and integration, it will also be confusing for SPAPs that have full benefit plans to know whether they should pay under their wrap-around when a PDP sponsor denies coverage. For example, when denials occur for a DUR reason, how will an SPAP know not to pay for a contraindicated drug? Certainly, SPAPs will want to continue with their own DUR programs to both protect their clients as well as prevent unnecessary costs. This will be challenging if the PDP sponsor and SPAP DUR programs do not have the same system edits.

Formularies

The proposed regulation does not go far enough to ensure that beneficiaries have access to medically necessary drugs. SPAPs that choose to continue full benefit programs will face substantial continued costs for non-formulary drugs that the PDP sponsor does not cover, if formularies are restrictive. Unlike a PDL, which requires PA based on a clinical review of the individual's case before a coverage or denial decision is made, a restrictive formulary results in a denial with no clinical review. Given the proposed appeal process, which entails no notice of denial and appeal rights and a very long review process, beneficiaries are likely to be left without access to needed medications for at least a period of time, as a result of formulary denials, unless they have secondary coverage for non-formulary drugs through an SPAP. Since states expect many duals to enroll in the SPAPs for just such protection, these SPAPs' costs could grow enormously over time. The dual population includes many severely ill individuals, who need access to drugs not

used by the typical commercial plan enrollee. This, formulary adequacy is of paramount importance to SPAPs from both a patient protection and cost perspective.

While section 1860D-4(b)(3)(A) of the Act requires that the formulary be "developed and reviewed" by a pharmaceutical and therapeutic (P&T) committee, it is CMS' interpretation (see page 46659 of the preamble) that the P&T committee may establish and change drugs on a formulary or PDL and that the committee's decision is binding on the plan. However, section 423.120 of the regulation requires only that a PDP sponsor's formulary be reviewed by a P&T committee, so the regulation should be amended to adopt CMS' intent about the binding nature of the P&T committee's decisions.

CMS will have to approve each PDP sponsor's formulary classification system or more simply certify it if the PDP sponsor utilizes the system developed by US Pharmacopoeia (USP). PDP sponsor formularies and PDLs and different cost-sharing arrangements will have to be approved by CMS as well.

In the interest of preserving continuity of care and minimizing both disruptions and the number of appeals, we advocate that CMS use data analysis to inform its evaluation process. For example, Medicaid data for dual eligibles will provide CMS a profile of which drugs are most used by persons with any given diagnosis. Particularly as the Part D program is being initially implemented, a reasonable formulary should assure that most patients with any particular diagnosis will be able to find their medication on the formulary and will not have to change their medication immediately. CMS should establish a formulary evaluation criterion that would trigger a much more detailed evaluation of the adequacy of the formulary if a drug plan failed to offer enough medication choices to assure that, for example, 90 percent of the beneficiaries will be able to continue on their current therapies. A formulary that requires vast numbers of elderly to switch or appeal will result in widespread dissatisfaction with the Part D program and in the potential for numerous interruptions in drug therapy that result in other medical cost and quality problems. It will also result in significant costs for full-benefit SPAPs that will pick up the costs of drugs that are denied as non-formulary drugs. The Commission does recognize that in drug classes where there is an array of equally effective drugs from which to choose, with similar side effect profiles, that it may make sense to start a new patient on the least costly medicine. However, the financial and quality impacts of switching someone who has already been stabilized on a medication, especially when it is difficult to titrate the medication for effectiveness and side effects, should be seriously considered before allowing large numbers of frail older and disabled persons to be forced to switch.

There is a requirement that PDP sponsors have at least two drugs in each class (section 423.120). It is of concern that the USP standards as proposed would

allow for a formulary that very limited and might exclude some key drugs, such as selective serotonin reuptake inhibitors, angiotensin II receptor blockers, statins, certain oral hypoglycemics, and other commonly prescribed, state-of-the-art medications. Further, it is also missing classes for numerous orphan drugs which are essential for certain individuals with rare, life-threatening diseases.

The final regulation must ensure that exception processes dovetail with SPAP PA processes and that SPAPs are allowed to be authorized representatives for the individual. We believe more work in the regulation has to occur surrounding coordination and disclosure between PDP sponsors and SPAPs to offer protection to states. While there is language mandating coordination by PDP sponsors with SPAPs, once arrangements are made coordination language appears lacking moving forward with implementation. A clearly defined role for the SPAP in any appeals of formulary denials or during PA for overrides on step therapy, dose limits, or generic substitution issues is important. Oftentimes, an SPAP may have better knowledge of a case history and may already have prior authorized certain drugs in its program.

It also may make good economic sense to allow an over-the-counter medication to be covered within the Part D program when prescribed by a physician, if this is determined to be a cost-effective alternative to prescription drugs.

Removing Drugs from Formularies

Section 1860D-4(b)(3)(E) of the Social Security Act states: "Any removal of a covered Part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists." Of concern is that CMS has interpreted "appropriate notice" to mean 30 days. Specifically, section 423.120 (page 46819) of the proposed rule reads: "A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug." However, there are two issues with allowing such deletions. First, 30 days simply does not allow enough time for the SPAPs to respond to or integrate the formulary change in their programs or for beneficiaries to appeal. Second, 30 days is not always long enough for a beneficiary to get an appointment with his or her physician to consider alternatives. Third, if a beneficiary has selected a PDP sponsor specifically because it covers her current medications, it is unfair to change the benefit she thought she bought, once she is locked in for a year. Furthermore, a PDP sponsor's formulary must meet standards to be approved during the bidding process. However, the regulations do not reserve the authority to CMS to

review and potentially disapprove a change in the formulary. As a protection against arbitrary changes to formularies, CMS should consider requiring that PDP sponsors certify that their proposed changes in formulary do not change the actuarial value of the benefit or the compliance of the formulary with USP and CMS standards, including two drugs per class and non-discrimination. CMS should not be obligated to "approve" every change, but should have the right to disapprove a change if it feels it is appropriate to do so. CMS could mimic the "file and use" approach of many state insurance departments, which allows CMS to scrutinize the changes without slowing down the plan's implementation of the changes.

Section 423-120(b)(6) prohibits a PDP sponsor from changing the formulary from the beginning of the open enrollment period until 30 days after the beginning of the contract year. The principle behind not changing during open enrollment is to prevent "bait and switch" tactics. This principle should apply for the duration of the contract year, not just the first month, for a patient who was using the medication at the time the plan was selected. Not only do such marketing practices constitute unfair and illusory marketing practices, but they also have serious consequences on patients for whom continuity of care is important. Either having to switch medications or having to appeal to stay on a medication that the beneficiary trusts and has used successfully is no small matter for an older person with chronic illnesses. It is of even larger consequence to a poor and disproportionately disabled population, who are likely to suffer lags in therapy due to their inability to pay for their own medications after a denial and their greater difficulties in promptly obtaining a new prescription for a covered drug. Three states have insurance laws that grandfather in coverage of a deleted drug for individuals who were already taking the medication or who bought the policy when the medication was on the formulary. These three states are CT, CA, and TX.

SPAPs are particularly concerned about these switches in formulary coverage because of the impact on SPAP and dual recipients from a clinical perspective and because the SPAPs will likely have to pick up the costs for these drugs for at least a period of time, in order to assure continuity of care.

PDP sponsors should not be allowed to change the formulary for the entire contract year. But, at a minimum we recommend that PDP sponsors should be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, unless the deletion is due to the new availability of a generic substitute or due to the Food and Drug Administration's (FDA) removal of the drug from the market due to safety reasons. This should not be construed as prohibiting a PDP sponsor from asking physicians to voluntarily switch their patients to less costly drugs, in a therapeutic substitution

initiative or the use of PA as a means to facilitate switching with the ability for the physician to override the switching when clinically necessary. Along with the grandfathering provision, a 90-day notice provision should be adopted as it is a much more realistic notice period to ensure continuity of care from beneficiaries and to aid SPAPs in any programmatic changes they need to engage in when a formulary changes in a Part D plan.

Furthermore, 30 days is not a long enough period for advance notice. In order to explore options for switching to a new formulary drug, people will have to make an appointment to see their prescribing physician. Getting an appointment with a specialist can take many weeks, and often physicians will not prescribe a new medication without an appointment to evaluate the patient. Assuming a patient can get in to see their physician, they may then decide with their doctor to seek an exception because the formulary drugs are not medically appropriate for them. Since a PDP sponsor can take 14-30 days to respond, there is a good chance that they will not receive the exception before their next refill is due, if it is even approved.

Beneficiaries should also be guaranteed continued access to lower copays if midyear increases are made by the PDP sponsors.

Special Needs Populations

Dual eligible skilled nursing facility residents and residents of ICFs/MR appear to be defined by reference as "institutionalized" under the Act and would be free of cost-sharing requirements. That may not be the case for residents of 1915(c) waiver group homes, assisted living facilities and other similar facilities for dual eligible persons with physical disabilities, mental illness or mental retardation. Because these special needs populations have substantially similar financial constraints and health needs as residents of skilled nursing facilities and ICFs/MR, we believe that all of these populations should be treated equally.

While residents of ICFs/MR and group homes and other facilities may have some income disregarded (those in nursing homes do not), their income is still extremely limited. The personal needs allowances (PNA) in skilled nursing facilities are generally well below $100 in most states, and need only be $30 per month according to federal Medicaid law. These PNAs must cover personal incidentals as well as co-pays and non-formulary drugs. If not deemed institutionalized or otherwise freed of cost-sharing, a medically fragile individual subject to cost-sharing and with multiple prescriptions could not afford even the minor cost-sharing under Part D. It should be noted that under Medicaid law, a recipient cannot be denied a prescription drug for failure to pay the copay, which will no longer be true under Part D.

Special needs populations in various long term care settings, including those in skilled nursing facilities and ICFs/MR otherwise free of cost-sharing, are not likely to be able to afford their medications or have true access to them if formulary restrictions apply. Formulary restrictions could force such special needs individuals to utilize the majority or all of their monthly income on medications if a needed drug is not on a formulary, and must be purchased out-of-pocket while pursuing an appeal. Indeed, in some cases, their PNA would not be adequate to cover such an out-of-pocket cost, resulting in a break in therapy. Furthermore, few of these individuals have the cognitive abilities to deal with appealing a formulary denial and it would be an enormous burden for their group home or case manager to have to navigate the appeals process on behalf of numerous clients.

Such populations may need special treatment because they are more sensitive to and less tolerant of many medications. Also, noted is that most LTC pharmacies have open formularies to respond to this fact. In general, the existence of any formulary restrictions and cost-sharing could easily lead to greater medical costs for non-drug benefits for these exceedingly medically fragile populations. Research published by the Center for Health System Change[2] has documented that barriers to access for drugs for the Medicaid population, including co-payments and PA, have led to reduced adherence to medically necessary drug regimens. Failure to properly comply with medication therapy results in exacerbations of chronic and acute illnesses that, at a minimum, bring these patients back to the physician and, at worst, puts them in a hospital or other institutional setting.

Some special needs populations must be exempt from both formulary restrictions related to their diagnoses (i.e., closed formularies) and cost-sharing, including for the following groups:

- Residents of skilled nursing facilities and other like entities.
- Residents of ICFs/MR.
- Residents of 1915(c) waiver group homes.
- Residents of state-run group homes that operate similarly to 1915(c) waiver group homes but have not technically met federal Medicaid qualifications.
- Beneficiaries who are otherwise on Medicaid community-based waivers (to avoid institutionalization) and therefore are allowed to retain only a

[2] Prescription Drug Access: Not Just a Medicare Problem, Peter Cunningham, Issue Brief #51, April 2002, Center for Health System Change

very limited share of their incomes, and have the same or even more complex prescription needs as those living in institutions, should also be exempted from cost-sharing and formulary restrictions. This would apply to individuals on home and community-based waivers for the elderly and disabled or children who qualify for Medicaid benefits through the "Katie Beckett" eligibility category in section 1902(e)(3) of the Social Security Act.

- Those with chronic mental illness, whether they qualified for federal SSI or not. These individuals often are required to have less-than-30-day supplies of prescription drugs because of suicidal tendencies or the need for close monitoring. Closed formularies and cost-sharing for this population would complicate the already major challenge of drug adherence for many of these individuals, whose very illnesses make it difficult to adapt to change. Furthermore, paying out-of-pocket for denied drugs would force these individuals to exhaust the vast majority of their income each month. Connecticut learned from its brief experience with copays that some individuals with chronic illnesses, including mental illness, may have been dissuaded from proper maintenance on medication as a result of the copays. States that have implemented even nominal co-pays on Medicaid recipients have at least anecdotally found that such co-pays have dissuaded the mentally ill from filling prescriptions. In addition, studies have documented that low income and Medicaid persons forego necessary medications as a result of copays and other barriers, including the mentally ill. [3], [4], [5], [6]This was the case even when Medicaid beneficiaries were told that federal law dictated that the drug could not be withheld due to lack of payment of co-pays. Thus, we know that financial barriers for this population result in under-treatment and consequently larger costs for non-drug services.
- Those with other chronic health conditions, such as human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome

[3] Effects of Limiting Medicaid Drug Reimbursement Benefits on the use of Psychotropic Agents and Mental Health Services by Patients with Schizophrenia, Steve Soumerai, New England Journal of Medicine, Vol 331: 650-655, #10.

[4] Adverse Effects Associated with Cost Sharing Among Poor and Elderly Persons, Journal of the American Medical Association, Jan 24/31, 2001, Vol 285, #4, p 421.

[5] Evaluation Report on the Impact of the Prescription Drug Plan, Robin Tamblyn, McGill University, Submitted to the Ministry of Health and Social Services of Quebec, March, 1999.

[6] Pharmacy Benefits and the Use of Drugs by the Chronically Ill. Goldman DP, Joyce GF, Escarce JJ, Pace JE, Solomon MD, Laouri M, Landsman PB, Teutsch SM. Journal of the American Medical Association, Vol 2291, No. 19, May 18, 2004, pp. 2344-2350.

(AIDS). These beneficiaries often have multiple prescriptions due to the complex nature of their conditions. As such, they would be unable to afford cost-sharing or the additional financial implications of being subjected to a restrictive formulary.

In the alternative, if CMS decides that totally open formularies should not be offered to special populations, CMS should give consideration to at least requiring that classes of drugs related to the recommended diagnoses (AIDS and mental illness) be unrestricted.

Cost containment with the special populations may still be reasonably pursued through therapeutic substitution conducted with the agreement and careful supervision of their treating physicians. In some instances lower cost alternatives may be appropriate and may not reduce clinical effectiveness or cause side effects. Step therapy or PA may also be an option to achieve savings for newly diagnosed individuals if it is accompanied by the kinds of protections available in Medicaid, including a 24-hour turn around time, access to a 3-day emergency supply, and coverage while seeking an exception or appealing.

Definition of Institutionalized Individuals

While institutionalized dual-eligible persons have no cost sharing for Part D drugs covered by their PDP sponsors, the definition of "institutionalized" is problematic. Consistent with the MMA statute, Section 423.782(a)(2)(ii) (p. 46729) rules out any cost-sharing for institutionalized beneficiaries, although page 46729 of the preamble may not completely comport with the outlined section. The preamble refers to 1902(q)(1)(B) of the Act:

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

It would appear that the SSA section above does define ICFs/MR as institutions, so those clients would not be subject to cost sharing. It is less clear whether individuals in 1915(c) waiver group homes, assisted living facilities, residential care homes, boarding homes and other such entities would be defined also as "medical institutions." For the reasons outlined in our comments on special needs populations, we strongly believe that all of these individuals need to be exempt from cost-sharing. Thus, the proposed rule should be clarified to include in the definition of "institutionalized beneficiary" all individuals in assisted living facilities, supportive living facilities, residential care homes, boarding homes and other such

therapeutic residential facilities, as well as those being served through 1915(c) home and community based waivers. The populations in these facilities are substantially similar to those in ICFs/MR and often are included in state contracts for pharmacy services for ICFs/MR.

This is clearly the best reading of the statute together with 1916(c), since these programs are designed to take individuals who would need to be institutionalized and structure their covered services so as to maintain their independence in the community. This not only improves their quality of life, it also is cost-effective for the government-financed health benefit programs that serve them. The copayment provisions of the MMA should not be interpreted in a way that undermines these program goals.

Recommendations

SPAPs should carefully evaluate the adequacy of formularies of the PDP sponsors available to their enrollees. If an SPAP does not select one or more preferred PDP sponsors with a good formulary for auto-enrollment, as advised elsewhere in this paper, then the SPAPs will want to be sure that the available PDP sponsors' formularies offer enough drug choice to be worth the SPAPs buying into them at all. Very narrow formularies will result in the SPAPs paying for many drugs that are denied by the PDP sponsors, potentially making the cost of the premium exceed the value of the coverage to the SPAP.

CMS should establish metrics for the initial formulary review. We would suggest a formulary evaluation criterion that would trigger a much more detailed evaluation of the adequacy of the formulary if a drug plan failed to offer enough medication choices to assure that most new enrollees will be able to continue on their current therapies at the start of the program. A formulary that requires vast numbers of elderly to switch or appeal will result in widespread dissatisfaction with the Part D program and in the potential for numerous interruptions in drug therapy that result in other medical cost and quality problems.

Special transition rules should be established for the early months of 2006 to ensure continuity of care for persons newly enrolling with PDP sponsors. These rules should assure that individuals who are on non-formulary drugs are given at least 90 days notice that their drug will not be covered, in order to allow them to transition to a formulary drug or to appeal for continued coverage. Without such transition protections, we fear that mass denials will occur, leaving many enrollees without coverage or shifting many costs to SPAPs.

PDP sponsors should share data and enter into agreements regarding continuity of care and coordination of such things as PA, generic substitution and formulary changes. Some deference should be given to the previous PA and generic substitution decisions made by SPAPs. To protect continuity of care,

procedures should be put in place before the January 2006 start date to mandate dialogue concerning SPAP clients that have already been prior authorized for certain brand drugs.

Mid-year formulary changes should be discouraged. Many on the Commission feel that mid-year formulary changes should not be allowed. At a minimum we recommend that PDP sponsors should be required to grandfather-in coverage of a deleted drug for anyone who was taking the medication prior to the deletion, except in cases of a safety issue or a new generic becoming available. This is not intended to prevent a PDP sponsor from seeking therapeutic substitution with the consent of the prescribing physician. Additionally, if CMS does allow mid-year deletions, then a clinical over-ride should be allowed based on medical necessity utilizing a prior authorization system similar to the one currently used by Medicaid programs.

If mid-year formulary deletions are allowed, a 90-day notice provision should be adopted (rather than the proposed 30-day notice) to ensure continuity of care for beneficiaries and to aid SPAPs in any programmatic changes they need to engage in when a formulary changes in a Part D plan. Beneficiaries should also be guaranteed continued access to lower copays if midyear increases are made by the PDP sponsors. As a last fall-back, if CMS does allow mid-year formulary changes even for already established patients on a medication, then a faster exceptions process is needed with continuous coverage of the older drug for the duration of the appeal.

If mid-year formulary deletions are allowed, CMS should require that PDP sponsors certify that their proposed changes in formulary do not change the actuarial value of the benefit or the compliance of the formulary with USP and CMS standards, including two drugs per class and non-discrimination. CMS should not be obligated to "approve" every change, but should have the right to disapprove a change if it feels it is appropriate to do so. CMS could mimic the "file and use" approach of many state insurance departments, which allows CMS to scrutinize the changes without slowing down the plan's implementation of the changes.

The Commission agrees with CMS that certain populations' needs for continuity of care trumps formulary design. Some special needs populations should be exempt from completely closed formularies, as well as cost-sharing, including a broad definition of "institutionalized" persons. These should include individuals who reside in nursing facilities and ICFs/MR, as well as individuals in assisted living facilities, residential care homes, boarding homes and other such therapeutic residential facilities, as well as individuals served in 1915 (c) home and community based waivers. Persons with severe and persistent mental

illness and AIDS may also need access to a broader array of drug choices. This would not prohibit use of other utilization management techniques, including PA.

CMS should explore setting up a retrospective medical necessity review framework in lieu of formulary denials, to protect the health of the patient and ensure minimal disruption and continuity of care, whereby a drug is authorized in favor of continuity of care for the beneficiary and the resolution occurs afterward. This assures continued coverage of a medication until an exception or appeal can be completed. Both PDP sponsors and SPAPs would have to be willing to take on the possible financial liabilities incumbent in such a system.

