The new drug benefit established by Part D of the Medicare Modernization Act (MMA) assures that all older and disabled persons have access to affordable prescription drug coverage and will subsidize many low-income persons who previously had no access to drug benefits through Medicaid or state pharmaceutical assistance programs. It also will result in significant changes in state programs that currently provide drug benefits to other populations. While the major decisions about the federal program’s design are now finalized and codified, there are many important decisions that states will make in the next few months regarding how state programs will adapt to the new MMA benefit.

States will see both significant savings opportunities (especially in their state pharmaceutical assistance plans [SPAPs] and retiree benefits; possibly in Medicaid) as well as significant new costs (especially in Medicaid) as a result of the Part D program. The decisions states make can affect both. Therefore, state legislators will need information and analyses about all the options and decisions before them.

However, the decisions made by state policy makers must not only reflect budget considerations, but also recognize the lead role that states have and always will have in providing a safety net to the poorest, frailest, and most vulnerable of our citizens. Related state policy decisions have the potential to influence the perceived success of the Part D program implementation. If states act to supplement and coordinate effectively with the Part D program, they may prevent future demands upon safety net services. Thus, the states have an essential role, complementing the federal role, to address the access and information needs of older and disabled persons who have Part D benefits, but who also rely, and may continue to rely, on various other state services.

Medicaid

The MMA makes its most sweeping impact on the Medicaid program, carving out the coverage of drugs for dual eligibles and transferring this responsibility to the Medicare program. Federal matching funds will no longer be available for Medicaid drug benefits provided to dual eligibles, except for drugs that are not included in the list of Part D drugs. However, the transfer of program responsibility is not a complete hand-off. The states are still largely financially responsible for the cost of drugs for dual eligibles, in the form of the “clawback.” “Clawback” is the popular term for the mandatory payment each state must make to the federal government toward the cost of Medicare drug coverage for the dual eligibles. The states must also establish new processes and enhance their infrastructure to accept and process applications for Part D low-income subsidies. In the course of processing these applications, they must screen for eligibility for Medicare savings programs available under Medicaid (QMB, SLMB, QDWI and Qi), thereby potentially discovering and enrolling significant new numbers of dual Medicaid/Medicare beneficiaries at new expense to the state. Additionally, states are assessing the impact of MMA on Medicaid cost containment initiatives and other programs such as disease management, drug utilization review, Medicare subsidies, and managed care benefit structures. While these requirements are finalized and will not likely be changed, states do have a number of opportunities to influence the effectiveness of the new Part D program and re-evaluate future Medicaid policy and program design decisions.

Access: As safety net providers, states want to assure that dual eligibles enjoy appropriate access to necessary medications after their transfer to a prescription drug plan (PDP). Because PDPs will have different formularies and prior authorization requirements than the Medicaid programs, as well as higher copays in some cases, some beneficiaries will face new barriers in obtaining needed medications. Although Medicaid programs cannot claim federal matching funds for coverage of copays or for Part D drugs not available under a PDP’s formulary, the states do have the option to use state funds to subsidize this access. Indeed, some Medicaid programs are considering
enrolling their duals into their state pharmaceutical assistance program (SPAP) as a vehicle for providing them such coverage. In addition, states may continue coverage of non-part D drugs (benzodiazepines, barbiturates, vitamins, over-the-counter drugs, etc.) under Medicaid and may receive federal matching funds for those costs.

The Centers for Medicare and Medicaid Services (CMS) has also indicated that pharmacies may waive copayments for dual eligibles at their own expense. Under federal Medicaid rules, in states that have Medicaid drug copayments, the pharmacists may not refuse to supply a prescription to a beneficiary who cannot afford the copayment. States may want to work with their state pharmacies to incentivize them to extend this same protection to dual eligibles enrolled in Part D plans. Alternatively, states may want to determine if they can extend their current mandates for pharmacists to serve those dual eligibles who cannot pay, even though the duals are covered by Part D plans.