Denials and Appeals

Problem Overview

Expenses for Part D drugs that are not on the PDP sponsor's formulary (or not otherwise approved for coverage by the PDP sponsor through PA, exception, or otherwise) will not count towards the beneficiary's out-of-pocket costs. This holds true whether these expenses are paid for by a beneficiary or an SPAP. Therefore, an SPAP that pays for non-formulary or otherwise-denied drug claims will be paying for those costs forever, without helping the beneficiary to eventually qualify for catastrophic coverage under Medicare.

Given that a full-benefit SPAP may have liability for all of such expenses, without limitation, and that the beneficiary bears little or no financial consequence whether or not the PDP sponsor pays, the SPAP is the only party with a vested interest in exhausting all exceptions and appeals processes available to the beneficiary. However, there are a number of hurdles for the SPAP to overcome in order to pursue these appeal rights on behalf of beneficiaries and the process is designed in a manner that is long and administratively burdensome.

Full-benefit SPAPs even have an interest in assuring that the appeals process for non-SPAP Part D enrollees is working well to assure access to necessary drugs. If numerous elderly and disabled individuals find that they cannot get their drugs covered though the PDP sponsor due to formulary and other restrictions, and they cannot figure out how to navigate their way through the appeals process for relief, then they may be both incentivized and better financially qualified (i.e. impoverished) to apply for SPAP coverage to fill in their formulary gaps. Indeed, SPAP states expect many dual eligibles to enroll in SPAP programs for just this reason.

Gap-filling SPAPs also will be affected by the accessibility and effectiveness of the appeal process, since higher tier copays can be appealed and can be set by the

PDP sponsor to be as high as 100 percent. These gap-filler SPAPs will be left fully liable for the cost of such "covered" drugs, unless they can successfully appeal to have the copays lowered on the basis of medical necessity.

Current SPAP Practices

SPAP rules vary substantially from program to program. Based on a review of the practices of five SPAPs, they may deny coverage for any of the following reasons: PA is required, step therapy is required, only formulary drugs are covered (these formularies include all drugs that offer a rebate, so formulary denials are rare), a refill is being requested too soon, a DUR edit indicates a clinical reason not to cover the drug (such as a drug-drug interaction), a non-participating pharmacy is being used, or the request exceeds monthly supply limits. In many of these instances the SPAPs have given the pharmacist authority to over-ride the denial by submitting information. All five states reviewed indicated they had few or no denials. States that make denials have appeal processes.

Current PBM or Likely Future PDP Practices

Notices in Commercial Drug Plans

Formulary denials result in no denial notice. Patients usually are not aware they can seek an "exception," because no notice is sent when they are refused coverage.

Pharmacists get on-line messages about **PA & step therapy** requirements, and usually take the first step to either contact the prescribing physician or tell the patient to contact the doctor to seek PA or an exception. (Failure on a step therapy edit usually kicks off the "PA required" notice, but could be treated as an exception.) Denial of PA usually results in a notice of appeal rights to the beneficiary, but not the physician.

Dose limits denials will result in patients being denied more than a certain quantity of drug per month, e.g., six doses of migraine medicine. No notice is sent, but the limit can sometimes be exceeded upon exception request.

Generic substitution laws vary by state. Many states have statutes allowing physicians to write "dispense as written" on the prescription, and then the PBM will pay for brand drug, even if there is a generic. However, they may call the physician to pursue a switch.

DUR denials can often be overridden by pharmacists. This sometimes requires a call to the prescriber to get clinical information and then a text message to the PBM. Denial notices are not sent to the patient if a denial is upheld due to a DUR edit.

Administrative denials are usually communicated by the pharmacist to the patient, e.g., came back too soon before 30-day refill period was over, not eligible on date of service, benefit is exhausted, deductible not met, supply limit is exceeded, mandatory mail order, non-participating provider. Denial notices are not sent.

When denial notices are sent, such as after a **PA request is denied**, notice is sent to the patient only, not their prescribing physician.

Notices in Medicaid

Medicaid law requires that a recipient be sent a notice whenever a benefit is denied. However, some states and their contracted PBMs do not send denial notices for drug claim denials.

Florida was sued for failure to send denial and appeal right notices. As a result they have instituted a requirement that pharmacies deliver notices to patients at the point of service, when their claims or PA requests are denied.

PA Process in Commercial Drug Plans & Medicaid

The patient's physician or pharmacist submits clinical justification for the drug by phone or fax. Approval or denial is usually sent within a couple of days or even instantly. Many Medicaid programs, for example, require a 24-hour turn around time for PA decisions. But some PBMs are slower or lose the requests occasionally.

In commercial plans there is no coverage while awaiting the PA decisions. In Medicaid the patient must be given a 3-day supply in emergency cases, while awaiting the PA decision. If they then decide to appeal, they must receive covered benefits until the appeal is resolved.

Either the PBM or plan sponsor/Medicaid agency may handle the clinical approvals of PA.

In commercial plans, patients may usually pay for a prescription and get reimbursed after the PA is granted, by filing a paper claim. One PBM expressed concern that if an SPAP paid and tried to get PA later, there would be an incentive for the PDP sponsor to deny the PA.

- The "**exceptions process**" applies only to commercial plans. It is generally the same type of clinical review as in PA, but it is not formally recognized as the same and instructions on how to seek exception are not usually included in standard plan info. The exceptions process is usually handled in a maximum of two to three days, and often is handled on the phone when the physician calls. The difference between exceptions and PA is as follows: "Drug X is covered but only if it has

approval through PA" versus "Drug X is not covered unless it has approval through an exception."

- **Appeals** generally are to the plan sponsor and use their standard appeal process. But if an exception request is required, the beneficiary cannot appeal unless they sought an exception first.
- Some PBMs contend that claims for non-formulary drugs are not real claims and non-formulary denials are not real denials for purposes of notice and appeal right requirements under the Employee Retirement Income Security Act, unless an exception has been sought and denied. (This approach is reflected in the proposed regulation.)

Cogent Statutory and Regulatory Language

Beneficiary **out-of-pocket costs**, whether paid by the beneficiary themselves or by an SPAP, count towards their deductible and out-of-pocket limit (and their eventual ability to get catastrophic coverage) only if they are approved/covered costs under the provisions of their PDP sponsor. Expenses for Part D drugs that are not on the PDP sponsor's formulary or not otherwise approved for coverage by the PDP sponsor through PA, exception, or otherwise, will not count towards the beneficiary's out-of-pocket costs.

Although neither the statute nor the regulation explicitly prohibit the SPAPs from steering enrollees to a **preferred PDP sponsor**, the preamble to the proposed regulations indicate that such steerage would be considered a violation of the statutory provision that prohibits SPAPs from discriminating "in determining eligibility and amount of assistance…based upon the part D plan in which the individual is enrolled."

PDP sponsors may use formularies, PA, step therapy, dose limits, and other **cost containment approaches**.

The statute requires PDP sponsors to have a "reconsideration and appeal" process that mirrors that of the managed care plans for non-pharmacy benefits. "PDP sponsor shall meet the requirements of (1) through (3) of section 1852(g)….in the **same** manner as… benefits under an MA plan…" and "shall meet the requirements of (4) and (5)…in a manner similar to…benefits under an MA plan…" The proposed regulation added an exceptions process & coverage determination request for formulary, step therapy, and dose limit denials, which is not in the "same manner" as non-drug benefits. Non-drug benefits claim denials are considered coverage determinations, and beneficiaries do not have to take the additional step of requesting a coverage determination/exception.

In general Medicare law says that a denial of benefits is considered an "adverse organization determination," and a **notice** must be sent explaining appeal rights.

But for drugs, the proposed regulation does not view the denial of an initial drug claim to be a coverage determination. Therefore, no denial notice is required after the claim is denied, until a coverage determination is sought and received. After receiving a denial at the pharmacy counter, the beneficiary, or their authorized representative or prescribing physician, would have to seek a "coverage determination."

The exceptions process established by the regulation will result in a decision by the PDP sponsor that will be considered equivalent to a coverage determination. PDP sponsors have up to **14 days to respond** to a request for coverage determination for benefits and 30 days for payment, so they therefore have 14-30 days to respond to the exception request. (Commercial plans are required in many states to respond within two days, and many times they do so even more quickly.) An expedited decision may be requested, but only if the drug is not already furnished…i.e. only if the patient does not buy the prescription on their own or obtain the medication as a result of SPAP coverage.

If the coverage determination is adverse, the beneficiary will be instructed that they may seek a re-determination by the PDP sponsor. The PDP sponsor has **30** days to make this re-determination if the request is "for **covered drug benefits**" and **60** days if the request is "for **payment**." A request for drug benefits is when a beneficiary has not paid for the prescription themselves, and a request for payment is when a beneficiary buys their own medication while awaiting the PDP sponsor's decision.

If the re-determination decision is adverse, they will get a notice of appeal rights. There are three levels of appeals:

- Reconsideration by an independent review entity (IRE),
- Review by the administrative law judge (ALJ)
- Then either review by the Medicare Appeals Council (MAC) or by filing suit in civil court.

While this external review process is largely the same as the appeals process for other benefits, the regulation makes one significant change. For other benefit denials, if the beneficiary is denied by the PDP sponsor in the re-determination, they are automatically sent on to the IRE. The regulations propose that for drug appeals, the beneficiary must actually submit a **request for independent review**. This extra requirement is justified on the basis that the IRE level of review is only available to a beneficiary if, according to statute, the prescribing physician attests that the drug is medically necessary because other drugs available on the formulary are ineffective or cause adverse reactions. The preamble further

states that drug appeals are anticipated to "involve relatively small amounts, raising doubts about the efficacy of forwarding all such cases to IRE."

Appeal to the ALJ is limited to claims involving **amounts in controversy** that exceed a threshold set annually by the Secretary ($100 now). The regulation provides that the $100 will be calculated for drugs based on the "projected value" of the benefits.

The regulation allows prescribing physicians and "**authorized representatives"** to seek a coverage determination (exception) on behalf of a beneficiary. However, the regulations do not allow physicians to seek a re-determination (unless it is expedited) or to seek reconsideration by the IRE, ALJ, or MAC. Neither does the regulation explicitly allow dispensing pharmacists to seek coverage determinations (as it does for physicians), although they could presumably obtain status as an authorized representative. Authorized representative is defined as "an individual authorized by the enrollee, or under state law, to act on his or her behalf in obtaining a coverage determination or in dealing with any of the levels of the appeal process…"

The regulation requires that PDP sponsors have a process to **expedite coverage** determinations and re-determinations, and the IRE is to make its decision "as expeditiously as the enrollee's condition requires," but there is no language about timeframes for the higher levels of appeals. The timeframes for the ALJ and MAC are already established elsewhere in law and do not allow for any expedited process. This rule applies equally to drug and non-drug benefits.

Once a drug is approved through exception or appeal, **refills** may not be subject to re-approval.

Tiered copay amounts can be set "without limit," as long as they do not discourage enrollment of a class of beneficiaries and the actuarial average of all copays is no more than 25 percent. Copays of 100 percent would be allowed, according to the preamble.

The MMA also allows **appeals of copay** levels, i.e., to get into a lower copay tier if medically necessary, but the beneficiary may only appeal for a lower copay if they sought an exception and were denied. The proposed regulation requires PDP sponsors to establish criteria for considering these exceptions and they are different from the criteria for considering formulary exceptions. Copay criteria include consideration of the difference in cost between preferred and non-preferred drugs, but do not include the comparison of safety & effectiveness required for formulary exceptions. The preamble also contemplates requiring PDP sponsor s to require a beneficiary to try a formulary drug and suffer adverse consequences before granting them an exception for a lower copay.

PDP sponsor s may **delete drugs from their formularies** with a 30-day notice to affected beneficiaries, among others. This notice is not defined in the regulation to be equivalent to a coverage determination. Thus upon receipt of such a notice, in order to appeal for continuation of a current medication, a beneficiary would first have to ask the PDP sponsor for a coverage determination. The only restriction on formulary deletions is during the open enrollment period and for one month thereafter.

A drug approved through exception may not be subject to a special tier or copay amount, but can be required to pay the copay of the highest tier in the plan…which may be 100 percent. Presumably, if a high co-pay is applied, that too can be appealed. There is no clear coordination between the appeal process for formulary denials and for copays, so this might require a two-stage appeal process. Also, the language about not creating a special tier for drugs approved through exception is not repeated for drugs approved through re-determination, IRE, ALJ, or MAC.

Section 423.562 states that "If an enrollee has no further liability to pay for prescription drugs furnished through a PDP, a determination regarding these items is not subject to appeal." CMS indicates that this provision would **prohibit SPAPs from appealing** if they have paid for the drug on behalf of the patient.

Issues of Concern

SPAP Authority to Encourage Enrollees to Choose Plans That Will Minimize the Likelihood of Benefit Denial

The NPRM's prohibition against SPAPs steering enrollees to a preferred PDP sponsor, which might otherwise be required to have a more expansive formulary and a smooth connection with the SPAP in the event of a denial, will make it more likely that the SPAP will bear the cost for more denials and the administrative burden of having to deal with many more PDP sponsor s' varying approaches to and contacts for obtaining exceptions. If SPAPs cannot minimize their costs for covering denied drugs and their administrative burden for pursuing appeals, they will be disincentivized from continuing as full benefit programs.

SPAP Standing to Appeal

SPAPs organized as full benefit programs will be subject to large and long term expenses due to PDP sponsor denials and therefore need the ability to prevent or overturn such denials on behalf of SPAP/Part D enrollees. However, the SPAPs' ability to pursue and/or obtain such relief is not entirely clear in the regulation and could be made more favorable. It is not clear what action is necessary to become an authorized representative (e.g. verbal agreement, written document). Could an SPAP be authorized by state law to be the authorized representative or could

they require all beneficiaries as a condition of enrollment to designate the SPAP as their authorized representative?

Pharmacists cannot initiate the exceptions request on behalf of an enrollee or an SPAP, unless they become an authorized representative for each patient. Given that the older person, who has just been told that their drug is denied, is most likely to turn to the first possible source of assistance (the pharmacist) for help, it seems appropriate to make it easy for the pharmacist to offer that assistance. Furthermore, pharmacists are used to requesting PA for drugs when required, and the exception process is similar if not identical to the PA process.

SPAP Liability and Patient Risk are Elevated by the Proposed Process

Enrollees in both Part D and full benefit SPAPs will have no incentive to appeal for drugs denied by PDP sponsors, since the SPAP will pay for them anyway. Thus the SPAP has full cost liability and needs to act in its own interest to appeal as the responsible party.

Pharmacies have no incentive to pursue full payment from PDP sponsors, if the SPAP is going to pay for denied drugs and high copays. They can simply obtain payment from the SPAP, rather than expending their own administrative resources to pursue PDP sponsor payments that might be available if further information is submitted or an exception is requested.

However, if SPAPs do not pay for denied drugs, many of the low-income enrollees of the program may not be able to afford to pay for their own drugs while awaiting the outcome of an exception request or appeal, if indeed, they can even figure out how to pursue these avenues. If these enrollees walk away without their medications, their health may be jeopardized and they may wind up in emergency rooms, doctors offices, and hospitals at a higher cost than the cost of the denied drug.

The preamble to the proposed regulations indicates that the IRE will not review the appeal de novo, but rather will rule only on whether the PDP sponsor applied its own criteria appropriately. This is not how the IRE functions for other non-pharmacy benefits and fails to protect beneficiaries in cases where a PDP sponsor's criteria are indeed flawed. Furthermore, since CMS itself believes there may be instances in which the PDP sponsor will not have seen the physician's certification of medical necessity, there is clearly new clinical evidence to consider and evaluate. The IRE should be able to use its own independent clinical judgment in reviewing an appeal, or there is little point to have an independent review.

Denial Notices

Both full benefit SPAPs and SPAPs which only pay to fill gaps should be concerned that patients will not get denial notices when they most need them, i.e., at the

point at which their claim is initially denied. Therefore, they will not know how to seek exceptions for formulary denials, step therapy, etc. These claim denials may motivate Part D enrollees to apply for full benefit SPAP programs to pick up costs they cannot afford. Furthermore these extra expenses erode Part D enrollees' assets, making them more likely to be eligible for SPAP.

Time Frames

It will be difficult for the SPAP to act in real time to obtain an exception or appeal while the patient is still at the counter, given the proposed process.

The exceptions process is not proposed to transpire "in the **same** manner" as other non-drug benefits, as required by statute, and adds fourteen days to the timelines for appealing. In the old M+C plans, the rules for appeals, notices, and timeframes were the same for all benefits, whether they were drug benefits or non-drug benefits. There was no separate exception process for drug coverage, and M+C plans were able to administer the process.

These proposed timelines are very long and may leave a beneficiary without access to drugs for a long time. If the SPAP pays during that time, it may be difficult for the SPAP to recoup. The PDP sponsor will have less incentive to overturn a denial and the patient and physician will have less incentive to assist in the appeal process, since his patient is already receiving the drug. And, if the appeal is successful, the PDP sponsor will pay the pharmacy and the pharmacy will have to then reimburse the SPAP. This reconciliation process is very administratively burdensome for both the SPAP and the pharmacy.

A 14-30 day turn-around is not necessary for an exception process. These routinely are processed in 24 hours for Medicaid agencies and within two to three days for commercial plans.

The proposed regulation prohibits expedited appeals for cases in which the "drug is already furnished." This treats the denial of a prescription as though it is a one-time event; and most of the prescriptions for this population are for chronic medications. A low income person may choose to pay for their own medication while filing an appeal, because they know their life depends upon it. But they may not have the resources to continue to pay for monthly refills until the slow process of appeals is fully played out. It is unfair and clinically dangerous to discourage a patient from refilling their medication, even at their own expense, in order that they can take advantage of a quicker appeal process.

The difference in timelines for re-determinations for "payment" versus for "benefits," does not make sense for persons consuming chronic medications which need monthly refills. A denial of payment for this month's supply is tantamount to a denial of benefit for next month's supply. Again, as mentioned

above, the rule would force the patient to go without their medication – at risk to their own health – in order to avail themselves of the shorter timeframe.

The proposed requirement that denials at re-determination would have to be affirmatively appealed in writing by the beneficiary, rather than being sent automatically to the IRE, will lengthen the timeframe for a beneficiary to obtain relief and add to the beneficiary's or SPAP's administrative burden. Indeed, for many older persons a requirement to submit an appeal in writing is in itself an impediment to the appeals process. Many older persons have visual and coordination impairments that make writing difficult or may have literacy problems. CMS should consider ways to assure that all persons have access to the appeals process, including requiring the PDP sponsor to assign a consumer advocate to help individuals, who face such challenges, to submit their appeals. This would include writing the request letter on their behalf.

The justification for not automatically forwarding denials to the IRE, as noted in the preamble to the proposed regulation, is not on target. It states that the appeal to the IRE must be accompanied by the physician's attestation that the drug is medically necessary because formulary drugs would not be effective or would cause adverse reactions. But information from the physician is routinely included in the documentation submitted to request an exception and can be easily forwarded by the PDP sponsor to the IRE. Indeed, 423.578(b)(4) allows PDP sponsors to require a physician's written certification of this very information. In cases where it is not already included in the documentation, the PDP sponsor could request it before forwarding the case to the IRE. The preamble further suggests that many drug appeals are for small dollar amounts and it would not be efficacious to have the IRE consider them. To the contrary, many drugs used by the elderly are for chronic illnesses. Therefore, even if they are not very expensive for a one-month supply, their projected value over their likely duration of use or over the period of the plan year can be far greater than services such as physical therapy or even hospital days.

Coverage Determinations and Re-determinations

A denial of a claim submitted by a pharmacist at the time of dispensing is not considered a coverage determination in the proposed regulations, although a claim denial for any other type of benefit is considered as such. This non-parallel treatment of pharmacy claims leaves the beneficiary without notice and lengthens the process for obtaining relief.

A notice of formulary deletion to affected beneficiaries is not described in the regulation as being equivalent to a coverage determination. So after receiving such a notice, the beneficiary would have to ask the plan for a coverage determination, which may or may not be allowed until they actually go to the

pharmacy to refill their prescription, which they already know has been removed from the formulary. Again, this extra step adds fourteen days to the process a beneficiary has to go through to obtain an exception. Meanwhile, they will either be left without access to their medication or the SPAP will have to pay for it and seek to recoup the cost later through the exceptions and appeals process.

The language prohibiting the use of special copay tiers for drugs approved on exception is not similarly applied to drugs approved through higher levels of appeals. This language should apply regardless of how the drug gets approved.

Projected Value of Benefits

The proposed regulation is not clear regarding the determination of whether a beneficiary's appeal meets the dollar threshold to go to the ALJ. Does "the projected value of the benefit" mean the value for the entire duration that the patient is likely to need the drug? For chronically ill enrollees, they may need a drug for the remainder of their lifetime or at least for a long duration.

Tiered Copays

The standards that CMS proposed for evaluating exceptions for copay tiers are different than for formulary and appear to be less clinically appropriate. The copay criteria are oriented to cost but do not ask about the efficacy and safety of the drugs under consideration. Further, the copay exception process does not consider a patient's known allergies, side effect profile or demonstrated lack of effectiveness from previous use of the drug or of a similar drug. Indeed, the preamble proposes a criteria for approving an exception that calls for an older person to actually experience adverse effects before being granted coverage. This lack of clinical sensitivity to the patient is inappropriate and could cause real and predictable harm to patients. Physicians know that some drugs will be ineffective or can cause interactions or side effects because of the diagnoses, prescription profiles, age, sex, weight, or other characteristics of the patient. Physicians will not want to knowingly prescribe a drug that is likely to cause harm, just so that they can prove to the PDP sponsor that the patient really needs the higher copay drug. Indeed, they would be liable for malpractice if they did so. A mechanism where the physician can dialog with the PDP sponsor to facilitate a clinical override where medically appropriate is necessary for the health of beneficiaries.

Although in theory an SPAP may wish to appeal on behalf of a beneficiary when a high tier copay is applied, there appears to be no way currently for the SPAP to know from claims information what tier the PDP sponsor used in paying the claim. This information is not included on the NCPDP transaction set at present. While SPAPs may infer from extremely high copays that they must be in a higher tier, their ability to appeal will be compromised by the lack of information, and they

will consequently have little recourse to simply paying whatever the co-pay amount is as reported on the claim.

Drugs approved on exception cannot, in the proposed regulation, be subjected to a special copay tier. However, the highest copay tier, which may be 100 percent, may be applied to all drugs covered on appeal. A PDP sponsor could establish a tier with very few drugs in it, just so that it could use that tier for all drugs covered upon exception. Drugs covered through exception or appeal should have the copay of the preferred formulary drug that the PDP sponsor felt was an appropriate alternative when establishing the formulary. Otherwise PDP sponsors can choose to always apply the highest tier. This would clearly discourage beneficiaries from bothering to appeal or seek an exception. The only benefit to appealing would be so that the out-of-pocket payment would count towards TrOOP, but many beneficiaries will never reach their out-of-pocket limit, so this has no value to them.

So to get real coverage of the non-formulary drug, after getting it approved as an exception to the formulary, a beneficiary would then have exercise their right to appeal again to get a lower copay tier for the drug. Given that they have just proved that the formulary drugs are not adequate to safely treat their medical condition, then it stands to reason that they could prove again that the high copay drug, for which they now have an approved benefit, should be granted the lower copay level of the preferred formulary drug. But why make them go through two sequential appeals? These decisions should be effectively combined to require that a PDP sponsor automatically grant the non-formulary drug the copay of the alternative preferred formulary drug.

Recommendations

Many issues raised in this report can be resolved through revisions to the proposed regulations. However, should CMS fail to take actions necessary to safeguard low income consumers' rights to an accessible and timely appeals process, then Congress should act to clarify its' intentions to assure that access to drugs for dual eligibles, SPAP enrollees, and other low income beneficiaries is not indeed compromised as a result of the implementation of Part D. Any or all of the recommendations below could be addressed statutorily.

SPAP Authority to Encourage Enrollees to Choose Plans that Minimize the Likelihood of Benefit Denial

Although it is mentioned elsewhere in this report, it is worth reiterating that **SPAPs should have the flexibility to endorse and default-enroll beneficiaries in one or more preferred PDP sponsors**, as long as a beneficiary is given a clear option to choose a different PDP sponsor and suffers no loss of benefits or eligibility for the SPAP program. This will enable the SPAP

to identify and enroll beneficiaries in PDPs which provide the best formularies and have a more collaborative and expedient process for handling exceptions and appeals.

SPAP Standing to Appeal

SPAPs should be specifically identified in the regulations or statute as authorized representatives to file exception requests and appeals to the PDP sponsor, without having to ask the beneficiaries to designate them as authorized representatives. If this recommendation is not implemented then, the currently proposed regulatory language should be interpreted to permit state law to designate the SPAP as the authorized representative. Or, the SPAP can make it a condition of enrollment that the beneficiary, by virtue of enrolling, is designating the SPAP as the authorized representative.

Dispensing pharmacists should also be allowed to act as authorized representatives to request exceptions on behalf of enrollees. In many cases, the pharmacist is who the older person will turn to first for help when an initial denial occurs. Furthermore, pharmacists are accustomed to seeking PA for drugs, and the exceptions process is basically the same as PA. Indeed the NCPDP format for PA could just as easily be used for PA under Part D.

Section 423.562 of the proposed regulation should be revised to **clarify that if an SPAP has paid for a drug, this in no way eliminates the beneficiary's or SPAP's right to pursue an appeal for coverage of the drug by the PDP sponsor.**

Give SPAPs the authority to challenge a PDP sponsor's pattern of decisions on a class of drugs, first by formally contacting the PDP sponsor and asking for a re-consideration of its policies and criteria, and secondly, if the first effort as resolution fails, by appealing to the IRE. If the SPAP's appeal is granted, then the PDP sponsor would be required to reimburse the SPAP for any SPAP payments made to pharmacies to cover the costs of the denied drug, in addition to amending its future decision-making process. SPAPs are in a unique position to track the patterns of PDP sponsor decisions, and to serve in a quality assurance role in this manner. But this approach also allows them to act to protect their own financial interests in an administratively efficient manner for both the SPAP and the PDP sponsor.

Exceptions and Appeal Process Options to Reduce SPAP Liability and Patient Risk

Require PDP sponsors, at least for dual eligibles, low-income subsidy beneficiaries and SPAP enrollees, to pay for a 3-day emergency supply of denied medications to enable the patient to have time to contact their physician for a prescription for an alternative formulary

medication or to appeal, and to pay for a continued supply of any medication that is under appeal, in order to prevent a break in therapy. This recommended requirement is modeled after Medicaid rules, which require an emergency three day supply be given at the time of initial denial, and, if the beneficiary appeals, then a continued supply is covered until the appeal is resolved. This is, again, especially important for an older person with a chronic illness, who has been successfully managed for some time on a medication and should not suffer a break in therapy while these administrative requirements play out. Such protection is essential for low income persons who do not have the resources to pay out-of-pocket for non-formulary drugs while awaiting the outcome of an appeal or exception request. Further, without such protections persons formerly obtaining drugs through the Medicare program will experience a diminishment of rights and access. Such a requirement will also serve to incentivize the PDP sponsors to complete the exceptions and appeals process quickly.

Require PDP sponsors to respond to requests for exception & PA over the phone or within 24 hours (as in Medicaid*)* to avoid delays and breaks in care, and to avoid putting SPAPs on the spot to pay the full cost. This is especially important for medications necessary for continuity of care. An individual who is stabilized on a medication for a chronic illness is put at great risk to their health if their drug therapy is interrupted for the sake of an administrative process.

Provide SPAPs with information about why a PDP sponsor claim is denied, so that the SPAP can decide whether to appeal. SPAPs need to know about denials (and the reasons for them) instantly so that they can initiate an appeal or seek exception on behalf of the patient. The NCPDP claim transaction set will give the pharmacy very detailed information about why a claim is denied. PDP sponsors and pharmacies should be required to use this data set, so that pharmacies can pass on the information at the same level of granularity to the SPAP in real-time.

Cases reviewed by the IRE should be reviewed de novo, and not limited to ruling only on whether the PDP sponsor applied its own criteria appropriately, as suggested in the proposed regulations. This assures that beneficiaries truly benefit from an independent review. This should not be interpreted to mean that the IRE can award benefits beyond the boundaries of the definition of Part D covered drugs. However, they should be free to exercise their own clinical judgment in rendering decisions regarding formulary denials, copays, and other clinical matters.

PDP sponsors should share clinical criteria with SPAPs for approval of PA requests, exceptions, and tiered co-pay exceptions, so that the SPAPs will not waste time pursuing appeals that will be justly denied on clinical grounds.

SPAPs that provide a full benefit plan could require pharmacies, whenever there is a formulary denial, to first contact the physician to see if an alternate formulary drug is acceptable, and if not, work with the enrollee (perhaps as their authorized representative) to initiate the exceptions request process. Pharmacists play this role now in obtaining PA for drugs when required. SPAPs could refuse to pay the cross-over claim unless the pharmacy has obtained a denial to the exception request or at least documented that such a request had been made. However, this may leave the beneficiary without a drug for fourteen days while waiting for the PDP sponsor to respond.

Denial Notices

PDP sponsors should be required to issue written notices of denial and appeal rights upon initial denial of a pharmacy benefit. PDP sponsors could either mail out the notices from their own claims system or have their contracted pharmacies print off notices. Pharmacy-issued notices could be screen prints or pre-printed leaflets (as in Florida Medicaid). If neither of those approaches is acceptable, at the very least, an explanation of benefits form (EOB) should also be delivered when benefits are denied, not just when they are covered, and an appeal notice should be included on the EOB. In any case, CMS should establish standards for how PDP sponsors should issue notices. In full-benefit SPAP states that choose to pay for the drug pending the outcome of an exception/appeal request, such notices could be revised to note the SPAP coverage for SPAP beneficiaries with the permission of the SPAP, to avoid upsetting the beneficiary. This recommendation for a notice requirement should not be construed as requiring a denial notice in cases where a generic substitution occurs or where an alternative formulary drug is prescribed by the physician and dispensed by the pharmacy at the point of service – thereby essentially withdrawing the request for coverage of the non-formulary drug.

Beneficiaries should be grandfathered or get a grace period of at least 90 days of coverage when they first trip a formulary, step therapy, dose limit, or PA denial for a drug they've been on previously. (See language in the National Association of Insurance Commissioners (NAIC) Model Act.) This gives them sufficient time to get a doctor's appointment to explore alternative drugs or to initiate an appeal if the alternatives do not work. At the point at which they first trip the denial, they should get a notice telling them how to seek an exception or to appeal, as appropriate.

Notices of formulary deletions should be considered notices of coverage determinations, and beneficiaries should be instructed how to submit medical information in order to seek a re-determination for their case. Since formulary deletion letters are clearly statements of a PDP sponsor's intention not to cover a drug, there seems little point in having a beneficiary ask

for a coverage determination – which is tantamount to asking whether the drug will be covered when they have received a letter telling them that it will not be covered.

Time Frames

The exception process should have a two day turn-around time to reflect current practice, as well as to serve patient needs. The proposed fourteen to thirty day timeframe not only exceeds current PBM practices enormously, but provides for very poor patient service, especially in continuity of care situations.

Denials of re-determinations should be sent by the PDP sponsor automatically to the IRE, as are all other benefit denials. If physician documentation is missing, the PDP sponsor can request this before forwarding the case. Furthermore, requiring the beneficiary to write a letter in order to seek external review is a significant barrier to many older persons or persons with disabilities who have arthritic hands, muscular degenerative diseases, cognitive impairments, or other disabilities.

There should be no bifurcation in the timelines for appeals whether the recipient (or SPAP) paid for the drug or went without the medication. This approach is modeled on medical benefits that are non-recurring, which is not the case for drugs taken for chronic illness. Such drugs are the most frequent targets of formulary exclusions and drug switching.

An expedited exceptions process should be available even when a patient has paid for the medication out-of-pocket subsequent to the denial, if further refills will be needed. Although they paid for the first refill, they may not be able to afford the next, and a standard exception timeline will not guarantee a decision prior to the next refill. In this case the patient is at risk of not having access to an essential medication. Perhaps the regulations are based on the precedent of non-drug claims, where it is reasonable to assume there is no urgency for surgery, for example, if the patient has already paid for it, because that service is only delivered once. But prescription drug needs are recurring, so a single payment does not mean the need has been addressed.

Coverage Determinations and Re-determinations

The initial claim denial should be considered a coverage determination, and a denial notice with appeal rights should be sent as a result of this coverage determination. If the final regulations fail to address this essential point, Congressional action is imperative. Failure to treat the initial denial notice as a coverage determination does not comport with the language of the statute or with standard practice for other Medicare claim denials. Without a notice

explaining beneficiary rights to a re-determination or exceptions process, most beneficiaries who experience a formulary denial will have no idea of their rights or how to pursue them. Congress may need to clarify that, in requiring CMS to establish an appeals process that is "the same as" or "similar to" that established for MA programs, it intended for CMS to establish a program at least as favorable to the beneficiary as the MA program. CMS's interpretation of "the same as" seems selective. The proposed regulations do use the same but inappropriately long time frames for exceptions processing as for MA coverage determinations, but they do not use the same process as MA plans insofar as claim denials at the point of service are not treated as coverage determinations and the extra step of an exception process (not envisioned by the statute or in the MA appeals process) is inserted. Certainly accommodations need to be made to adapt the MA appeals process to drug benefits. But those adaptations should be favorable, not unfavorable, to the beneficiaries.

The exception process should be considered the re-determination or at least explicitly treated as a brief step between the coverage determination and the re-determination, since both the exception request and the re-determination step offer the PDP sponsor the opportunity to re-think its initial denial based on the specific clinical needs of the patient. Current commercial practice supports a faster turn around time for exceptions.

Formulary deletions should be considered coverage determinations, as noted above.

Projected Value of Benefits

The projected value of a medication, for purposes of meeting the threshold to go to the ALJ, should be clarified to be projected over the full likely duration of the drug's use for that patient. Otherwise, a shorter duration will not truly reflect the patient's likely out-of-pocket costs, for which they are appealing coverage. If CMS refuses to require that the projected value be over the likely duration of the drug's use by the patient, then at a minimum, it should be considered as the likely duration over the plan year.

Tiered Copays

The criteria for considering copay exceptions should consider the medical effectiveness and safety of the drugs and the specific clinical profiles of the appellants, as in formulary exceptions. Beneficiaries should have access to the non-preferred drug at the preferred copay rate if the preferred drug is likely to cause an adverse effect or is likely to fail to control their symptoms or disease. The proposed exception criteria for tiers which focus on costs and not clinical factors are not appropriate. Furthermore, patients should not be required to suffer adverse effects from a

preferred tier drug before being given the lower copayment rate for a non-preferred drug. Prescribing physicians can base such predictions on past use of similar agents, or characteristics of the patient, such as age, body mass, or race, which can be correlated in studies with effectiveness or lack thereof for specific drugs.

Drugs covered through exception or appeal should have the copay of the preferred formulary drug that the PDP sponsor felt was an appropriate alternative when establishing the formulary. Otherwise, a beneficiary granted coverage of a non-formulary upon appeal may have the highest copay tier applied (e.g.100 percent) and will have to appeal all over again for a lower tier, even though the medical necessity for the drug was already established in the formulary appeal.

CMS should work with NCPDP to establish a standard claim processing field that all payors and pharmacies would then be required to use for purposes of communicating which tier is applied. This information can then be shared at the point of service with the beneficiary, as well as on written EOBs. Otherwise, neither the beneficiary nor the SPAP is likely to know which copay tier is applied to a given drug and therefore neither is likely to know if they can appeal for a lower copay. With copays possibly varying for multiple tiers, in- and out-of-network status, and mail order use, confusion about tiers is inevitable.

Beneficiary Education

Brief Statement of the Problem

As January 2006 and the transition to the new Part D drug benefit rapidly approaches, SPAPs anticipate the urgent need to prepare their beneficiaries, as well as those who are ineligible for SPAP enrollment, and dual eligibles through an education campaign. This campaign will need to focus on the use and coordination of benefits with a goal of avoiding the confusion that we anticipate beneficiaries will experience as they try to make sense of their benefits. MMA and the proposed regulations direct the PDP sponsors with respect to their role and responsibilities in education, but provide no direction to SPAPs to educate current or prospective beneficiaries on how to use and coordinate the new benefits.

The experience of SPAPs in the integration of drug discount cards into their existing benefit structure provides some guidance. As the transition date approaches, SPAPs are not advocating for statutory or regulatory directives on the integration of the open access environments of the SPAPs with the more market-driven and hence restrictive parameters of the Medicare Part D benefit.

SPAPs want to maintain maximum flexibility in the implementation and program guidelines and in the quantity of information provided to beneficiaries. Ideally, SPAPs will have an auto-enrollment option, decreasing the need for extensive beneficiary education.

One of the SPAPs' key concerns is the ability to eliminate confusion that may result if the PDP sponsors were to send the standard information to SPAP beneficiaries. The confusion would arise from generic information meant for the entire pool of potentially eligible beneficiaries. The material would not take into account the different aspects of SPAP benefits, including out-of-pocket costs that would be different for SPAP participants than for other PDP sponsor participants. Coordination and planning between SPAPs and private plans is critical to a smooth transition. Accordingly, we must anticipate these concerns and also consider and learn from the best practices and shortcomings of drug discount card implementation across the country. With a goal of ensuring consumer continuity of care, no disruption of service, and minimizing consumer fear, distrust and confusion, beneficiary education must be focused, timely, and appropriate for each of the intended audiences.

PDP Practices

One of the greatest challenges posed by the January 2006 change in benefits is that there will be new prescription drug benefit plans introduced. The challenge lies in needing to coordinate future activities without knowing the landscape. SPAPs will need a sense of how many plans will be available, where they will serve, and the options they offer in order to assess the implications of this change for future education needs. To adequately prepare the beneficiaries and ourselves, we will need to anticipate where the real growth is going to be.

The expectation is that the PDP sponsors will be issuing standard education material designed to meet the presumed needs of all potential members. This one-size-fits-all approach to beneficiary education will prove to be extremely confusing to SPAP beneficiaries whose benefits and financial responsibilities for drug benefits will differ from the beneficiaries of private plans. The potential confusion associated with generic education pieces suggests that SPAPs and PDP sponsors need to coordinate their education efforts, at least to the extent that education materials produced by the PDP sponsors provide additional explanations that respond to the concerns of SPAP beneficiaries that will be raised by this broader information.

Cogent Statutory Language

Current statutory language directs beneficiary education by PDP sponsors.

Section 1889 of the statute addresses education of Medicare providers of services and suppliers to be conducted by Medicare contractors. Training relates to billing, coding, and improvement of accuracy, consistency and timeliness of contractor responses. This section also requires the contractor to maintain a website for frequently asked questions (FAQ) and materials it publishes.

While caregivers and family members may get their information about the drug benefit from a website, the Internet, as an education tool for the majority of beneficiaries, is not the most effective tool for communication. At least one secondary source of communication should be adopted for the beneficiary population.[7]

Section 1860D-1 (c) Providing Information to Beneficiaries. CMS is charged with the responsibility to broadly disseminate information to Part D eligible and prospectively eligible individuals. The information must first be made available at least 30 days prior to the initial enrollment period which begins on November 15, 2005. Information must be similar to what is required by §1851(d) (providing information to promote informed choice of Medicare + Choice plans) and include the toll-free telephone number of comparative information for prescription drug plans and MA-PD plans. Comparative information with respect to qualified prescription drug coverage must include: benefits, monthly premium, plan's quality and performance, required beneficiary cost-sharing, results of consumer satisfaction surveys. CMS is not required to provide comparative information during the first year of a plan and for the next year if the information is not available or it is impracticable to do so. Beneficiaries must also be informed of late enrollment penalties.

Section 1860-D-4 Beneficiary Protections for Qualified Prescription Drug Coverage. This section of the proposed regulation requires PDP sponsors to provide at enrollment and at least annually thereafter, the information required to be provided for Medicare Advantage plans by §1852(c)(1). The information must detail drug specific information including access to specific covered Part D drugs, identification of pharmacy networks, how the formulary works, cost-sharing requirements, and the medication therapy management program that the PDP

[7] See, AARP National Survey on Consumer Preparedness and E-Commerce: A Survey of Computer Users Age 45 and Older, Executive Summary (March 2000) http://research.aarp.org/consume/ecommerce_1.html. In 2000, the survey examined computer use of adults, age 45 and older. Of that group, 81 percent reported having Internet access. 38 percent described themselves as novice users, and those tended to be older, less educated and less affluent than more experienced users. AARP's implications for this study included that "users age 65 and older, less affluent users, and less educated users are generally less proficient and less confident that those who are younger, more affluent, and more educated…. Thus, a significant proportion of computer users age 45 and older are potentially at risk in an increasingly technology-driven commercial environment." Moreover, they conclude that "Future changes in industry and government policies that increase dependency on automation for business transactions should be sensitive to the range of skill levels among users."

sponsor must have in place. PDP sponsors must be responsive to beneficiary questions and provide a timely response to enrollees through a toll-free number and written information. Changes in the formulary must be made available in a timely manner through an Internet website. With respect to claims information, the PDP sponsor must furnish each enrollee with an easily understandable explanation of benefits and when prescription drugs are provided, the initial coverage limit for the year and the annual out-of-pocket threshold for the year.