**Education and Assistance:** Although CMS will be responsible for enrolling duals (voluntarily or randomly) into PDPs, there are likely to be many individuals who do not understand their benefits, who are enrolled in a plan not best suited to their needs, or who in some way need further assistance once they are initially enrolled. The final regulations enable dual eligibles to switch plans as often as they like, but many individuals may not recognize that they have this right, or that they may be able to gain access to a drug that is not covered by the PDP in which they initially enrolled. Furthermore, they may not have the technical ability to evaluate plan options against their personal needs in order to determine best fit. Similarly, the federal regulations provide for an exception and appeal process that enables enrollees to pursue coverage of a denied drug. But the process will be unfamiliar and the duals may need assistance to navigate their way through it. If the state does not establish a dedicated resource unit for providing such assistance, the duals will inevitably contact their case workers, case managers, and other state resource people in the Medicaid agency and elsewhere. Therefore, states may want to fund an education and assistance unit, especially during the early phase of transition to the new program in order to assure that beneficiary needs are met to the best degree possible. They may also want to coordinate their efforts with Area Agencies on Aging, State Health Insurance assistance Programs (SHIPs), and other non-profit organizations that provide outreach and information services to older and disabled populations.

In addition to educating and assisting members, the Medicaid agency and/or health department might also consider sending information to or holding seminars for other providers who will be affected by the Part D program. Nursing homes, Intermediate Care Facilities for Persons with Mental Retardation (ICFs-MR), and other residential treatment facilities will be affected by provisions pertaining to long-term care pharmacies and copayment exemptions for institutionalized dual eligibles. These facilities can and should play a role in assisting their clients to apply for subsidies, select PDPs, and effectively use the Part D benefits to which they are entitled.

### State Pharmacy Assistance Programs

State Pharmacy Assistance Programs (SPAPs) enjoy special treatment in the MMA and will reap savings as Medicare takes on primary payor status for many members. SPAPs have several options to consider in how they will coordinate with the Part D program in the future:

**SPAP Status:** In order to be recognized as an SPAP under the MMA, an SPAP:

- Must provide financial assistance for the purchase or provision of supplemental benefits, i.e., benefits that wrap around the Part D benefits,
- May not discriminate in the treatment of their enrollees based upon which Part D plan they enroll in, and
- Must meet coordination of benefits requirements related to the Part D plans as primary payors.

In exchange for meeting these requirements, SPAP payments of Part D deductibles and copayments are granted special treatment: they count towards “true out-of-pocket costs” (TrOOP). Note: SPAP payments for drugs not covered by the PDP’s formulary or for drugs not covered by Part D of Medicare do not count towards TrOOP, and therefore do not assist beneficiaries in reaching their catastrophic benefit level. Likewise, payments made by most other third party payors do not count towards TrOOP, however, payments made by relatives and bona fide charities, including patient assistance programs supported by pharmaceutical manufacturers, will count towards TrOOP.
Several states are considering whether the special treatment of their payments is sufficient incentive to give up their desire to auto-enroll all of their members into a preferred PDP, since CMS has indicated that such action would constitute “discrimination” and cause them to lose their bona fide SPAP status. Thus, the first option a state has is whether to continue its SPAP program as a recognized or unofficial SPAP under CMS rules. It should be noted that the decision to continue the SPAP as such could have a negative impact on the SPAP’s potential savings from the Part D program if the SPAP includes enrollees who are above the low-income subsidy levels. The loss of special status for SPAP payments as counting toward TrOOP will result in the delay of a member reaching the out-of-pocket threshold for catastrophic benefits. This delay in reaching federal catastrophic benefits will leave the SPAP’s responsible for continued higher copayments in an extended “donut hole.” Furthermore, CMS has indicated that it will not approve certain aspects of some of the specific proposals that states have considered as non-qualified SPAPs.

Enrollment Options: If an SPAP elects to be a bona fide SPAP under CMS rules, it may encourage or require its enrollees to enroll in a PDP of their choice and, if they fail to enroll voluntarily, the SPAP may randomly assign them to a PDP or evaluate which plan is best for each individual and enroll them accordingly. The SPAP may not, however, enroll everyone who fails to choose their own PDP into a single “preferred” PDP. This is considered a violation of the rule noted in SPAP Status above regarding discrimination.