Section 423.128(a) and (b) of the proposed regulations direct the PDP sponsors when establishing rules for dissemination of plan information and content of the plan description. Section 423.128(d) of the proposed regulations requires a mechanism for providing timely, specific information to current and prospective enrollees, including a toll-free phone number, Internet website, and written responses. These requirements pertain only to PDP sponsors.

Based on existing law and proposed regulations that pertain to PDP sponsors, there are clearly some guiding principles with respect to timely and responsive information that must be modeled. Further, it is clear that whatever information SPAPs determine is appropriate for them to deliver, that information must be coordinated with both CMS and the PDP sponsors to ensure consistency of message and minimal confusion. Such a coordinated effort would be consistent with the intent and spirit of the proposed regulations that place a heavy emphasis on coordination between SPAPs and Part D plans. (See, Preamble at 46700 – 46702.)

Issues of Concern

The nature of the materials. A careful distinction must be made between educational and promotional materials. While promotional materials are designed to advance the popularity of a particular product, educational materials are designed to support the development of knowledge or skill through a learning process.

It is the SPAPs' role to provide beneficiaries with education materials. A strategy must be identified for the development and dissemination of clear and concise information that will be useful to current and prospective beneficiaries in anticipation of the transition to, and implementation of, the new Medicare prescription drug benefit in January 2006.

Education must be phased in. The following questions frame the education strategy:

- What opportunities / requirements are going to be offered?
- How do beneficiaries evaluate their options and choose an appropriate product? (Educate on specific plan choices.)

- How do beneficiaries effectively use the product they have chosen?

The information must be useful and specific without encompassing overwhelming detail. Materials should not just set forth the range of products that are available. AARP and other organizations have produced some useful materials upon which we may be able to build.

The need for flexibility. SPAPs must maintain their current flexibility with respect to the information each elects to disclose to beneficiaries. PDP sponsors must also have flexibility to be able to modify materials to be sent to SPAP enrollees, subject to the approval of the SPAPs, that is otherwise federally required. First and foremost, deference must be afforded to SPAPs and PDP sponsors to include or exclude information in its educational materials. New Jersey's experience with its approved decision not to publish a detailed drug list for its SPAP is an example of the desired degree of flexibility. If some information is fluid and subject to change, then SPAPs need the discretion to exclude particulars from published information. On the other hand, if selection of a plan is dependent upon the availability of specific information, then we must ensure that beneficiaries are able to access that information at the time and place that they need it. SPAPs must be committed to providing adequate information that is relevant to the present stage of the beneficiary (e.g., prospective or current enrollee). The goal is to provide concise, useable, and clear information to the beneficiary.

Lessons Learned. It is essential to consider the SPAPs' experience with current operational programs as well as experience with drug discount cards. This experience can be used as an example of why flexibility for both SPAPs and PDP sponsors is essential. A successful education campaign must use examples of what we already know works well. This strategy avoids duplication of effort and results in an approach with which consumers are currently familiar and presumably receptive.

The benefits of collaboration. There must be sufficiently broad flexibility to allow PDP sponsors and SPAPs to work together to create a single information packet to go to consumers if they so choose. This strategy may be particularly effective if SPAPs had the option to work with a preferred PDP sponsor. While these collaborative efforts work well under the current drug benefit plans, many are hesitant to formalize this strategy in favor of maintaining flexibility. A collaborative effort between SPAPs, PDP sponsors to create a single, all-inclusive education piece that communicates a consistent message to beneficiaries is key.

Coordination with PDP sponsors The challenge lies in the coordination of SPAP efforts and outreach with what is available in the private sector. If a PDP sponsor is sending out standard information to a group that includes SPAP beneficiaries, then there is a potential to create even greater confusion among SPAP

participants. In this instance, the PDP sponsor must inform and coordinate with the SPAP in order to ensure that beneficiaries receive accurate and complete information that is necessary to informed decision making. See, §1851 (d) (providing information to promote informed choice of Medicare + Choice plans). The issue goes well beyond what materials may be sent to SPAP enrollees, to also include the fact that under current law, SPAPs may never even know that their enrollees are going to receive the information from a PDP sponsor. Even if there is a will to include SPAPs in the process, there is not currently a way to accurately identify the SPAP enrollees from the larger group of current and potential Part D beneficiaries.

The relationship between product quality and success of education strategies. The quality of the products offered has a tremendous impact on the ability to successfully educate beneficiaries. States that did not have a strong drug discount card product to market struggled with beneficiary education. In fact, it was nearly impossible to educate consumers in an easy and concise way. There was a lot of confusion and variability in the products, which made consumers more resistant to education efforts. As a result, consumers delayed or avoided all together their involvement with the new program. We want to provide useful information to the consumer, but with the complexities of the new law, it will be difficult to communicate well about the new products. By raising the quality of the products, our job as educator is easier. Information about less desirable products must also be communicated, although that communication will be more challenging.

Take advantage of the opportunities presented. CMS has a unique opportunity to regulate the PDP sponsors regarding the quality of the materials they are disseminating. Education materials must be written at appropriate literacy levels, in fonts and colors that those with reduced visual acuity can absorb. We also have a duty to develop and disseminate materials in a culturally and linguistically appropriate manner. Now is also the time to reconsider the section of the law (§1860D-4(a) (3) (B)) that requires PDP sponsors to post notices of changes in formularies on the Internet. Given the small percentage of older consumers who have regular access to the Internet, this is not the most effective way to get timely notice to them. [8]

Diversity of the aging population and dual eligibles create unique education challenges. The population eligible for Medicare Part D benefits essentially encompasses two generations of older consumers. New eligibles are more

[8] See, AARP National Survey on Consumer Preparedness and E-Commerce: A Survey of Computer Users Age 45 and Older, Executive Summary (March 2000) http://research.aarp.org/consume/ecommerce_1.html.

diverse than those already in the system and younger populations have needs and preferences that are often distinct from older eligibles. In addition, all education materials must be culturally and linguistically appropriate.

Dual eligibles also need special attention. Their Medicaid prescription benefit is ending and there is uncertainty whether the enrollees' extensive, complex and varying needs can be met through the new program. Duals will need to find plans with the least restrictive formularies for their serious conditions and disabilities. The regulations currently assure that duals have access to information prior to enrollment to determine whether a particular plan will give them affordable access to the prescription medications they may need, but the selection process promises to be more challenging, thereby calling for even a greater concentration of effort in educating this group about their choices.

Carefully consider timing. The amount of time to conduct an effective social marketing program is significant. The more time we have, the better. Even a September start to an education campaign presents a very tight timeframe to be effective. It is generally acknowledged that the discount card education program was not successful because there was not enough time.

Timing with state legislatures is also critical. State legislatures may need to act quickly to enact laws regarding state wrap around options, if desirable.

Evaluation and feedback mechanisms are essential. Effective education can only be accomplished if partnered with timely and periodic feedback from consumers. Information and data as to the effectiveness of the education strategies will enable SPAPs to make necessary adjustments at critical junctures during transition to ensure that beneficiaries are integrated into the new system in a seamless and non-disruptive manner.

Recommendations

Maintain a high degree of flexibility to allow SPAPs to determine the level and extent of the information they will provide to beneficiaries enrolled in these programs. Auto-enrollment would ensure the highest degree of transparency, with limited needs for education, as eligible beneficiaries transitioned to the new benefit in a seamless and non-disruptive manner.

We must take a lesson from the Medicare Drug Discount Cards and make certain there is regulation of product quality and clear, concise, appropriate and timely information available to consumers. Whatever educational strategies are implemented must be sensitive to the requirements of a changing marketplace. As new products are introduced, such as the current resurgence of MA (formerly Medicare + Choice plans) in non-urban areas, consumers will be faced with myriad unfamiliar choices.

Educational materials and campaigns must be developed with the recognition that not only are SPAPs diverse in their methods of operation, but that the consumers represent age and ethnic diversities which must be considered in developing education campaigns and materials. Pay particular attention to the identification of unique populations that may require particular and/or supplemental efforts.

Develop a specific strategy to target dual eligibles. This population arguably faces the greatest challenges in transitioning from Medicaid drug benefits to the new Medicare drug prescription plans.

A separate plan to train caregivers and providers should be established in order to ensure a smoother transition. While written materials can be the main thrust of an education campaign for beneficiaries, there will be a continuing need for individual beneficiary counseling that could be provided through caregivers and providers.

Encourage the development and use of educational templates and materials that can be localized. Look to CMS for adaptable materials. Several advocacy organizations have also published materials that contain explanations upon which we may be able to draw. Standardizing materials that can be adapted for local use not only ensures quality and coordination of message, but uses resources in a cost-effective way.

Closely regulate the PDP sponsors regarding the quality (i.e., readability) and content of the information they provide and their coordination with SPAPs.

Do not rely on the use of the Internet as the sole or main means by which information is disseminated; additional forms of communication must be made available. At least one secondary source of communication – in addition to the Internet – should be adopted for the beneficiary population.

Phase in the education campaign beginning September 1, 2005 or as soon after finalization of the regulations as possible. Time is of the essence not only for beneficiaries but also with state legislatures that must develop policy and enact wrap around legislation.

PDP sponsors must be required to work with SPAPs on education and education materials. PDP sponsors, with SPAP approval, should be allowed to modify educational materials they send to SPAP enrollees, so that the SPAP enrollees are not getting the standard issue material that is sent to others. At a minimum, PDP sponsors should reference SPAPs in their materials and indicate that if the reader is enrolled in an SPAP, the cost sharing requirements of this PDP

sponsor's benefit may not apply to him/her. In that situation, the materials should refer them to their SPAP for more information.

Program Evaluation and Quality Improvement

Brief Summary of the Problem

There is no statutory or regulatory requirement that CMS conduct an overall program evaluation for the purpose of improving the quality of the program. Quality improvement (QI) and evaluation programs are critical to achieving and sustaining an effective drug benefit program. Ongoing quality assurance (QA) measurements should set forth a menu of critical components to ensure a quality prescription drug program. Implementation and operation should be monitored and data must be routinely collected and evaluated to determine if standards consistent with a high quality program are met. The program evaluation results must then be utilized as a means to quality improvement. QI requires that the information obtained through data collection and analysis is utilized directly for the purpose of program change – including administrative as well as clinical program aspects. QA and evaluation are thus intricately connected and dependent upon one another.

Evaluation of the program's impact is dependent upon access to complete patient data, which is most thoroughly captured in the Medicare database. With access to this database, researchers can assess not only what is happening to individual beneficiaries but also recognize whether and how the health care system may be positively impacted as demonstrated by indicators in non-drug utilization arenas including, but are not limited to, beneficiary access to medications, patient hospitalizations and nursing facility residencies, utilization of home and community based services, and fiscal implications. It does not matter if beneficiaries can purchase affordable drugs if they are misprescribed, not being prescribed, or are not accessing appropriate medications for their individual needs. The link between access to affordable and appropriate medications and the ultimate impact on quality medical care is the essence of a high quality drug benefit program.

Recognizing the diversity that characterizes the SPAPs, it is clear that not all SPAPs have the capacity or inclination to implement an extensive QI / evaluation program, and furthermore, their scope would only be limited to SPAP beneficiaries, and all Medicare beneficiaries should be the subject of program evaluation and improvement. However, SPAPs will need to understand the importance of QA, be exposed to best practices, and implement those best practices that fit within their constructs for purposes of improving their own SPAP programs and their integration with the larger Part D Program. Furthermore, SPAPs are in a unique position of experiencing consumer issues on a

larger scale than any individual beneficiary, and the SPAPs therefore should be invited to contribute to any efforts to evaluate the Part D program overall. SPAP QA and evaluation processes can serve as mechanisms for identifying deficiencies in the larger Part D system and help in addressing the overall success of the program in providing a high quality pharmacy benefit. In further support of SPAPs' participation in QA, they should be given an opportunity to collaborate with the PDP sponsors to ensure that program improvement is an integral and ongoing part of the new drug benefit program.

SPAP Practices

SPAPs, with their extensive experience in working with beneficiaries and creating a system to support drug benefits, are uniquely poised to identify those issues which most impact on quality assurance and result in meaningful contributions to program improvement. If given the ability to access complete medical history data on beneficiaries SPAPs could fully evaluate the impact of drug benefits on non-drug benefit components and the quality of health care overall. At the same time, it is important to note that not all SPAPs have the same capacity or inclination to do extensive QA or evaluation. Smaller states in particular may face significant cost issues as they recognize the importance of these activities counterbalanced by budget realities. Nonetheless, through the identification and dissemination of best practices from SPAPs that have been particularly successful with QA and evaluation, it is possible to improve the overall quality of the programs in proportion to the capacity of the program.

In general, there is broad variation in how SPAPs currently approach the matter of QA and evaluation. In smaller states with limited budgets, limited QA and evaluation is undertaken. Further limitations exist with respect to improving beneficiaries' health care overall due to the SPAPs' inability to access other systems, like Medicare, that they may be using. With the exception of Pennsylvania, SPAPs have not linked their drug benefit programs to the Medicare database to enable access to complete beneficiary data. In fact, Pennsylvania is the only state that has elected to purchase this data and has been successful in using it to assess the impact of the drug benefit program on non-drug benefits and quality of life. In other words, to the extent that beneficiaries receive better medical outcomes as indicated by such factors as decreased utilization of hospitalization, Pennsylvania can better demonstrate that the drug benefit program is in fact helping, and not hurting its participants. When indicators suggest the need for program adjustment, the evaluation results are used as the trigger for program improvement. This impact data, then, supports the quality of the benefit program as scientific input is looped back into QI.

PBM/PDP Sponsor Practices

In considering the current practices of PBMs and PDP sponsors, it is important to make the distinction between QA and QI. PBMs and PDP sponsors have implemented QA procedures that better ensure that beneficiaries are receiving the correct medications. Activities in this regard include the identification of medication errors and screening for drug interactions. The challenge of messaging back to pharmacies any detected errors and having the pharmacies follow-through with corrected actions is significant to PBM/PDP sponsor QA. Their current practices, however, do not reach the level of quality improvement. While detection and correction occur on an individual beneficiary level in reaction to error, the information is not compiled in the aggregate, analyzed and ultimately fed back into an institutionalized quality improvement program, - i.e. there are few programs in which the basic processes and policies are systematically reviewed and re-engineered to improve outcomes and efficiency.

Cogent MMA Language

Section 423.153(c) requires each PDP sponsor to have a QA program. PDP sponsors must include QA measures and systems for:

- Reducing medication errors;
- Reducing adverse drug interactions; and
- Improving medication use.

The QA program must have processes for concurrent drug utilization review, patient counseling, and patient information record keeping. These standards are consistent with currently accepted standards for contemporary pharmacy practice.

There is no specific regulatory requirement for SPAPs to maintain a quality assurance program.

Section 423.153(b)(2), pertaining to cost-effective drug utilization management requires policies and systems to assist in preventing both the over-utilization and the under-utilization of prescribed medications.

The preamble to the proposed regulations suggests that there are elements of effective quality assurance systems that must be considered for adoption by PDP sponsors, including:

- Electronic prescribing (See § 423.159)
- Clinical decision support systems
- Educational interventions
- Bar codes
- Adverse event reporting systems

- Provider and patient education

(See, Proposed Regulations at 46667).

Section 423.162 provides for the use of Quality Improvement Organizations (QIO) for assistance with quality improvement pertaining to health care services, including prescription drug therapy.

While QIOs are required to offer practitioners, MA organizations and PDP sponsors quality improvement assistance, there is no additional mechanism of reporting incidents that may trigger the need for QI other than the beneficiary grievance process. Specifically, there are no provisions that compel CMS or PDP sponsors to acknowledge deficiencies identified by SPAPs. Moreover, there are no set parameters or indicators that would ensure consistent quality measures throughout the program. (See, Proposed Regulations at 46672).

The preamble to the proposed regulations also states that there is no expectation that all elements itemized above will be adopted by a single plan provider, but that there will be substantial innovation and rapid development of improved quality assurance systems. (See, Proposed Regulations at 46667).

Issues of Concern

The essential elements of QI must be identified to guide implementation. While it is understood that not all SPAPs will have the capacity to implement a full-scale QA and evaluation program, it is no less important that the elements be set forth with the expectation that at least some elements will be implemented in every SPAP with a goal of continuous program improvement. Best practice identification and dissemination is one means by which SPAPs can be guided in their efforts. However, QA should be a minimal requirement to assure that SPAPs meet the standards it had previously set for case by case transactions, i.e. error reduction, etc. QI measures must be in place to set and achieve higher performance goals based on process improvements, and the SPAPs must also be allowed an opportunity to participate in this process.

The critical underlying message must be to identify the importance of quality improvement and its integration with program evaluation. As we recognize that SPAPs aim not only to ensure affordable access to necessary medication, but also ultimately impact quality of life through a more scientifically based system, the new Part D benefit becomes less about dispensing drugs and more about how SPAPs can best meet the individual needs of their benefit recipients. The information that SPAPs evaluate to assess whether the drug benefit programs are of high quality should be woven back into program improvement that may require some action by CMS or the PDP sponsors for overall Part D improvement.

Section 423.153(b)(2) of the proposed regulations, pertaining to cost-effective drug utilization management, requires policies and systems to assist in preventing both the over-utilization and the under-utilization of prescribed medications. While this regulation is not directed to SPAPs, it is still important that the focus be on both, and not just based on an assumption that if prescription medications are more easily affordable, that providers will over-prescribe and patients will over-utilize.

Technology is a key element of QA. If electronic prescribing rather than handwritten scripts were implemented, then there would be a significant reduction in errors.

There is quite a bit of diversity among the SPAPs with respect to size and capacity. For this reason, it is not suggested that the regulations mandate quality assurance and program evaluation activities for all SPAPs. In the alternative, there should be sufficient flexibility to allow and encourage collaborative efforts between SPAPs and PDP sponsors in this regard. That flexibility and opportunity to work together, coupled with the definition of effective QA programs and scientific evaluation tied to program improvement, will increase the likelihood that each SPAP will participate in some meaningful level in these efforts.

QA and program evaluation must be based on where the SPAP can and wants to be involved. Not all SPAPs will elect to perform these measures in the same way and to the same extent as best practices would suggest.

Access to adequate data becomes a significant issue when the focus is on meaningful and effective program evaluation. In Pennsylvania, the SPAP purchases data from CMS. It is the only SPAP to do so. This is a significant investment that yields positive results for program improvement, but not every SPAP has the resources to access and evaluate the data. SPAPs should be ensured unrestricted and affordable access to Medicare data so that each can assess the impact of the drug benefit according to its own means and ability.

In providing for unrestricted access to Medicare data, consideration must be given to requirements under the Health Insurance Portability and Accountability Act (HIPAA).

The effective communication of the data to providers and beneficiaries ultimately improves medication use. By focusing on program design, administrative infrastructure and how information is fed back to improve the system overall, we can arrive at program improvement. It is important to focus on improvements at the program design level.

Consideration should be given to narrowing the focus of QA around specific disease states to ensure that in specific cases of chronic disease, beneficiaries receive quality and appropriate care for their specific needs.

Consumer satisfaction surveys, as required by §423.156 for PDP sponsors, are recognized as one aspect of effective program evaluation and improvement.

The proposed definition of medical error contained in the preamble to the proposed regulations (at 46667) is acceptable for the purposes of QA and program evaluation. More importantly, it sets the standard that quality improvement initiatives should aim to achieve. It has not been set forth in the proposed regulations as currently written. The important focus for medical error rests on what types of data are needed to ensure that medication errors do not occur.

Recommendations

Our goal is a better quality of life for beneficiaries, not just better access to drugs. We envision a drug benefit system that includes elements of drug utilization review, patient counseling, and patient information record keeping. QA is supported by meaningful data collection and periodic scientific evaluation to make sure these standards are met. SPAPs must have access to complete data on individual beneficiaries through the Medicare database to ensure that the program is contributing in a significant way to improved health care for all eligible participants. Evaluation results are used to support continuous program improvement. With these factors in mind, we make the following recommendations:

Require that CMS undertake an annual evaluation of access to drugs and of utilization of non-drug benefits, pre- and post- implementation and produce an annual report. The annual report should assess the effectiveness of the Part D drug benefit program and its impact on non-drug benefits. Those aspects include, but are not limited to, beneficiary access to medications, patient hospitalizations and nursing facility residencies, utilization of home and community based services, and fiscal implications. This evaluation should be an ongoing effort and consider costs across the entire Medicare budget. Annual reports will enable SPAPs to better evaluate their own program impact and make improvements to their own programs.