Because the SPAP will be paying for some or all of the deductible, coinsurance, and “donut hole” that might apply to its enrollees, as well as potentially any non-formulary drugs not covered by the PDP, the SPAP has a financial interest in assisting its enrollees in obtaining the most extensive PDP coverage possible for the needs of each individual. Therefore, SPAPs may want to consider developing a tool for matching individuals to PDPs on the basis of their formularies and copayments, rather than simply randomly assigning people to plans.

Note that, regardless of how the SPAP decides to assist enrollees in signing up for a PDP, the state may want to pass legislation changing the eligibility rules for the SPAP to require SPAP enrollees who are eligible for Part D to enroll in Part D plans and apply for low-income subsidies as a condition of their SPAP enrollment. This will help to assure that the SPAP is reaping all of the possible savings from the Part D program.

Eligibility Applications for Low-income Subsidies: It is in the SPAP’s financial interest to get its enrollees promptly signed up for Part D low-income subsidies. Although SPAPs cannot make eligibility determinations, they can submit applications on behalf of their enrollees using the information they already obtained during the eligibility process. The Part D application also requires information about assets, so SPAPs will need to gather that information from their enrollees. To facilitate the application process, SPAPs will want to develop an information technology solution to map their eligibility information to the application form required by the Social Security Administration allowing the forms to be completed in an automated fashion.

Program Design: Each state can decide how it wants to design its program in relation to the Part D program. They have a variety of options, which all comport with federal requirements and enable SPAP payments to count towards TrOOP. Their options most simply are:

a. To continue as a full benefit plan and simply act as a secondary payor. This means they need not change their benefits and everyone enrolled in their program receives the same or better benefits in total than they received before Part D implementation. The SPAP simply deducts what the PDP paid from what the SPAP would otherwise pay. If the SPAP has an open formulary, it would pay when the PDP denies coverage of a drug that is not on the PDP formulary. The SPAP would also pay for “covered” drugs during the donut hole and deductible periods, and might pay part of the copayments due under the Part D plans, depending on the relative copayment structures of each plan.

b. To provide only “supplemental” or “wraparound” coverage, like a Medigap plan. This means they would pay only the copayments and deductibles for PDP-covered drugs, and would pay nothing for drugs denied by the PDPs.

c. To purchase wraparound coverage for SPAP enrollees from the PDPs and simply pay them an extra premium for covering copayments and deductibles, rather than processing claims directly as an SPAP.

d. To subsidize any beneficiary premium due for those beneficiaries who do not qualify for full federal Part D low-income premium subsidies. This would assist all SPAP beneficiaries to enroll in PDPs, but provide them no additional SPAP benefits.
e. A combination of the above options, in which the SPAP both subsidizes the PDP premium and also provides full or wraparound SPAP benefits.

**Use of Savings:** Because the SPAPs will have a significant portion of their previous benefit costs offset by Part D plan benefit payments, there will be program savings. Each state will need to decide how to use those savings. One state, for example, is considering expanding their SPAP program eligibility.

**SPAP Authority to Appeal:** If a state is planning to provide a full benefit and cover drugs that are denied by the PDP, then the state will want authority to act as the “authorized representative” of the enrollee for purposes of appeal. Indeed, even if the SPAP only plans to cover wraparound benefits, the SPAP may want the authority to appeal for lower copayments on behalf of beneficiaries whose only medication options are in a high copayment tier. The enrollees themselves may have no incentive to appeal if they can still get their drug covered at the SPAP benefit level, so the SPAP needs to be able to take the lead in pursuing an exception. States can either require each SPAP enrollee to sign a legal document designating the SPAP as their authorized representative or they can pass legislation designating the SPAP as such, with or without the enrollee’s signature.