CMS should also **make all data available to independent researchers**, who can conduct their own studies of program effectiveness and make recommendations for programs improvements.

Emphasize the importance of QA and program evaluation by SPAPs by identifying key components and disseminating best practices. Best practices will

include those elements already identified in the preamble, as well as other elements in use by the SPAPs. While SPAPs should be strongly encouraged to implement QA, SPAPs should not be mandated to do so, nor should they be expected to implement all components of a QA program. Rather, SPAPs should have the flexibility to implement quality assurance programs according to their means and capacity and should also have the flexibility to work with PDP sponsors to coordinate their efforts.

For effective QA, it is important to **permit SPAP access to the Medicare database.** There is no other way in which to ensure quality. The data is used to understand the impact of the prescription drug plan on overall health and utilization of non-drug benefits. Pennsylvania invested considerable effort and resources to make this connection. Not all SPAPs have the means to make this investment, but unrestricted access must still be an option for all SPAPs.

SPAPs should be encouraged to link with medical peer review groups to ensure scientific evaluation. The preference of scientific over anecdotal evaluation feeds back to meaningful program improvement.

Alternative Program Redesign and Part D Coordination

Brief Summary of the Issue

Section 1860D-23 of the statute requires that the Secretary establish requirements for effective coordination of benefits with part D plans, including an option to use a "lump sum per capita method." No other details are provided in the Act, however, the Commission felt that this option was an important one for states seeking flexibility to explore alternative approaches for their SPAP programs to provide meaningful benefits while minimizing administrative burdens. We therefore developed ideas described below to assist CMS in establishing the implementing regulations for a lump sum methodology.

The Commission's objectives were to maximize states' flexibility to use available financial resources to help lower income citizens who might not otherwise be able to participate in Part D or who might need more financial assistance than is offered through Part D while –

- Providing for coordination in a manner that is least disruptive to SPAP participants and that provides a single point of contact for enrollment and processing of benefits.
- Protecting financial and flexibility interests of states.
- Being consistent with the principles of Medicare modernization under the MMA.

Current SPAP Benefits:

The research available to the Commission reveals that there is an enormous diversity of types of SPAPs:

- Some are full, state-funded pharmaceutical benefits that process claims, maintain pharmacy networks, and arrange for manufacturer discounts
- Some provide assistance directly to individuals to defray expenditures for certain limited types of drugs
- Some provide assistance in purchasing insurance coverage for drugs
- Some provide a state-administered program of pharmacy and manufacturer-sponsored discounts for otherwise uninsured elderly or uninsured, and
- Some have tried to use state funds and CMS waivers to provide a partial Medicaid drug benefit to low-income seniors.

This diversity reflects the creativity and flexibility of states over 20 years of attempting to fill the void in Medicare. The transition to the new Part D administrative structures will differ for each of these different types of programs. *To fulfill the intent of the legislation, CMS should make clear that all of these types of state-established programs are "State Pharmaceutical Assistance Programs" under the law and that manufacturer rebates to all state-administered programs are exempt from the Medicaid best price computation.*

Cogent Statutory and Regulatory Language

Anticipated Part D Structure:

The MMA provided a unique role for SPAPs that choose to coordinate with Part D plans through a special rule under which expenditures by SPAPs "count" as expenditures by the Part D enrollee toward the annual out-of pocket threshold, which the proposed regulation defines as "True Out-Of-Pocket Costs" (TrOOP). § 1860D-23(C)(4). Thus, unlike the disregard that occurs with respect to coordination of benefits with other health plans (§ 1860D-24(b), the PDPs or MA-PD's – and the SPAPs – as well as beneficiaries, will have the benefit of the federal subsidy (and lower cost-sharing for individuals) for expenditures above the out-of-pocket threshold.

The MMA defines a state pharmaceutical assistance program (SPAP), in part, as a "State program which provides financial assistance for the purchase or provision of supplemental prescription drug coverage ***or*** provision of supplemental drug benefits on behalf of part D eligible individuals." § 1860D-23(b)(1) (*emphasis added*).

"Supplemental prescription drug *coverage*" is defined by the MMA as consisting of either or both of the following:

- "a reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit…[that] increases the actuarial value of basic prescription drug coverage."
- "coverage of any product that would be a covered Part D drug but for their exclusion from coverage by the statute (i.e., the OBRA'90 excludables).

Section 1860D-2(a)(2)(A). Accordingly, in implementing MMA, the special provisions relating to SPAPs must apply both to SPAPs that provide a supplemental benefit, *and* to SPAPs that arrange for supplemental coverage.

Issues of Concern

Some SPAPs may want to continue offering a full prescription drug *benefit* that will need to coordinate prescription claims with PDPs and MA-PDs, and their transition needs will involve coordination of benefits issues much like those that will affect other health plans that coordinate with Part D plans. *These rules (discussed more fully in other sections of this report) – and the fact that PDP sponsors must coordinate with SPAPs – need to be clear conditions that must be adhered to by all Part D plans from the first day of the Medicare implementation.*

Other SPAPs will want to offer *supplemental coverage* as defined in the MMA, which may involve far less administrative effort than administering a drug benefit, and could permit greater financial flexibility for states with smaller budgets and/or less predictable funding sources.

Some SPAPs may want to offer supplemental coverage that is only for drugs that are not statutorily covered Part D drugs, or for drugs that are covered Part D drugs but are not included on a PDP sponsor's list of preferred drugs. The statute is quite clear that SPAPs can pay for drugs that the Part D plan otherwise would not pay for on behalf of the SPAP enrollee. *CMS should make clear that **all** SPAP expenditures on prescribed drugs covered by the SPAP program, whether or not they are covered Part D drugs (e.g., OTCs, prescribed nutritional supplements, benzodiazepines) **and** whether or not they are excluded from the PDP sponsor's formulary, count toward TrOOP.*

Other SPAPs may want to offer supplemental coverage in the form of reduced cost-sharing for the Part D plan selected by SPAP enrollees.

- If, in 2006, the PDP sponsors are not yet offering "supplemental coverage" (or alternative enhanced coverage) for purchase by their enrollees, the statute is clear that SPAPs are nonetheless permitted to

directly provide this kind of "supplemental coverage" – help with deductible, coinsurance, expenditures during the "donut hole."

- SPAPs may want to provide this supplemental coverage through MA-PDs as well as PDPs.
- Both in 2006 and in subsequent years, some SPAPs may want to offer supplemental coverage only for some covered Part D drugs or categories of drugs, or that covers a smaller percentage of cost sharing than what a specific PDP sponsor is offering.

In their offer of *supplemental coverage*, some SPAPs may want to make special arrangements with one or more Part D plans to provide a unique package of benefits, such as an enhanced formulary or special cost sharing, care management, or other arrangements such as those that might be desirable for a special needs population.

We believe that this is specifically authorized by the statute. Thus, the Commission is particularly concerned about the way CMS has construed another provision of the statute as prohibiting this essential function of SPAPs. The statute says that an SPAP must "in determining eligibility and the amount of assistance to Part D eligible individuals under the program, provide[ ] assistance to all such individuals in all such Part D plans and […] not discriminate based upon the Part D plan in which the individual is enrolled." Section 423.464(e) of proposed regulation is similar, but the preamble to the proposed regulation goes further by saying that this would prohibit SPAPs from steering or encouraging enrollees towards preferred plans.

We believe that the preamble language is unnecessarily restrictive in its interpretation of the statutory language, as it is inconsistent with other express provisions of the statute permitting special relationships between SPAPs and Part D plans. To be consistent with the statute, the final regulation's provision relating to "discrimination" by SPAPs should be modified to comply with the statutory language permitting the "co-branding" of PDP sponsors and SPAPs (1860D-23(c)(2), and specifically stating that "nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide financial assistance with respect to any PDP sponsor's plan." 1860D-23(c)(5). In keeping with the statute, the regulation specifically acknowledges and permits SPAPs to have special endorsement relationships with some *but not all* PDP sponsors offered within their state.

The confusion created by the preamble comments arises from an overly broad interpretation of the "non-discrimination" provision in the statute that is designed to protect each Medicare beneficiary's free choice of Part D plans. Under the statute, a State program's assistance with cost-sharing counts toward TrOOP only

if the SPAP "in determining eligibility and the amount of assistance to part D eligible individuals… provides assistance to such individuals in all Part D plans and does not discriminate based upon the part D plan in which the individual is enrolled." Social Security Act section 1860D-23(b)(2). Nothing in this definition prohibits the SPAP from having a special program of benefits with one or more Part D Plan sponsors. Rather, it merely permits each SPAP enrollee to request that the value or "amount" of assistance available through the SPAP to be payable to a different Part D plan if the individual has enrolled in one that does not have a special arrangement with the SPAP. For example, the SPAP may have a special package of benefits available through a PDP sponsor, but an SPAP enrollee may be an enrollee of an MA plan who is obliged to obtain part D benefits through his MA plan's MA-PD. Under the statute, it is clear that the value of the SPAP coverage, e.g., the actuarial equivalent of the SPAP benefit, should be payable as a lump sum to the MA-PD (or another PDP selected by the enrollee) for use by the enrollee in meeting cost sharing requirements, even if the SPAP has otherwise arranged for its benefits to be available through a single PDP sponsor with which it has arranged for special formulary, pharmacy network or other arrangements.

SPAPs are established and operated under *state* law. The MMA merely provides that Part D plans allow them to enhance the benefits available to enrollees that are eligible both for Part D and SPAP coverage. The MMA does not authorize CMS to establish criteria for the funding and operation of these state programs or to construe the MMA provisions facilitating coordination as being applicable to some state operated programs and not to others.

Because the statute emphasizes the importance of state flexibility and the desirability of states using available funds to enrich the Part D benefit, CMS should take steps to permit such uses of funds, consistent with applicable state law, including provider taxes and donations, etc. The Medicaid law may restrict these options where state expenditures are being matched with federal dollars; however MMA does not preclude these options as long as it's legal in a state.

CMS must clarify that the broad new definition of SPAP in the statute means PDP sponsors must work with new programs, not just those that were operating at the time of enactment.

Recommendations

HHS should make clear that assistance with the purchase of supplemental coverage includes assisting the individual with payment of premiums for basic, basic alternative or basic enhanced coverage. HHS should specifically acknowledge that Part D Plans must allow SPAPs to pay all or part of premiums on behalf of their beneficiaries and that SPAPs can establish the specific premium subsidy payable on behalf of SPAP-eligible individuals. The

reduced cost sharing available to these beneficiaries as a result of the premium paid by the SPAP must count toward TrOOP in the same way that federal subsidy payments count toward TrOOP.

HHS should modify the regulation to specifically construe the non-discrimination provision of the statute as being satisfied by SPAP arrangements to determine the actuarial value of the benefit that it provides to enrollees, and to pay such amount to the PDP sponsor in which an SPAP beneficiary has enrolled. The amount may be used to pay some or all of the premium that HHS has agreed can be charged a part D-eligible individual by a PDP sponsor for basic coverage, basic alternative coverage or enhanced alternative coverage. Where the PDP sponsor selected by an SPAP beneficiary does not offer enhanced alternative coverage, the amount payable by the SPAP shall be applied by the PDP sponsor to cost-sharing owed by the individual, after payment of any premium charged to the enrollee. Where the SPAP establishes a benefit that is available only through one or more preferred PDP sponsors, CMS should specify that the non-discrimination criterion is satisfied by arrangements to pay what the statute refers to as a "lump sum" that is equal to the actuarial value of the SPAP's benefit to enrollees of the endorsed PDP sponsor, *i.e., the SPAP can make its program non-discriminatory simply by ensuring that it will pay a premium amount for actuarially equivalent benefits to whatever PDP sponsor the SPAP enrollee chooses.*

For SPAPs that provide supplemental coverage by picking up all or part of the enrollee's cost-sharing requirements, CMS should provide for at least the following three different options for coordinating with PDP sponsors:

"Federal Base Premiums." CMS should estimate (and publish in advance of each calendar year) a national capitation amount appropriate to the marginal cost of the financial assistance provided to individuals eligible for each of four levels of low-income assistance under Part D, as defined at 1860D-14(a)(1)(D) and (a)(2). Level 1 (clause (i)) is the same as that provided to "institutionalized individuals;" Level 2 (clause (ii)) is that available to "lowest income dual eligible individuals;" Level 3 (clause (iii)) is described as "other individuals; and Level 4 (1860D-14(a)(2)) is described as individuals with income below 150 percent of the poverty line. The purpose of these published estimates will be to give SPAPs the basis on which to make monthly risk-adjusted capitation payments to Part D plans in return for supplemental coverage that improves the beneficiary's benefit from the level for which the beneficiary is otherwise eligible to one of the other levels. To be considered in compliance with the MMA's requirement to coordinate with SPAPs, all Part D plans should be required to sell such supplemental coverage(s) to the SPAP at this nationally-established marginal price.

Example with hypothetical rates: The national estimated value of improving the package from Standard to Level 3 is $45 per month for a beneficiary with a risk score of 1.00000. The marginal value from Level 3 to Level 2 is $12 per month. The marginal value from Level 2 to Level 1 is $7 per month. In this case, an SPAP that wishes to move a beneficiary's benefit from Level 3 to Level 1 would be guaranteed a monthly capitated price of $19 per month from each Part D plan.

"Fee-for-Service Cost Sharing." To be considered in compliance with the MMA's requirement to coordinate with SPAPs, all Part D plans should be required to enter into good-faith negotiations with SPAPs on arrangements that improve the SPAP-enrolled beneficiary's benefit to a specified (lower) level of beneficiary cost-sharing, done within the context of that PDP sponsor's normal operations. Each PDP sponsor would be required to compute (and then invoice the SPAP at an agreed-upon frequency) for the actual incurred marginal cost of that benefit improvement. Like a Medigap plan, the SPAP would relinquish any role in formulary, pharmacy network, etc.

"Customized Supplemental Coverage." To be considered in compliance with the MMA's requirement to coordinate with SPAPs, all PDP sponsors must enter into good-faith negotiations to establish customized supplemental coverage(s) that improve the SPAP-enrolled beneficiary's benefit. At the option of the SPAP, these services may include different cost-sharing, formulary, pharmacy network, or care management and support services, coverage/cost-sharing for only specific drugs, etc. Where the program is designed to meet specific state requirements, the package can be designed to be available to enrollees through any willing PDP sponsor.

DATA SYSTEMS AND CLAIMS PROCESSING INFRASTRUCTURE

Overview of Issues

In order to effect a smooth coordination of benefits between Medicare and SPAPs that ensures the beneficiary receives immediate and full access to all available pharmacy benefits and ensures payers provide the benefits they are responsible for, sufficient and current data must be exchanged between the parties involved. The following issues surrounding that data exchange and claims processing infrastructure were identified:

- *"Real-time" data sharing and mechanics of delivery* – what data is needed by whom and how will it be obtained?
- *Industry protocols and communications standards* - what standards are available to support benefits coordination and are they sufficient?

- *Practical and financial claims processing issues* – are processes efficient and cost effective?
- *Standardization of Part D and SPAP identification cards* – Are ID cards effectively serving their purpose?
- *Dealing with point-of-sale denials* – who will be responsible?
- *PDP sponsors, beneficiary, Medicare, and states' role clarification* – will responsibilities be clearly defined and how will parties be held accountable?
- *Provider and PDP sponsor incentives to coordinate benefits* – are they sufficient to promote seamless coordination?
- *Education of beneficiaries, prescribers and pharmacies* – who needs to know what to fulfill their responsibility in ensuring seamless coordination?
- *Coordination of education and messaging efforts* – communications from various sources must be coordinated to avoid miscommunication and/or misunderstanding
- *Program assessment – data collection and reporting/evaluation* – how effectively are benefits being coordinated between Medicare and SPAPs?

The above issues are combined into the following areas for ease of presentation and "coordination" of overlapping and interrelated items:

- **Real-Time Coordination of Benefits (COB)**
- **Education of Beneficiaries, Prescribers and Pharmacies**
- **Program Assessment**

Real-Time COB

Data Requirements: Pharmacies

The success of properly coordinating benefits is dependent upon the pharmacy having easy access to accurate and current information on the beneficiary's drug coverage(s) and the applicable claim billing requirements. Easy access means standardized, simple, timely, and cost-beneficial. Costly, complicated, inconsistent or slow processing requirements will interfere with a pharmacy's ability or willingness to facilitate coordination.

Insurance information is the primary area of concern that must be addressed, so pharmacies know at the POS what plan(s) to bill and how to bill them. Identification of the insurance plan is currently available from the payer ID card presented by the beneficiary. The card sometimes includes plan billing information such as the bank identification number, processor and group

numbers. Billing information for plans that pharmacies contract with is typically integrated into the pharmacy computer software. Often, in the absence of a card, the plan is verbally conveyed by the customer and often will require a phone call by the pharmacy to the payer to confirm coverage and/or billing information. Also, payer ID cards often have insufficient information, requiring pharmacies to spend time obtaining the necessary information to bill. The use of standard ID cards that include needed information is legally required by 25 states, with varying degrees of compliance. The potential use of joint ID cards is supported by the MMA proposed regulations, though are challenged by difficulty in coordinating coverage periods and status between plans.

The dependence on ID cards for communicating necessary plan information to pharmacies is not sufficient. The cardholder does not always have their card(s) with them, or uses only one card when another valid card is available. Even if all valid cards are presented, the pharmacist does not always know which to bill first. Further, cards do not always provide all the information needed, and do not always present data consistently and clearly. Pharmacies often call the plans to obtain needed information, which is inefficient and not always effective, and requires knowledge of the plan(s). Pharmacies waste time and transmission costs when claims are submitted to the wrong payer, and access to needed medication is sometimes denied when coverage cannot be determined.

Benefit coverage information is needed by the pharmacy before claim submission to avoid time and expense of claims denied by the plan formulary, dispensing limits, prior approval, or other requirements. Very limited information is available from the customer, prescriber, or plan network contract and written communications. More often, pharmacies acquire knowledge of plan benefits through billing experiences, which wastes time and money.

Beneficiaries

The beneficiary should have a good understanding of what coverage they have available and how to use it effectively in order to maximize their benefits and minimize their costs. At a minimum, they should know what benefit plan(s) they have, what types of drugs are covered by the plan(s), cost-sharing requirements, how to contact the plan and what pharmacies they can use. This information is typically received directly from the plans, supplemented by plan websites and through pharmacies. Medicare requires extensive and specific information about Part D coverage be disseminated to members, though more information often results in more confusion. However, communication on using benefits does not typically address situations when SPAP or other coverage exists, leading to confusion or misunderstanding of how to use their benefits properly. As a result, individuals may not receive all the benefits to which they are entitled and may need, and payers may be billed inappropriately.

SPAPs

SPAPs need to know what other insurance coverage enrollees have in order to make sure it is properly coordinated with SPAP benefits, which are typically payers of last resort. This information would be used to "cost avoid" or deny claims not submitted to the primary payer first. The more information available on the formulary and other primary payer limits, and the current status of the other coverage (e.g. deductible, donut hole, catastrophic limits, disenrollment), the better able the SPAP is to customize their claim processing system to avoid inappropriate denial of benefits and ensure beneficiary access to needed medications is not compromised. Beneficiaries are not dependable sources of this information. Confusion about insurance benefits often results in plans being misidentified or not reported. Disincentives to report other coverage often exist. Plans themselves are potential sources of such data, but presently they have little incentive to coordinate benefits. Legal requirements have been used by some states, but are difficult to enforce and thus often ineffective. Medicare is another source, but has not been effective to date in providing such information to SPAPs. In addition to patient-specific coverage information, SPAPs will need timely information on plan changes and/or terminations in order to properly educate their enrollees on available Part D benefits and coordination with SPAP benefits.

Part D Plans

Part D plans need information about any SPAP coverage in order to facilitate the coordination of available benefits. While the beneficiary should be able to inform the plan of other coverage, it would be more reliable and up-to-date to receive such information routinely from the SPAP. Also, Part D Plans need to know what out-of-pocket costs were incurred by beneficiaries or by an SPAP on behalf of the beneficiary, in order to accumulate TrOOP costs for beneficiaries to provide catastrophic coverage when appropriate. This information must be received in an efficient and timely manner, so as not to delay the catastrophic coverage the beneficiaries need and are entitled to.

Prescribers

In order for prescribers to help the beneficiary best use the coverage(s) they have to meet their prescription needs, they need to know what plan(s) the beneficiary has and what coverage is available. While prescribers may acquire knowledge of formulary and coverage restrictions through experience with the more prevalent plans, it is neither dependable nor comprehensive. If prescriptions are written without this information, restrictions or unaffordable prescriptions are encountered at the pharmacy. These prescriptions result in inefficient processing and added pharmacy costs, and impede access to the prescribed medications. PA is an example of a common restriction that often delays the dispensing of

medications while pharmacies contact prescribers, depending on the particular requirements of the plan, to obtain the needed authorization or modify the prescription.

Industry Protocols and Communications Standards

Pharmacy claims processing has benefited from clear, comprehensive and universally applied telecommunication standards established and maintained by the NCPDP. NCPDP standards provide protocols, data sets, field definitions and record layouts to accommodate real-time submission and adjudication of pharmacy claims for covered products and services. Increasingly, pharmacy claims involve multiple payers. In coordinating benefits between Part D plans and SPAPs, NCPDP standards must be able to provide for prescription claims processing and COB that optimize service levels to beneficiaries while supporting cost effectiveness for the payers and providers –consistent with the principles of the MMA.

Concerns

After reviewing current capabilities and practices of the NCPDP standards and those under development, the following information is offered:

- NCPDP standards provide for the coordination of benefits between payers through a process that uses multiple claims transmissions initiated by the pharmacy to coordinate payment for a prescription.
- NCPDP standards support the transfer of provider/member enrollment information between plans and other payers.
- NCPDP offers a standard ID card format and specifications that provide consistent and sufficient information to the pharmacist that identifies the plan and billing information.
- NCPDP provides implementation guidelines that allow a plan (such as Medicaid) to seek reimbursement from other payers after a pharmacy has been paid for a claim.
- Several NCPDP standards under development are relevant to SPAP issues:
    - Benefit standard – for the transfer of formulary status, requirements for coverage exclusions, co-pay information, PA information, etc.
    - Post-adjudicated history standard – for retrospective DUR, auditing, program assessment, etc.

- PA transfer standard – for transfer of PA requirements of a health plan/benefit program from one claims processor to another.

Practical and financial claims processing issues must be addressed in designing the infrastructure for coordinating pharmacy benefits among payers. These include

- The need to identify and recognize administrative costs for plans, processors and providers, in order to insure fair payment for services provided and avoid cost shifting.
- Consistency among plans, processors and pharmacies in using NCPDP standardized fields and free-form text for optimal recipient service levels.
- Direct communication to beneficiaries and providers about patient levels of coverage, etc. in order to avoid reliance on pharmacies and further facilitate the coordination between PDP sponsors and SPAPs.

Claim Denials at the POS

CMS anticipates that enrollees will contact their Part D plan when a prescription is not covered at the pharmacy and the plan will send written notice of a whole or partial denial to the enrollee. This process is not adequate and SPAPs will end up covering these costs, leaving no incentive for the beneficiary to appeal. Further, the appeals process is cumbersome and may take days to complete in some cases. Some questions to consider are:

- Is this process adequate for optimal patient care and proper coordination of benefits?
- What role should the plan, processor and pharmacy play in the denial process?
- What are the cost considerations?

Incentives for Part D Plans and Providers to Coordinate Benefits

The MMA has a potential conflict between the stated goals of maintaining benefits for people covered under SPAPs, minimizing the administrative burden for beneficiaries, and establishing a competitive marketplace for PDP sponsors. Ostensibly, the requirement in Section 1860D – 23 (b) (2) that SPAPs not discriminate against PDP sponsors is to ensure that states do not interfere with the establishment of a competitive marketplace for PDP sponsors. After the implementation of Medicare Part D in January of 2006, SPAPs will be reliant on the PDP sponsors to help coordinate benefits for beneficiaries enrolled in both programs. In addition, the benefits are offered by a PDP sponsor will effect the state's spending for an SPAP beneficiary.

To effectively transition beneficiaries from SPAPs into a Part D plan, states will need to entice and facilitate both beneficiary plan selection and seamless benefit coordination. States are facing several challenges on this front. They appear to be allowed to entice the full, enthusiastic cooperation of the Part D plan to design a SPAP-specific and SPAP-friendly wraparound program. The "enticement" in this instance is extended by CMS in the form of a regulatory requirement of forced cooperation with states that wish to provide enrollees with additional, state-sponsored benefits in excess of those offered by the regional plan. States can offer assistance in the form of benefit wraparound, and cost-sharing and premium subsidies. Seamless coordination of these offerings will be key to both beneficiary satisfaction and smooth transition from SPAP to Part D Plan.

The Congressional mandate from the MMA is one of private sector involvement in the delivery of health benefits to Medicare beneficiaries. Key to the success of this public/private cooperation is sufficient incentives to both parties to affect the dutiful cooperation that will ensure a smooth transition of beneficiaries from SPAPs to PDP sponsors.

As we have seen from the discount card, bold initiatives aimed at promoting both beneficiary choice and cost savings can lead to confusion because of market-driven options tailored toward many different subpopulations. With every state having access to over twenty discount cards (at a minimum), beneficiary enrollment should, intuitively, be approaching full utilization – the cards have been proven effective, yet enrollment is only 60 percent of target after three full months of publicity and marketing. This cannot be repeated with the prescription drug benefit. Unlike the discount card, CMS will penalize beneficiaries who enroll after the mandated enrollment period.

The SPAPs that decide to wraparound the Part D benefits have a clear incentive to cooperate with the plans. That incentive is cost savings to state taxpayers through better health and coordination of benefits. Since the Medicare benefit will become the primary payer for the seniors now receiving drug benefits from the state, education about enrollment options and plan design will be a key factor in facilitating enrollment into Part D plans. State programs that will provide cost sharing and off-formulary drug coverage have a major incentive to coordinate with one of the regional PDP sponsors to minimize administrative overhead and costly overutilization, especially when alternative therapies are less expensive and therapeutically equivalent.

Under the proposed regulations, states are bound by rather broad anti-discrimination language. Auto-enrolling beneficiaries with a PDP sponsor, or otherwise facilitating a transfer into a particular prescription drug program on behalf of its SPAP members without their positive election, are among issues we have examined. We submit that the proposed regulations can and should be

interpreted to allow states to act as agents in selection and coordination of benefits with one or more preferred PDP sponsors within the region encompassing their state. By acting as such, states are able to leverage their respective enrollment bases to entice PDP sponsors to accommodate the current thoughtful program design and learned experiences. Absent this leverage, PDP sponsors have little more than a statutory requirement to "coordinate" with the states in the transition from state programs. Under this proposed scheme, benefits accrue to all parties: the states, the plans and, most importantly, the beneficiaries.

We have seen under the discount card that states act in good faith, partnering with carefully selected vendors to facilitate enrollment that otherwise might not have occurred. If the beneficiary is left to his or her own devices to affirmatively select a prescription drug plan, the new drug benefit could suffer the same fate as the drug discount card – that of under-enrollment and the unwitting forfeiture of benefits on the part of eligible seniors. This is especially troubling for the segment of the population that qualifies for the low income subsidy benefit, as they are "leaving money on the table" – either from confusion over choices or uninformed apathy. In either case, under-enrollment represents a clear possibility under the current regulations, which are silent on states' assisting members find, enroll and enjoy their new benefit under the MMA.

Recommendations

CMS should establish a Centralized Data System to facilitate data exchange through a single entry point so that all involved parties have access to timely and accurate data needed for the "real-time" coordination of benefits. A centralized, HIPAA-compliant database should be established that can easily be accessed by all parties, including PDP sponsors, SPAPs, CMS, pharmacies and other participating plans. Standardized data and transaction formats, such as those established by NCPDP, should be utilized for efficiency. A centralized system will eliminate the inefficiencies associated with exchanging data between multiple parties using different processing and data requirements. The data system should provide access to current coverage information for each beneficiary, at a minimum including coverage under all Part D plans, SPAPs and other subsidized plans, though possibly could be extended to include non-subsidized insurers willing to participate.

The SPAP involvement in this data system would be two-fold – to provide SPAP enrollment data, and to obtain other coverage information in return for their SPAP enrollees. SPAP enrollee files would be submitted routinely, for update to the central database with current enrollment information, and a return file to the SPAP will identify Part D and any other coverage information. Such information should include basic information on the current level of coverage, e.g. accumulated

deductible, initial coverage limit status, accumulated incurred costs, catastrophic limit met, etc. Monthly updates, at a minimum, are recommended. With reliable data on other coverage available, SPAPs can help enrollees maximize the use of available benefits while avoiding costs that are the responsibility of other payers. Beyond beneficiary specific data, it is important that SPAPs have timely access to data on plan terminations and disenrollments. In addition, formulary files should be made available to SPAPs electronically to provide up-to-date and sufficient information to identify all drugs covered by each plan. This data is needed, at a minimum prior to each calendar year, to enable the SPAP to facilitate selection of a Part D plan by its enrollees based on their particular needs.

Part D and other plans should be required to exchange enrollment data with the centralized system in similar fashion. Coverage data is needed to facilitate the tracking of TrOOP costs for SPAP enrollees (see TrOOP recommendation). We understand the exchange of claim data may be required between plans and other payers, and this centralized system may or may not be the appropriate mechanism for that exchange. In addition, this data enables plans to more effectively coordinate benefits at the point-of-sale in order to maximize member benefits and ensure proper payment by payers.

Pharmacies should have access to this central data system in order to determine what plan(s) the beneficiary is covered under, and which is primary, secondary, etc. The mechanism developed needs to be cost-effective, real-time, simple, and standard to be beneficial. For example, if the process requires yet another electronic transaction that will only increase time and transmissions costs, pharmacies may not find it beneficial.

We would support use of an outside vendor to facilitate development and implementation of the database by the 2006 deadline, if needed. Database maintenance could be transitioned back to CMS, or another party, once the database was operational. We suggest that CMS develop an oversight taskforce consisting of representatives of all involved parties to develop user requirements for the database.

Quality of the data is paramount to the development of a central database to support the facilitation of transactions for purposes of coordination of benefits. We recommend quality standards be developed and adhered to by all users to ensure the credibility and integrity of the data.

Establish a Long-term Technical Task Force – We recommend that a long-term technical taskforce of stakeholders be established as soon as possible to include representatives from all parties involved, including applicable standard-setting organizations such as NCPDP, to provide ongoing technical advice and recommendations. The technical expertise and perspectives of the taskforce

members would be beneficial in identifying real or potential problems with the Part D system infrastructures, and developing solutions for the future. The group would be beneficial in promoting and/or taking advantage of new technological advancements, continually working to ensure a more reliable, efficient, recipient-friendly electronic process for coordinating benefits between payers, processors and pharmacies.

Allow SPAP Endorsement of Preferred Plan(s) – It is highly recommended that SPAPs be allowed to endorse one or more plans in order to ensure full cooperation between the preferred plan(s) and SPAPs needed to effectively coordinate benefits. Further, to mitigate the high possibility of under-enrollment, states must be allowed to endorse a particular plan, or plans, so as to provide the most seamless migration to the new Part D delivery vehicle for its members.

If a market-based model is to be honored in the new benefit, both the PDP sponsor and the state must have an incentive to cooperate with the other to design, implement and operate a program that best suits the needs of the served population. In our model, a state's solicitation of offers from PDP sponsors to coordinate benefits with the SPAP accomplishes this mutual exchange of consideration. The state will gain a willing partner in the delivery of the primary and secondary benefits to enrollees through a mutually agreed upon program that best serves the needs of their SPAP enrollees. Additionally, the states will now be able to concentrate most, if not all, administrative activities surrounding this coordination effort on one, or a few, PDP sponsors, thereby lessening the overhead in COB initiatives. Likewise, the PDP sponsor will benefit (and be enticed to cooperate) from the potential enrollment *en masse* of the SPAP members. This potential for a large-scale migration from the SPAP to the PDP sponsor will surely facilitate competitive behavior among the regional PDP sponsors. This will reduce costs to the state in multiple ways, such as in the form of the administrative reimbursement for coordination of SPAP benefits (allowed under the regulations) and the administrative costs associated with coordination of benefits with what could be multiple PDP sponsors within the region. The discount card is, again, an example of the price compression that accompanies transparent pricing and competition for enrollees.

If states are compelled to work with all PDP sponsors, regardless of the administrative or service cost to provide a standard benefit, the states will be less likely to continue to provide this program to recipients and will be less able to avoid the administrative complications for the beneficiaries.

To address this problem, CMS must either regulate many aspects of PDP sponsor operations in relation to SPAPs, or allow market forces to work by giving PDP sponsors an incentive to work effectively with SPAPs. The challenge of the regulatory option is the difficulty of anticipating all the coordination and benefit

issues in this new program and also providing enough flexibility to address the differences between states and their SPAPs. The best alternative is to give PDP sponsors an incentive to work with SPAPs. This incentive could be accomplished in two ways:

- Allow states to auto-enroll SPAP beneficiaries into selected PDP sponsors with the recipient retaining the right to affirmatively opt out of the PDP sponsor selection.
- Allow states to auto-enroll SPAP beneficiaries and only continue financial assistance for those that maintain enrollment with selected PDP sponsors. The state would be required to provide the same assistance for all PDP sponsors that met their coordination and benefit standards.

The advantages of these alternative is that they meet the goals of the non-discrimination language in the statute by encouraging competition between PDP sponsors for the significant enrollment of SPAPs and will also encourage states to continue to offer assistance to low income beneficiaries by minimizing the state's administrative costs and allowing the states to obtain the best value for their tax dollars.

Part D Plans must be <u>required</u> to coordinate benefits with SPAPs. Rather than simply "permit" SPAPs to coordinate benefits with Part D plans, CMS should establish clear guidelines, protocols, and detailed requirements that plans must follow to ensure effective and efficient coordination with participating SPAPs as required by Section 1860-23 of the MMA. Without specific requirements imposed on plans as needed to effectively coordinate benefits, plans have no incentive to invest time and resources to the various tools to enhance coordination such as those recommended herein. In fact, they have a financial disincentive to cooperate which, in the absence of clear and specific requirements, is likely to prevail based on SPAP experience.

Part D plans should be required by CMS to inform the pharmacy on a claim response of any secondary coverage (e.g. SPAP), whether the claim is paid or denied. The Part D plan will have obtained this information from the central data system, and it will be readily available on their claim processing system for the tracking of TrOOP. The pharmacy will then readily know what plan to bill for secondary coverage, in case they were not aware of such coverage. CMS guidelines should specify the protocol for such communication, in accordance with NCPDP claim transaction standards.

Require the Use of Standard ID Cards – CMS should require compliance with the NCPDP standard ID card format, whether joint cards are used or not, to further facilitate the communication to the pharmacy of coverage plan and billing information (BIN, processor, and group numbers), mailing information and

helpline contact information. Standardization helps to ensure pharmacies interpret and use the information accurately, and that sufficient data is provided, reducing billing errors that are costly and result in delays.

Eprescribing should be implemented within the Part D Program– We support the eprescribing standards currently under development, and recommend that CMS proactively pursue and support the establishment of those standards and their future implementation within the Part D program. The practice of electronic prescribing will enhance formulary management and compliance, as well as reduce prescribing and dispensing errors.

Establish and Implement a Universal Payer ID – CMS should provide for the establishment of a universal payer or insurer ID for implementation with Part D in January 2006. The current NCPDP claim transaction format provides for this data element to support the coordination of benefits between plans, by identifying the payer to applicable parties throughout the coordination of benefits process. Currently, when pharmacies submit claims to plans, there is not a universal payer ID to identify to the plan any prior payer for which adjudication data is provided. This limits the ability of the plan to enforce the coordination of benefits.

User Fees for COB should not be imposed on or by SPAPs – Part D plans should not be able to impose user fees on SPAPs, nor vice versa, for coordinating benefits. Standardized and reasonable coordination of benefit requirements should instead be defined by CMS and all Part D plans expected to comply and factor resources into their bids. In coordinating, or wrapping around, the Part D benefit, the SPAP contribution enhances the entire benefit offered – which is advantageous to the plan. It is unreasonable to expect that SPAPs be charged a fee, without restriction or even being able to discriminate against such plans.

Require the Future Use of Payer-to-Payer Transmissions by PDP sponsors – NCPDP telecommunication standards envision the transmission of claim transactions between payers to facilitate efficient claim adjudication involving multiple payers, rather than depend on pharmacies to incur added time and expense to successfully identify and complete claim submission process with each payer individually. A reasonable implementation date should be defined by CMS for Part D plans to be required to support this use of NCPDP standards.

PDP sponsors should be required to participate in a retroactive recovery process. Such process should use standard claim transaction formats as specified in CMS guidelines, to address and properly reimburse SPAPs for claims inappropriately submitted to and paid by the SPAP as primary. Pharmacies should not be held responsible for coordination problems. Reasonable time periods for recoveries should be defined by CMS, consistent with common timely filing requirements. Given the real-time claim processing environment and

centralized data system envisioned, this retroactive processing should be minimal. However, exceptions and/or appeals will occur that will justify such a process to ensure the appropriate party ultimately pays for the prescription.

Part D Plans should be responsible for TrOOP Tracking and should immediately credit SPAP enrollees for incurred costs – The centralized data system will provide Part D Plans with other coverage information on their members. A Part D Plan knowing their member is also enrolled in an SPAP should **automatically apply all incurred costs toward TrOOP**, knowing that either the member and/or the SPAP covered it. It is irrelevant to the PDP sponsor how much the SPAP paid, and would impose significant unnecessary administrative burden on SPAPs and plans to exchange this information. If the PDP sponsor knows (from the centralized data system) that the member has no other coverage, the participant cost share can also then be applied toward TrOOP. If the PDP sponsor knows (from the central system) that the member has other coverage that would not be eligible for application toward TrOOP, only then might the plan consider requiring claim data from the other plan to determine benefit costs to be excluded from incurred costs. But the beneficiary's access to catastrophic coverage should never be delayed while imposing additional burden on beneficiaries to require proof that no other benefits or reimbursement were received. How can the beneficiary prove something if it does not exist?

The Part D benefit should be administered in an efficient manner, using technology and standard processing already well established in the pharmacy industry to promote online pharmacy benefit management. The population being served are typically elderly, often frail, and on fixed incomes. For those with catastrophic costs, it is unreasonable to expect them to cover costs beyond the out-of-pocket threshold until the PDP sponsor receives and processes proof from other plans or the beneficiary that the beneficiary or an SPAP on their behalf "incurred costs" to be applied to their TrOOP. Even a one-hour delay may result in the beneficiary leaving the pharmacy without their drug, often finding it difficult to make a return trip.

Education of Beneficiaries, Prescribers and Pharmacies

Overview

SPAP beneficiaries and Medicare Part D providers will expect a comparable level of service to that which they have become accustomed. This may or may not include the added benefits some have realized with the current discount card system. Success will be measured to a great extent by the experience the beneficiary has when entering the system to acquire a prescription. This could occur locally in a variety of pharmacy settings or via mail order pharmacy. The

ability of programs to deliver this level of service is dependent on the components of the established system and the ability of all parties involved to efficiently navigate and use the system to provide the benefit.

Additional challenges in efficient use of the system will affect all beneficiaries, as new methods for the coordination of benefits between Medicare and the SPAPs will need to be established. Once established, knowledge of these methods will need to be disseminated to all parties involved in the delivery of that benefit. In regard to the prescription transaction, the beneficiary, the pharmacist and the prescriber are the key participants. Each will need to have working knowledge regarding eligibility determination, claims processing and coordination of benefits, and problem resolution.

Concerns

Determination of specific content of educational programs and methodology for delivery will not be possible until details of the proposed program components are finalized. However the following areas (Table 1) are likely topics for educational programming for one or more of the key participants in the prescription transaction. While CMS may develop and deliver some general materials, PDP sponsors may need to develop their own materials, as they implement their specific plans. Educational program material development should be done in consultation with groups of beneficiaries and practitioners to ensure appropriate breadth and depth of material and manner of delivery.