**Mail Order Drug (MOD):** Most SPAPs do not allow their enrollees to obtain benefits through a MOD facility, as they are usually licensed out-of-state and the SPAPs usually only cover in-state pharmacies. Furthermore, most SPAPs do not cover three-month supplies typically provided by MOD facilities. States will need to decide whether to change their SPAP rules to allow their beneficiaries to obtain SPAP secondary coverage for MODs or extended supplies.

**Out-of-Network Benefits:** Although most SPAPs have virtually all in-state retail pharmacies in their networks, they typically do not cover out-of-state pharmacies or home infusion pharmacies. Many PDPs will cover a region that is larger than the SPAP’s state, and indeed some PDPs will be national in scope or will offer affiliated networks in other states for “snow birds.” In addition, PDPs are required to cover home infusion pharmacies. Thus, the PDP networks will likely have pharmacies that are not in the SPAP network. Again, states will need to decide whether to change their SPAP rules to allow their beneficiaries to obtain SPAP secondary coverage for out-of-state/out-of-network pharmacies and home infusion pharmacies.

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**Other State Agencies**

Other state agencies that serve the aged and disabled will inevitably feel the impact of the MMA in some fashion, as their clients adapt to using their new benefits. At a minimum, case managers and direct care workers in agencies such as the departments of Mental Health, Mental Retardation, Aging, and Health should be given some training about the new program and about where beneficiaries can go for help with enrollment, plan selection, premium subsidies, appeals, and benefit information.

In addition, programs serving high risk individuals such as persons with AIDS or mental illness, should be particularly alert during the transition phase for problems their clients may encounter in gaining access to their medications, since those medications may not be on the formularies of the new PDP in which a dual eligible or other beneficiary may find him or herself enrolled. Contingency planning may be appropriate to prevent breaks in therapy, including plans to make available short term supplies of certain medications while a patient exercises appeal rights.

State psychiatric hospitals should revise their discharge planning procedures to consider the availability of selected medications on an outpatient basis from each patient’s Part D plan. If a patient is being stabilized on a drug during their inpatient stay, it should either be confirmed as available for outpatient use or the hospital should complete the exception request process before the patient is discharged.

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**Program Evaluation**

Many states and advocacy groups will closely observe the ability of PDPs, most of whom have never traditionally served low-income populations, to ascertain their ability to sensitively serve the needs of low-income individuals. However, without documentation of patterns and trends, states may have little leverage in effectuating any necessary future policy adjustments. States are in a unique position to collect data as a collective consumer in a manner that any individual beneficiary could not do. For example, SPAPs will receive the same notices as CMS regarding formulary changes. Medicaid and the SPAPs will have information about which PDPs their clients enroll in and disenroll from. If either agency elects to pay for non-formulary drugs or copayments, they will have information about denials and cost sharing levels. If either
agency decides to assist beneficiaries to appeal or to appeal on their behalf, they will have information about the turnaround times and outcomes of exception requests and appeals. And, of course, the Medicaid agency and Department of Mental Health, for example, will have information about use of non-drug benefits that they offer to Part D enrollees. Given this access to information, states should consider funding the ongoing evaluation of the impact of the Part D program on state budgets and on beneficiaries’ access to care. The following data elements would be useful to monitor for purposes of future policy making:

- Number of claim denials for non-formulary drugs and other reasons, and the outcomes (e.g., were exceptions requested, were alternative drugs prescribed, did patients simply fill no prescription?)
- Turnaround times for exception decisions
- Frequency of enrollment changes to different PDPs
- Utilization trends in non-drug services that might indicate failure to follow drug regimens, such as Medicare cross-over claims for coverage of copayments, deductibles, or non-Medicare services
- Frequency of PDP formulary deletions
- Number of enrollees in Medicare savings programs

State Retirees

Like all employers, the states will be able to pursue federal subsidies for drug benefit costs for Part D eligible retirees who are covered by the retiree plan in lieu of a Part D plan. In order to collect these subsidies, states (or their health plan administrators) will need to certify that their plans are at least actuarially equivalent to Part D benefits and will need to report their benefit costs. The subsidy is equal to 28 percent of costs per retiree between $250 and $5,000. In other words, states can collect a per retiree subsidy of up to $1,330.