TABLE 1: Topics for Educational Programming			
	Probable Primary Interest Group		
Transaction Related Educational Need	**Beneficiary**	**Pharmacist**	**Prescriber**
Determination of beneficiary PDP sponsor/SPAP coverage and current eligibility (central data repository, telephone numbers to call, or use of information off standard ID card)		x	X
Determination of pharmacy participation and preferred status	x		
Information on maximizing benefit for beneficiary (90 day supply, etc.)	x	x	x
Procedures to ensure proper claim submittal (dependent on COB methods?)		x	
Procedures to determine appropriate beneficiary co-pay or deductible (dependent on COB methods?)		x	
Alternative procedures to implement claims processing if real-time processing or COB methods fail		x	
Procedures for resolution of claim denials at the PDP sponsor and/or the SPAP transaction	x	x	
Procedures for resolution of formulary differences, prior authorization, etc. between PDP sponsor and SPAP	x	x	x
Methods to shift COB back to PDP sponsor and SPAP		x	
Methods to access relevant formulary information		x	x
Contact information and procedures for real-time problem resolution	x	x	x
Contact information and procedures for appeals	x	x	x
Appropriate utilization of information available from transaction or available in central data repository		x	x

Recommendations

Education Funds – CMS should dedicate necessary funds to educate beneficiaries, providers and in particular pharmacists. prescribers, and community organizations, or include this as appropriate in PDP sponsor requirements. These funds would be in addition to those dedicated to the education of SPAP enrollees on plan selection and transition to Part D.

Educational Content – CMS should determine minimum components of educational programs to prepare beneficiaries, pharmacists and providers to receive or efficiently deliver the benefit respectively.

Educational Program Delivery – CMS should determine which educational components are to be delivered through its control and which would be delivered by PDP sponsors or SPAPs. All programs should be delivered in an appropriate mixture of methods and/or frequency to assure access of the education to the interested group(s).

Program Development – Focus groups of beneficiaries, pharmacists and prescribers should be used to develop educational materials to ensure educational programs adequately prepare the respective group to efficiently receive or deliver the benefit.

Beneficiary COB Education – PDP sponsors should be required to explain in plan materials how to coordinate benefits with other coverages, to make it clear when their plan should be used first and how other coverages may be used to cover out-of-pocket expenses or non covered purchases.

Program Assessment – Data Collection and Reporting/Evaluation

Overview

CMS should embark upon an assessment of the success of the implementation (coordination) of the new programs so that changes can be monitored and deficiencies can be readily identified and corrected.

Recommendation

To assess the success of the implementation of the coordination of Medicare Part D and SPAPs, system measures should be obtained at least quarterly, including a baseline measurement before implementation for involved SPAPs, pharmacists and patients. Satisfaction measures should be conducted at baseline, three months post implementation and annually unless needed otherwise. All of these measures should be compared with previous results, as well as baseline measures, to identify both positive and negative changes in

satisfaction and other measures. While the satisfaction metrics will assess perceptions of the system implementation, the system metrics will be used to monitor additional changes in the SPAPs (e.g. the number of patients enrolled, patient demographics, total expenditures, expenditures per patient, number of failed transactions per month, and changes in prescription mix of formulary and non-formulary prescriptions). These metrics also should be broken down by PDP sponsor so system problems can be identified separate from specific PDP sponsor challenges. Since the monitoring will focus on changes in the metrics, it is difficult to overemphasize the importance of baseline measures *before* program implementation.

ADDITIONAL RECOMMENDATIONS

CMS Should Form an SPAP Advisory Committee

Several SPAPs have been in existence for almost 30 years. State policy makers and program managers have learned that people's needs for pharmaceuticals and the markets that serve them are not static. Over the lifetime of SPAPs, States have made changes in policy and program design to accommodate those changing needs. Even relatively small SPAPs experienced speed bumps along the way as they rolled out new programs or new features of existing programs. CMS will undoubtedly need additional advice and input from experienced state officials as Part D is implemented and perhaps modified over the course of the next few years.

The Commission recommends the formation of an ongoing advisory committee to CMS as soon as possible. This committee should be composed of representatives from SPAPs. The committee could serve to advise CMS through the transition of actually implementing Part D and coordinating the benefits of SPAPs and Part D. Although the Commission has attempted to point out all areas where we anticipate problems with transition, we believe it would be beneficial to CMS to have a formal mechanism for consulting with various SPAPs as Part D is rolled out. There is no one group that can better advise CMS about what to expect when implementing a drug benefit than the state officials who have done the same.

New SPAPs

Nothing in the MMA, or rules and regulations associated with Part D, should be construed as prohibiting a State from developing a new SPAP in order to enrich (and coordinate with) the benefits of Part D.

Risk Adjustment

In the NPRM, CMS proposes to establish a risk adjustment methodology to reflect the differences in actuarial risk placed on plans due to the health status of their enrolled populations. The exact methodology for such risk adjustment has not yet been determined, but it will be based on diagnosis information obtained from Parts A and B claim data. Regarding low-income subsidy (LIS) beneficiaries, the preamble indicates, "the methodology should provide neither incentive nor disincentive for enrolling LIS individuals."

The SPAPs are very concerned that CMS make this risk adjustment methodology extremely sound, because the population we serve is known to have higher cost per capita. This higher cost per capita is caused by three different phenomena:

- Morbidity. Research is persuasive that LIS beneficiaries have, on average, greater morbidity than the typical Medicare beneficiary.
- Better benefits. The LIS beneficiaries' coverages are simply better than Standard. They will cost more, even if utilization is unchanged.
- Induced demand. Research is persuasive that better Rx benefits induce greater Rx utilization, all else being equal. The LIS beneficiaries' coverages are substantially better than Standard.

We assume that the Part D diagnosis-based risk adjustment system will be designed to reflect morbidity, but only morbidity. The PDP sponsor will be reimbursed directly for better benefits, so that is not a concern. However, induced demand remains to be addressed.

Prospective PDP sponsors will be concerned about the potential of getting a disproportionate share of low-income enrollees because of induced demand. One way they can easily avoid getting such enrollees is to have a higher premium than the federal low-income subsidy will cover. Even though the preamble states that there will be a low income adjuster established that will offset their higher costs, quite frankly, many private sector companies are skeptical that it will be adequate. Their inexperience with this population leads them to be more cautious about them and to expect that they will be a big drain on not only drug costs but on administrative resources as well.

The only way to assure that PDP sponsors will not discriminate in enrollment against low-income individuals is to assure them that low-income beneficiaries will have the same revenue-to-risk ratio as high-income beneficiaries. The Commission recommends that CMS consider a methodology that overtly includes an induced-demand factor for low-income beneficiaries, while remaining budget neutral overall. Further, we suggest an additional temporary (one or two year) subsidy of LIS

beneficiaries, designed to overcome PDP sponsors' reluctance to serve these unfamiliar populations.

Report Distribution

CMS should make this report available to State policy makers, State and Federal officials, and the general public through the CMS website and other distribution mechanisms.

Unresolved Issues

Rebates

The issues surrounding managing manufacturer rebates remains unresolved. The Commission discussed several aspects including whether SPAPs, PDP sponsors, or both collect rebates; and how transparent rebate collection information can be between SPAPs and PDP sponsors if they are coordinating benefits. We did not come to consensus on formal recommendations.

CHARTER

STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION

Purpose

The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 106 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), to establish a State Pharmaceutical Assistance Transition Commission (the Commission). The Commission will develop a proposal for addressing the unique transitional issues facing State Pharmaceutical Assistance Programs (SPAPs) and SPAP participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act, as added by section 101 of the MMA.

Authority

Section 106 of the MMA (Public Law 108-173). The Commission is governed by the provisions of PL 92-463 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Function

The State Pharmaceutical Assistance Transition Commission will advise the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on ways to address the unique transitional issues facing SPAPs and SPAP participants and will develop a proposal addressing these issues.

The Commission shall develop the proposal in a manner consistent with the following principles:

- Protection of the interests of program participants in a manner that is least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.
- Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.
- Principles of Medicare modernization under the MMA.

The Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate. The report is due no later than January 1, 2005.

Structure

The Commission shall consist of the Secretary, or his designee, and up to 70 members, including the Chair. Members shall be selected by the Secretary according to the following:

1). A representative of each Governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program (SPAP) that provides for eligibility and benefits that are comparable or more generous than the low-income assistance and eligibility and benefits offered under section 1860D-14 of the Social Security Act;
2). Representatives from other States that the Secretary identifies have in operation other SPAPs, as appointed by the Secretary;
3). Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs 1 and 2 combined;
4). Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary; and
5). The Secretary (or the Secretary's designee) and such other members as the Secretary may specify.

The Secretary shall designate a member to serve as the Chair. Members shall be invited to serve for the duration of the Commission.

A quorum for the conduct of business shall consist of a majority of currently appointed members.

As necessary, standing and ad hoc subcommittees composed of members of the parent committee, may be established to perform functions within the commission's jurisdiction. The Department Committee Management Officer shall be notified upon the establishment of each standing subcommittee and shall be given information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Center for Medicaid State Operations, CMS.

Meetings

Meetings shall be held between 1-3 times per calendar quarter, at the call of the Chair, who shall also approve the agenda.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

All members will serve in a voluntary status without compensation pursuant to advance written agreement. Members of the Commission shall be entitled to receive reimbursement of travel expenses and per diem in lieu of subsistence, in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operation of the Commission, including travel and per diem for members, and logistical support, but excluding staff support, is $466, 380. The estimated annual person-years of staff support required is .40, at an annual cost of $36,457.

Reports

By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

In the event a portion of a meeting is closed to the public, a report shall be prepared which shall contain, at a minimum, a list of members and their business addresses, the Commission's function, dates and places of meetings, and a summary of Commission activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

The State Pharmaceutical Assistance Transition Commission shall terminate 30 days after the date of the submission of the report to Congress, but no later than January 31, 2005.

APPROVED:

March 1, 2004
Date

Tommy Thompson /s/
Secretary

A P P E N D I X – B

COMMISSION ROSTER

Clifford E. Barnes, Esq.
Epstein Becker & Green, P.C.
Washington, DC

Donna A. Boswell, Ph.D., J.D.
Partner
Hogan & Hartson, LLP
Washington, DC

James Chase
Executive Director
Minnesota Community Measurement
St. Paul, MN

David L. Clark, R.Ph., MBA
Vice President, Pharmacy Services
The Regence Group
Portland, OR

Jay D. Currie, Pharm.D.
Associate Professor
The University of Iowa College of Pharmacy
Iowa City, Iowa

Barbara Edwards
Deputy Director
Office of Ohio Health Plans
Columbus, OH

Nora Dowd Eisenhower, J.D.
Secretary
PA Department of Aging
Harrisburg, PA

Janice O. Faiks, J.D.
V.P. Government Affairs & Law
Pharmaceutical Research and Manufacturers of America
Washington, DC

Dr. Dewey D. Garner
Chair and Professor of Pharmacy Administration
University of Mississippi School of Pharmacy
University, MS

Karen Greenrose, R.N.
President
American Association of Preferred Provider Organizations
Borden, IN

Joan F. Henneberry (Chairperson)
Director
Consulting & Research
Policy Studies, Inc.
Denver, CO

Laurie Hines, J.D.
Executive Director
Missouri Senior Rx Program
Jefferson City, MO

Mary Liveratti
Deputy Director
Nevada Department of Human Resources
Carson City, NV

Anne Marie Murphy, Ph.D.
Administrator of Medical Programs
Illinois Department of Public Aid
Springfield, IL

Julie A. Naglieri
Director
New York State Elderly Pharmaceutical Insurance Coverage (EPIC) Program
Albany, NY

Robert P. Power, M.B.A., C.E.B.S.
Senior Medical Economist
HealthPartners
Bloomington, MN

Susan C. Reinhard, R.N., Ph.D.
Deputy Commissioner
New Jersey Department of Health and Senior Services
Trenton, NJ

COMMISSION ROSTER (CONTINUED)

Sybil M. Richard, J.D., M.H.A., R.Ph.
Bureau Chief
Florida Medicaid Pharmacy Services
Tallahassee, FL

Elizabeth J. Rohn-Nelson
Public Advocate
Sun City, AZ

Marc S. Ryan, M.P.A.
Secretary
State Office of Policy and Management
Hartford, CT

Linda J. Schofield, BSN, MPH
Schofield Consulting
Simsbury, CT

Martin Schuh, M.B.A.
External Affairs
ACS State Healthcare
Atlanta, GA

RECOMMENDATIONS FROM THE COMMISSION

- SPAPs should be allowed to endorse one or more preferred Part D plans for their enrollees.
- SPAPs, at their own option, should be allowed to determine eligibility for low-income subsidies.
- The final Part D regulations should eliminate or allow exclusions to the asset test.
- Marketing, enrollment, and educational materials should include clear and concise explanations of how the SPAP and the PDP sponsor will coordinate prescription benefits.
- The final Part D regulations should allow an SPAP to automatically enroll its beneficiaries into one or more preferred PDP sponsors.
- CMS should include safeguards for all vulnerable populations against ill advised disenrollments and should notify each coordinating SPAP of all disenrollments of that SPAP's beneficiaries.
- Final Part D regulations should provide for a process similar to the Medicare Part B buy-in to allow states, at their option, to pay Medicare Part D premiums on behalf of SPAP beneficiaries.
- SPAPs that pay premium costs, including late fee penalties, on behalf of their beneficiaries should pay minimal late enrollment penalties.
- PDP sponsors should be required to submit network plans that offer the same cost-sharing requirements for all in-network pharmacies.
- CMS should clarify that the geographic standards for access apply in each zip code, not just on average across all urban, suburban, rural areas in the defined region.
- PDPs should be required to approach any willing LTC pharmacies in the service area for participation in a plan's network.
- The definition of LTC facility should be broadened to include ICFs/MR, intermediate care facilities for the developmentally disabled (ICF/DD), assisted living and other supportive housing facilities, including group homes under 1915(c) home and community based waivers.
- CMS should establish a standard policy and set of procedures for all PDP sponsors addressing the acceptable grounds for using an out-of-network pharmacy, and how the claims will work.

- The final regulations should make it clear that any price differential, paid for retail versus mail order, would count as an incurred cost toward the out-of-pocket threshold (TrOOP) for the enrollee, whether paid by the enrollee or the SPAP.
- SPAPs will need to consider how they will handle snowbirds and establish appropriate policy on a state by state basis.
- The regulations should also require the PDP sponsors to detail their visitor/traveler benefits to members and SPAPs.
- SPAPs should carefully evaluate the adequacy of formularies of the PDP sponsors available to their enrollees.
- CMS should establish metrics for the initial formulary review.
- Special transition rules should be established for the early months of 2006 to ensure continuity of care for persons newly enrolling with PDP sponsors.
- PDP sponsors should share data and enter into agreements regarding continuity of care and coordination of such things as PA, generic substitution and formulary changes.
- Mid-year formulary changes should be discouraged.
- If mid-year formulary deletions are allowed, a 90-day notice provision should be adopted (rather than the proposed 30-day notice) to ensure continuity of care for beneficiaries and to aid SPAPs in any programmatic changes they need to engage in when a formulary changes in a Part D plan.
- If mid-year formulary deletions are allowed, CMS should require that PDP sponsors certify that their proposed changes in formulary do not change the actuarial value of the benefit or the compliance of the formulary with USP and CMS standards, including two drugs per class and non-discrimination.
- The Commission agrees with CMS that certain populations' needs for continuity of care trumps formulary design.
- CMS should explore setting up a retrospective medical necessity review framework in lieu of formulary denials, to protect the health of the patient and ensure minimal disruption and continuity of care.
- SPAPs should be specifically identified in the regulations or statute as authorized representatives to file exception requests and appeals to the PDP sponsor.
- Dispensing pharmacists should also be allowed to act as authorized representatives to request exceptions on behalf of enrollees.
- Section 423.562 of the proposed regulation should be revised to clarify that if an SPAP has paid for a drug, this in no way eliminates the beneficiary's or SPAP's right to pursue an appeal for coverage of the drug by the PDP sponsor.
- Give SPAPs the authority to challenge a PDP sponsor's pattern of decisions on a class of drugs, first by formally contacting the PDP sponsor and asking for a re-

consideration of its policies and criteria, and secondly, if the first effort as resolution fails, by appealing to the IRE.

- Require PDP sponsors, at least for dual eligibles, low-income subsidy beneficiaries and SPAP enrollees, to pay for a 3-day emergency supply of denied medications to enable the patient to have time to contact their physician for a prescription for an alternative formulary medication or to appeal, and to pay for a continued supply of any medication that is under appeal, in order to prevent a break in therapy.
- Require PDP sponsors to respond to requests for exception & PA over the phone or within 24 hours (as in Medicaid) to avoid delays and breaks in care, and to avoid putting SPAPs on the spot to pay the full cost.
- Provide SPAPs with information about why a PDP sponsor claim is denied, so that the SPAP can decide whether to appeal.
- Cases reviewed by the IRE should be reviewed de novo, and not limited to ruling only on whether the PDP sponsor applied its own criteria appropriately, as suggested in the proposed regulations.
- PDP sponsors should share clinical criteria with SPAPs for approval of PA requests, exceptions, and tiered co-pay exceptions, so that the SPAPs will not waste time pursuing appeals that will be justly denied on clinical grounds.
- PDP sponsors should be required to issue written notices of denial and appeal rights upon initial denial of a pharmacy benefit.
- Beneficiaries should be grandfathered or get a grace period of at least 90 days of coverage when they first trip a formulary, step therapy, dose limit, or PA denial for a drug they've been on previously.
- Notices of formulary deletions should be considered notices of coverage determinations, and beneficiaries should be instructed how to submit medical information in order to seek a re-determination for their case.
- The exception process should have a two day turn-around time to reflect current practice, as well as to serve patient needs.
- Denials of re-determinations should be sent by the PDP sponsor automatically to the IRE, as are all other benefit denials.
- There should be no bifurcation in the timelines for appeals whether the recipient (or SPAP) paid for the drug or went without the medication.
- An expedited exceptions process should be available even when a patient has paid for the medication out-of-pocket subsequent to the denial, if further refills will be needed.
- The initial claim denial should be considered a coverage determination, and a denial notice with appeal rights should be sent as a result of this coverage determination.

- The exception process should be considered the re-determination or at least explicitly treated as a brief step between the coverage determination and the re-determination.
- Formulary deletions should be considered coverage determinations, as noted above.
- The projected value of a medication, for purposes of meeting the threshold to go to the ALJ, should be clarified to be projected over the full likely duration of the drug's use for that patient.
- The criteria for considering copay exceptions should consider the medical effectiveness and safety of the drugs and the specific clinical profiles of the appellants, as in formulary exceptions. Beneficiaries should have access to the non-preferred drug at the preferred copay rate if the preferred drug is likely to cause an adverse effect or is likely to fail to control their symptoms or disease.
- Drugs covered through exception or appeal should have the copay of the preferred formulary drug that the PDP sponsor felt was an appropriate alternative when establishing the formulary.
- Maintain a high degree of flexibility to allow SPAPs to determine the level and extent of the information they will provide to beneficiaries enrolled in these programs.
- We must take a lesson from the Medicare Drug Discount Cards and make certain there is regulation of product quality and clear, concise, appropriate and timely information available to consumers.
- Educational materials and campaigns must be developed with the recognition that not only are SPAPs diverse in their methods of operation, but that the consumers represent age and ethnic diversities which must be considered in developing education campaigns and materials.
- Develop a specific strategy to target dual eligibles.
- A separate plan to train caregivers and providers should be established in order to ensure a smoother transition.
- Encourage the development and use of educational templates and materials that can be localized.
- Closely regulate the PDP sponsors regarding the quality (i.e., readability) and content of the information they provide and their coordination with SPAPs.
- Do not rely on the use of the Internet as the sole or main means by which information is disseminated; additional forms of communication must be made available.
- Phase in the education campaign beginning September 1, 2005 or as soon after finalization of the regulations as possible.
- PDP sponsors must be required to work with SPAPs on education and education materials. Require that CMS undertake an annual evaluation of access to drugs and

of utilization of non-drug benefits, pre- and post- implementation and produce an annual report.

- CMS should also make all data available to independent researchers, who can conduct their own studies of program effectiveness and make recommendations for programs improvements.
- Emphasize the importance of QA and program evaluation by SPAPs by identifying key components and disseminating best practices.
- For effective QA, it is important to permit SPAP access to the Medicare database.
- SPAPs should be encouraged to link with medical peer review groups to ensure scientific evaluation.
- HHS should make clear that assistance with the purchase of supplemental coverage includes assisting the individual with payment of premiums for basic, basic alternative or basic enhanced coverage.
- HHS should modify the regulation to specifically construe the non-discrimination provision of the statute as being satisfied by SPAP arrangements to determine the actuarial value of the benefit that it provides to enrollees, and to pay such amount to the PDP sponsor in which an SPAP beneficiary has enrolled.
- For SPAPs that provide supplemental coverage by picking up all or part of the enrollee's cost-sharing requirements, CMS should provide for at least the following three different options for coordinating with PDP sponsors:
    - Federal Base Premiums
    - Fee-for-Service Cost Sharing
    - Customized Supplemental Coverage
- Establish a Centralized Data System to facilitate data exchange through a single entry point so that all involved parties have access to timely and accurate data needed for the "real-time" coordination of benefits.
- Establish a Long-term Technical Task Force – We recommend that a long-term technical taskforce of stakeholders be established as soon as possible to include representatives from all parties involved, including applicable standard-setting organizations such as NCPDP, to provide ongoing technical advice and recommendations.
- Part D Plans must be required to coordinate benefits with SPAPs.
- Part D plans should be required by CMS to inform the pharmacy on a claim response of any secondary coverage (e.g. SPAP), whether the claim is paid or denied.
- Require the Use of Standard ID Cards – CMS should require compliance with the NCPDP standard ID card format.
- Eprescribing should be implemented within the Part D Program

- Establish and Implement a Universal Payer ID – CMS should provide for the establishment of a universal payer or insurer ID for implementation with Part D in January 2006.
- User Fees for COB should not be imposed on or by SPAPs – Part D plans should not be able to impose user fees on SPAPs, nor vice versa, for coordinating benefits.
- Require the Future Use of Payer-to-Payer Transmissions by PDP sponsors.
- PDP sponsors should be required to participate in a retroactive recovery process.
- Part D Plans should be responsible for TrOOP Tracking and should immediately credit SPAP enrollees for incurred costs.
- A Part D Plan knowing their member is also enrolled in an SPAP should automatically apply all incurred costs toward TrOOP.
- Education Funds – CMS should dedicate necessary funds to educate beneficiaries, pharmacists and prescribers, or include this as appropriate in PDP sponsor requirements.
- Educational Content – CMS should determine minimum components of educational programs to prepare beneficiaries, pharmacists and providers to receive or efficiently deliver the benefit respectively.
- Educational Program Delivery – CMS should determine which educational components are to be delivered through its control and which would be delivered by PDP sponsors or SPAPs.
- Program Development – Focus groups of beneficiaries, pharmacists and prescribers should be used to develop educational materials to ensure educational programs adequately prepare the respective group to efficiently receive or deliver the benefit.
- Beneficiary COB Education – PDP sponsors should be required to explain in plan materials how to coordinate benefits with other coverages, to make it clear when their plan should be used first and how other coverages may be used to cover out-of-pocket expenses or non covered purchases.
- To assess the success of the implementation of the coordination of Medicare Part D and SPAPs, system measures should be obtained at least quarterly, including a baseline measurement before implementation for involved SPAPs, pharmacists and patients.

STATE PHARMACEUTICAL ASSISTANCE PROGRAM CHART: MEDICARE ENROLLEES

State	Program Name	*Medicare Enrollees
CT	ConnPACE	48,319
DE	Prescription Assistance Program	5,707
IL	Circuit Breaker	52,989
IN	Hoosier Rx	16,763
KS	Senior Pharmacy Assistance Program	2,021
MA	Prescription Advantage	76,567
ME	Disabled and Elderly Drug	39,464
MD	Senior Prescription Drug Plan	32,973
MI	EPIC	13,267
MN	Prescription Drug Program	7,032
MO	Senior Rx Program	18,255
NC	Senior Care	22,166
NJ	PAAD and Senior Gold	214,879
NV	Senior Rx Program	7,724
NY	EPIC	322,523
PA	PACE and PACENet	222,062
RI	Prescription Assistance for the Elderly (RIPAE)	36,868
TX	Kidney Health Care Program	17,045
VT	V-Script Expanded	3,092
WI	Senior Care (above 200 percent FPL)	20,851
WY	Prescription Drug Assistance Program	960
	Total	1,181,527

*** Number of Medicare Beneficiaries as of 10/1/03, as reported to CMS.**

Source: Chart of State Pharmaceutical Assistance Program Transitional Grants Distribution Awards on CMS website at: http://www.cms.hhs.gov/medicarereform/spap_state_awards.pdf

A P P E N D I X – E

Covington & Burling Legal Opinion

COVINGTON & BURLING

1201 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004-2401
TEL 202.662.6000
FAX 202.662.6291
WWW.COV.COM

WASHINGTON
NEW YORK
SAN FRANCISCO
LONDON
BRUSSELS

September 30, 2004

MEMORANDUM

To: Kathleen Mason
New Jersey Department of Health

From: Caroline M. Brown

Re: SPAP Auto- Enrollment in Medicare Part D Plans

You have asked us to look into the question of whether State Pharmaceutical Assistance Programs (SPAPs) can select a Medicare Part D Prescription Drug Plan (PDP) on behalf of their beneficiaries and can auto-enroll the beneficiaries in the selected plan. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, is silent on the issue of auto-enrollment, although it envisions a high degree of coordination between SPAPs and Medicare PDPs. The proposed regulations, recently promulgated for comment at 69 Fed. Reg. 46632, also do not expressly provide for (or prohibit) auto-enrollment by state programs.

It appears to us that an SPAP should be permitted to auto-enroll its beneficiaries into a selected PDP, provided that the SPAP is considered the "authorized representative" of the beneficiary under state law. However, the SPAP could not discriminate against (treat differently) an enrollee who elected to enroll in a PDP other than the one selected by the State. The Part D program provides that "[t]he Secretary shall establish a process for the enrollment,

disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans." (§ 1860D-1(b)(1)(A)). The Secretary is to ensure "that each part D eligible individual has available . .. a choice of enrollment in at least 2 qualifying plans." (1860D-3(a)(2)). The language on enrollment in PDPs is almost identical to the language for enrollment in the Medicare Prescription Drug Discount Card program, also established as part of MMA. Under the discount card program, the Secretary is similarly required to "establish a process through which a discount card eligible individual is enrolled and disenrolled," (§1860D-31(c)(1)), and must likewise ensure that "there is available to each discount card eligible individual a choice of at least 2 endorsed programs." (§ 1860D-31(h)(2)(D)(i)).

The Secretary interpreted the discount card provisions as permitting an SPAP to auto-enroll its beneficiaries if, under state law, it could act as the beneficiary's "authorized representative," and if a beneficiary were given the opportunity to opt out. Although there is no formal rule-making on this issue, it appears that the Secretary interpreted the language in Section 1860D-31(c)(1) calling for a process "through which a discount card eligible individual is enrolled and disenrolled" as not prohibiting auto-enrollment by a representative empowered to act on the individual's behalf. That same reasoning would permit enrollment by an authorized representative under Section 1860D-1(b)(1)(A), which similarly calls for the establishment of "a process for the enrollment [and] disenrollment . . . of part D eligible individuals in prescription drug plans."

You have noted Section 1860D-23 as a potential concern. That section provides that the Secretary shall establish requirements for prescription drug plans to coordinate with SPAPs, with respect to payment of premiums and coverage and payment for supplemental prescription drug benefits. For purposes of this section on coordination, an SPAP is defined as

one which, among other things, "in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled." (§ 1860D-23(b)(2)). We do not believe the non-discrimination language in this section prohibits auto-enrollment, for its language comes into effect only ***after*** enrollment. That is, it does not prohibit an SPAP from selecting one PDP over others for purposes of enrollment but rather is directed only to differential treatment "based upon the part D plan in which the individual is [already] enrolled."

We interpret the language of Section 1860D-23 of the MMA as permitting an SPAP that is an "authorized representative" of its beneficiaries under state law to select one or more preferred PDPs in which to enroll its beneficiaries. Consistent with the approach used for discount drug cards, a beneficiary would have to be given the opportunity to "opt out" (*i.e.*, not have the SPAP act as his or her representative) and to select a different plan. In such a case, the SPAP could not, under the terms of the statute, treat the opt-out differently than those beneficiaries whom it has enrolled in the preferred PDP. The statute requires that all beneficiaries, whether they accept or reject the auto-enrollment, be treated the same for purposes of "eligibility" and "the amount of assistance" provided. However, the statute does not prohibit a State from selecting a preferred PDP, and the use of specific language prohibiting discrimination in "eligibility" and "amount of assistance" strongly suggests that preferential treatment in selection of plans is permissible.

Such an interpretation is also consistent with the statutory intent to establish an effective coordination mechanisms between SPAPs and PDPs. As stated in the legislative history: "This legislation allows state pharmacy assistance programs to act as administrative

intermediaries **for the purpose of facilitating enrollment of SPAP members** in prescription drug plans and in the discount card program." H.R. Conf. Rep. No. 108-291, at 485 (2003). An interpretation of the statute that would prohibit auto-enrollment would not "facilitat[e]" enrollment in PDPs and would complicate rather than promote coordination between the two programs.

We therefore disagree with the vague but troubling statement in the preamble to CMS's proposed regulations that it is interpreting the non-discrimination language to mean that a State "may not steer beneficiaries to one plan or another through benefit design **or otherwise**." 69 Fed. Reg. 46697 (emphasis added). That statement, we believe, goes beyond the language in the statute and in the proposed regulation itself, which simply states that a qualifying SPAP must "provide[] assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls." 69 Fed. Reg. 46832 (proposed § 423.464(e)(i)(ii)).[1] The proposed rule itself is silent on the question of "steering" beneficiaries to a selected plan.

Please feel free to call me if you have any questions.

[1] A state pharmacy assistance plan is not mandated to meet the MMA's definition of an SPAP, but if it does not, it will not be entitled to the special status accorded to qualifying SPAPS, including shared cards, mandated coordination with the PDPs, and being able to count SPAP contributions towards true out-of-pocket costs for purposes of calculating catastrophic coverage. 69 Fed. Reg. 46697.

A P P E N D I X - F

HOGAN & HARTSON
L.L.P.

COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910
WWW.HHLAW.COM

M E M O R A N D U M

October 12, 2004

RE: Part D Enrollment Assistance by SPAPs

This memorandum is in response to your request for an analysis of whether the Medicare Modernization Act (MMA) permits State Pharmacy Assistance Programs (SPAPs) to facilitate or "auto-enroll" part D eligible individuals into prescription drug plans. In my view, it is clear that the statute would permit a State to set up a mechanism for facilitating enrollment in specific part D plans, provided that certain protections are in place to protect the SPAP enrollee's ability to transfer the "amount" of the benefit available under the SPAP to a part D plan of his or her choosing. There are three key statutory provisions that govern this question and lead to this answer.

First, in the MMA the Congress provided funding to SPAPs specifically designated to be used for (a) "educating part D eligible individuals enrolled in the [SPAP] Program about the prescription drug coverage available through part D plans"; (b) "providing technical assistance, phone support, and counseling for such enrollees to facilitate selection and enrollment in such plans"; and (c) "other activities designed to promoted the effective coordination of enrollment, coverage and payment between such Program and such plans." Social Security Act § 1860D-23(d)(2). *This evinces Congress' interest in affording SPAPs a special role both for evaluating part D plans available to their enrollees, facilitating enrollment in appropriate plans, and the critical role of enrolling individuals in plans that will ensure effective coordination of benefits between the PDPs and the SPAPs.*

Second, the MMA specifically permits SPAPs to enter into arrangements with one or more PDPs to offer "co-branded" cards that inform Medicare part D beneficiaries that their drug benefits under such a card are the result of benefits coordinated by their PDP and their SPAP. Social Security Act § 1860D-23(c)(2). *This provision of the statute would have no meaning if SPAPs could not assist beneficiaries to ensure that they were enrolled in the co-branded PDP. It is*

clear that the federal statute permits the assistance provided by an SPAP to provide greater value to an individual enrolled in one plan, even if the amount paid by the SPAP on behalf of an individual enrolled in another plan is the same.

Third, the MMA specifically protects the market power of SPAPs in choosing which of the various PDPs and MA-PDs to partner with. The statute says "Nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide assistance with respect to any part D plan." Social Security Act § 1860D-23(c)(5). *This provision protects the role of SPAPs as effective advocates providing cost-effective access to drug benefits for their enrollees. Without it, the part D plans could simply compel the SPAPs to follow their rules and procedures in order for individuals to receive SPAP benefits. Congress clearly provided for a level playing field in this area, so that the market power of SPAPs (who already have enrollees) can be used to reward the part D plans that have benefit structures and formularies that are most conducive to coordination of benefits with the SPAP.*

Anti-Discrimination

HHS Interpretation. In marked contrast to Congress' explicit provision for special arrangements by SPAPs for their enrollees, language in the preamble of HHS' proposed rule opines that SPAPs "may not steer beneficiaries to one plan or another through benefit design or otherwise." 69 Fed. Reg. at 46697 (Aug. 3, 2004). Under the law, HHS does not have authority to promulgate such a policy, as it specifically contradicts the express language and intent of the three provisions quoted above.

HHS says that it reached this conclusion in interpreting a separate provision of MMA which is included in the statutory definition of "State Pharmaceutical Assistance Program." The provision says that for purposes of part D, a state pharmacy assistance program is *not* considered a "state pharmaceutical assistance program" unless –

> "in determining *eligibility and the amount* of assistance to part D eligible individuals under the [SPAP] Program, [it] provides assistance to such individuals in all part D plans and *does not discriminate based upon the part D plan in which the individual is enrolled.*" Social Security Act § 1860D-23(b)(2) (*italics* added).

The preamble language is based on a misreading of this statutory provision.

Statutory Construction. The plain language of the statute says nothing that could be construed as prohibiting SPAPs from having special benefit designs that favor one part D plan over another, or from providing a service to SPAP enrollees that "automatically" enrolls them in specific part D plans that have been evaluated by the State and determined to be the ones that are best suited to "coordination of enrollment, coverage and payment between" the SPAP and the selected part D plans. To the contrary, this is an express a goal *and* use of federal grant funds specifically authorized by the MMA. Social Security Act § 1860D-23(d)(2)(C). The reading of this "anti-discrimination" provision of the MMA that is proposed in the preamble arguably is impermissible under the statute, as it renders at least one, and likely all three of the other statutory provisions quoted above, meaningless. Under long-accepted principles of statutory construction, each provision of the statute must be construed as having been intended to have meaning; an agency has no authority through construction of one provision to render another meaningless.

Statutory Roots in Free Choice of Plans. Examination of the structure of part D reveals that this "anti-discrimination" provision likely is designed to protect the Medicare beneficiary's right to

choose from at least two plans. Social Security Act § 1860D-3(a)(1); SSA 1860D-1(b)(1)(B)(ii). But nothing in the statute permits this provision to over-rule requirements also applicable to SPAPs and their beneficiaries. Thus, while an individual is entitled to a selection of at least two plans, this language cannot be construed, in the case of SPAP enrollees, as a mandate requiring the State to spend funds for services or in amounts not otherwise authorized by the State law.

To use a simple example, suppose there are two part D plans in a state – one with a $35/mo. premium and one with a $50/mo. premium. Suppose the sole benefit available under state law authorizes the SPAP to pay up to $35/mo. premium to the part D plan selected by the individual. It is clear that the "anti-discrimination" provision of the federal law would not authorize the Secretary to require the State to pay the $50 premium for individuals selecting that plan. To the contrary, if the individual did not pay the $15/mo. premium difference between the SPAP coverage and the premium of the plan selected by the enrollee, the statute appears to permit the part D plan to terminate the individual's enrollment in the plan. SSA 1860D-1(b)(3)(A)(iii). Such a result is not in the interest of the beneficiary, who not only would lose part D coverage but also likely would incur premium penalties if he or she attempted to re-enroll. In order to effect the intent of the statute under these facts, there can be no doubt that the Secretary should permit the SPAP to "auto-enroll" individuals who are eligible for SPAP coverage in the part D plan whose premium is fully covered by the SPAP, *unless the individual chooses to enroll in the other plan and expressly assumes responsibility for paying the higher premium.*

Congress' Implementation of Free Choice. In fact, this is precisely the way Congress implemented the statutory provision requiring free choice with respect to dual eligible individuals. Congress provided for an auto enrollment process that is limited to plans whose premiums would be covered by the premium subsidy. The dual eligible individual's right to a choice of plans is protected through a right to disenroll from the plan to which he or she is assigned, and to select another plan, even one with a higher premium, *if* the premium in excess of the federal subsidy is in fact paid by or on behalf of the individual.

In light of the relationships among the various provisions relating to the critical role Congress establishes for SPAPs in enhancing the benefits available under part D, a far better interpretation of the anti-discrimination language in the definition of SPAP would be to analogize to that provided for "dual eligible" Medicaid beneficiaries. Although Congress *required* the Secretary to facilitate enrollment in plans appropriate to the federal coverage subsidy through establishing an "auto-enrollment" process for dual eligible part D individuals, Social Security Act § 1860D-1(d)(2), Congress could not mandate the Secretary to auto-enroll SPAP beneficiaries because the Secretary has no authority over the state laws that provide for these benefits. However, the plain language of the statute relating to SPAP coordination with part D is clear that the State should be permitted to do so, at its discretion. In fact, the statutory provision requiring the Secretary to establish a process for enrollment, including a process for auto-enrolling of dual eligibles, arguably would permit the Secretary to use the same auto-enrollment, disenrollment, and special reenrollment processes established for dual eligibles, to facilitate enrollment of SPAP beneficiaries at the request of a State.

Recommended Implementation of SPAP Anti-Discrimination Language. The MMA requires the Secretary to establish a process for enrollment of part D eligible individuals that is consistent with the beneficiary's exercise of choice. SSA 1860D-1(b)(1)(B)(ii). For part D-eligible individuals who also are eligible for SPAP coverage and/or benefits, HHS should give effect to the three primary provisions of the statute allowing an SPAP to evaluate part D plans for their

enrollees, to selectively "co-brand" with part D plans that they would recommend to their enrollees, and to decline to coordinate benefits, at its discretion, with one or more plan. HHS also should permit an SPAP, at its discretion to "facilitate enrollment" in plans appropriate for its beneficiaries, by creating its own process for "auto-enrolling" its beneficiaries. HHS should permit the SPAP to meet the non-discrimination requirement by (1) protecting an individual's right to choose plans by permitting the individual to disenroll and choose another plan, in a manner similar to that permitted for dual eligibles, so long as there is sufficient time for the individual to select another plan prior to the conclusion of the enrollment period, and (2) where an SPAP enrollee selects a part D plan where the SPAP has elected not to coordinate benefits, the SPAP can meet the non-discrimination requirement by ascertaining the "amount" of the benefit to be provided under the SPAP and arranging to make the amount payable as a premium subsidy and/or assistance with cost sharing to the part D plan elected by the individual. Such an approach is expressly consistent with the statutory language regarding non-discrimination, as well as the requirement that the Secretary, before July 1, 2005, establish a "lump sum per capital method" under which part D plans are required to coordinate the supplemental coverage provided to part D eligible individuals by an SPAP. SSA 1860D-23(a)(1) &(3).

Nothing in the MMA would prohibit the Secretary from permitting a state to pay a lump sum amount for supplemental coverage on behalf of one of its enrollees while providing other enrollees a special benefit package coordinated with one or more part D plans, so long as the "amount" of the supplemental coverage provided to the two groups is equal. SSA 1860D-23(b)(2). As is the case elsewhere under the MMA, vastly different benefit structures between two plans are regarded as the same, if they are demonstrated to have the same "actuarial value" to enrollees. *See, e.g.*, SSA 1860D-13(b)(5) (defining "actuarially equivalent" coverage as creditable coverage for purposes of protecting an individual from premium penalties imposed for late enrollment); SSA 1860D-2(c) (defining "alternative prescription drug coverage" as the actuarial equivalent of standard coverage).

Implications

It is clear that the statute does not prohibit the Secretary from allowing states to establish processes for "auto" enrolling their SPAP beneficiaries in plans that are co-branded, endorsed or otherwise selected by the SPAP, so long as there is an opt-out process to protect the individual's choice by selecting a plan other than that preferred by the SPAP, and so long as the State will meet the "non-discrimination" requirement by allowing the "amount" of the per person benefit provided through its preferred part D plan to be paid to a plan selected by the individual in the form of a premium subsidy and/or toward a reduction in cost-sharing imposed on the individual by the part D plan. Moreover, it is clear that Congress recognized that low income persons who depend on government subsidies – whether the subsidies are provided under federal or state law – may need special assistance in ensuring that the plan selected is appropriate to their ability to pay any excess premium or cost-sharing over the government subsidy. The best interpretation of the MMA, therefore, would be for HHS to expressly permit States to carry out activities that will maximally ensure that individuals are enrolled in appropriate part D plans, including their auto-enrollment in plans evaluated by the SPAP for purposes of effective coordination of benefits and payment of coverage on behalf of the individual.

I hope this analysis of the several provisions of the MMA is useful. Please call if you have questions or would like to discuss further.