Employers, including states, may also pursue an alternative approach to maintaining their retiree benefits but collecting federal revenue: they may seek a waiver to become a PDP. As a waivered PDP, they would provide their usual retiree benefits as long as they are at least actuarially equivalent to Part D benefits, and they could collect federal premium subsidies and low-income subsidies like any other PDP. The waiver would exempt them from certain other PDP requirements, such as requirements related to the service area and enrollment of all applicants other than their own retirees.

Of course, a state may also decide to drop its retiree benefits entirely. Or states may require their retirees to enroll in Part D plans, including Medicare Advantage plans, and provide them only supplemental benefits, such as coverage during the donut hole. It is important to note, however, that such supplemental coverage will not count toward TrOOP and therefore will not assist the retiree in reaching the catastrophic benefit threshold.

States should conduct a fiscal analysis to determine which option yields the greatest savings and make choices accordingly.

For more information, follow these links:

- Centers for Medicare and Medicaid Services (CMS) at [www.cms.hhs.gov/pdps](http://www.cms.hhs.gov/pdps) or [www.cms.hhs.gov/medicare](http://www.cms.hhs.gov/medicare)
- Kaiser Family Foundation at [www.kff.org](http://www.kff.org)
- Academy Health (for state coverage initiatives) at [www.statecoverage.net/pdf/medicarepartd.pdf](http://www.statecoverage.net/pdf/medicarepartd.pdf)
Summary

The MMA has established an important new benefit for senior and disabled Medicare beneficiaries, thereby assuring their access to a full array of medical services. States have numerous policy decisions to make in implementing the Part D drug benefit, including several options to enhance the Part D program. These decisions must be made quickly in order to be ready for the January 1st, 2006 implementation date. As the safety net provider for many vulnerable individuals, the state’s choices on these matters are important to the future well-being of the elderly and disabled.

A brief summary of potential state actions and legislation includes:

**Medicaid**

- Cover non-Part D drugs, non-formulary drugs and/or copayments for dual eligibles.
- Incentivize or mandate pharmacies to waive copayments for dual eligibles that cannot pay.
- Establish a dedicated unit for education and assistance for dual eligibles related to plan selection, benefit use, and appeals.
- Re-evaluate existing and planned cost containment policies.
- Re-evaluate current DUR program structure and objectives.
- Re-evaluate disease and case management program structure and vendor contracts.
- Review current managed care program structure and benefit design.
- Review current and proposed LTC programs and alternative structures.

**State Pharmaceutical Assistance Plans**

- Become a bona fide SPAP within CMS rules or forfeit federal SPAP status.
- Mandate that SPAP enrollees apply for low-income subsidies and enroll in Part D plans, if eligible.
- Provide a mechanism to enroll eligible individuals in a Part D plan if they fail to do so voluntarily.
- Provide assistance to enrollees to apply for low-income subsidies.
- Revise current benefit design to become a wraparound or premium assistance program, or continue as a full benefit program.
- Use program savings to expand program benefits or eligibility.
- Designate the SPAP as the authorized representative for purposes of appeals.
- Amend program rules related to use of mail order drug services and out-of-network providers.

**Other**

- Fund training and education for other affected agencies.
- Fund contingency drug supplies for high risk patients.
- Fund a program evaluation to inform future policy decisions.
- Decide how to structure retiree drug benefits to produce savings.

For more information, follow these links:

- Centers for Medicare and Medicaid Services (CMS) at [www.cms.hhs.gov/pdps](http://www.cms.hhs.gov/pdps) or [www.cms.hhs.gov/medicare](http://www.cms.hhs.gov/medicare)
- Kaiser Family Foundation at [www.kff.org](http://www.kff.org)
- Academy Health (for state coverage initiatives) at [www.statecoverage.net/pdf/medicarepartd.pdf](http://www.statecoverage.net/pdf/medicarepartd.pdf)

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