MANATT HEALTH SOLUTIONS

Filling the Gaps: Medicaid, EPIC and ADAP and the Medicare Prescription Drug Benefit in New York

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Executive Summary

Implementation of the new Medicare Part D prescription drug benefit (Part D) on January 1, 2006 reduced out-of-pocket costs and expanded access to medications for many Medicare beneficiaries. However, for millions of beneficiaries across the nation who relied on state-based pharmacy programs, the implications have been more complex. Because the Part D benefit is less comprehensive than the benefit offered by many state-based programs, and because these state-based programs serve low income and medically needy populations, state policy-makers have been faced with a series of complex decisions about how state programs should operate within the context of the new federal Medicare benefit.

The purpose of this paper is to examine the ways in which three New York State-based programs – Medicaid, Elderly Pharmaceutical Insurance Coverage (EPIC), and the AIDS Drug Assistance Program (ADAP) – are interacting with the new Medicare prescription drug benefit. Based on interviews with senior program officials and consumer advocates, and independent research, the paper finds that the three state-based programs have played important roles in filling prescription drug coverage gaps for vulnerable Medicare beneficiaries during this first year of the Medicare drug benefit.

The paper also finds, however, that limited and at times conflicting federal guidance, as well as fragmented state policy-making, has resulted in a lack of coherence across state programs. The three state programs have developed different approaches to the Part D benefit, including the extent to which they fill cost-sharing and formulary gaps in Part D coverage; the extent to which the programs require or encourage Part D participation for eligible enrollees; their outreach and education efforts related to Part D; and their efforts to mitigate disruptions in care coordination as a result of the new drug coverage.

The paper concludes with a series of recommendations.

- As long as there are significant gaps in Part D coverage, the state pharmacy programs should continue to offer comprehensive wrap-around benefits for Part D beneficiaries. Medicaid particularly should continue its formulary wrap-around beyond December 31, 2006.
- Policy-makers should consider changes to the state pharmacy programs that will make coverage more equitable across populations and target state funding based on program enrollee needs and resources. Medicaid-Medicare "dual eligibles" receive less comprehensive coverage than either EPIC enrollees or non-dual eligible Medicaid enrollees.
- The three state pharmacy programs should collaborate more closely on key program management and monitoring issues. Specifically, the three programs should share information on best practices, create a single centralized resource to provide appeals assistance and information for Part D enrollees, and, where appropriate, negotiate and communicate collectively with the Centers for Medicare and Medicaid Services ("CMS") regarding Part D-related initiatives.
- All three state programs should play a role in automatically recommending or

assigning beneficiaries to a Part D plan best suited to their prescription drug needs, with opportunities for beneficiaries to opt for another plan choice.

- The State should seriously consider requiring that all EPIC enrollees participate in Part D, and it should pay for EPIC enrollees' Part D premiums. ADAP and Medicaid already require Part D enrollment as a condition of eligibility. Such a requirement for EPIC could significantly reduce state costs.
- In the absence of federal leadership, state policy-makers should make a focused and coordinated effort to collect and analyze prescription drug data for state program enrollees, in order to monitor and improve the quality of care provided to Part D beneficiaries.

Introduction

In 2005, more than 500,000 very low-income or medically needy Medicare beneficiaries ("dual eligibles") in New York received prescription drug coverage through Medicaid; nearly 400,000 received drug coverage through the Elderly Prescription Insurance Coverage (EPIC) program; and about 1,500 received prescription drug assistance funded through the AIDS Drug Assistance Program (ADAP). While each program had its own complex eligibility, coverage and cost-sharing policies, as a general matter, all three programs provided generous drug coverage for enrollees.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act" or "MMA"), created a new Medicare prescription drug benefit, Medicare "Part D," that makes drug coverage available to beneficiaries through private prescription drug plans. While the new benefit has made prescription drugs more affordable for many beneficiaries,[1] the standard Part D benefit is not comprehensive. Part D plans use limited drug formularies, limited pharmacy networks, and substantial utilization management tools that may restrict coverage of prescribed medication. In addition, certain commonly-prescribed medications are excluded from Part D coverage altogether, including benzodiazepines and barbiturates. Most Part D plans also charge monthly premiums, deductibles, and cost-sharing for covered drugs, and all but a handful (which charge supplemental premiums) feature an annual coverage gap, or "donut hole," of nearly three thousand dollars in 2006. Many low-income beneficiaries are eligible for subsidies that significantly reduce Part D cost-sharing and eliminate the coverage gap, but beneficiaries who receive the subsidies are still subject to formulary and pharmacy network restrictions.

Since Congress began considering the MMA, state and federal policymakers have been debating what role, if any, state-based prescription drug programs[2] should play for Part D-eligible beneficiaries. Some have argued in favor of a continued robust role for these programs, noting the limited coverage Part D provides; the difficulties that vulnerable populations could face in changing prescription drug coverage; and the need for outreach, education, and care coordination. Others have argued for a reduced role for state-based programs with Part D implementation, noting that the federal benefit equalizes coverage nationwide, that it can relieve some states from ongoing funding obligations, and that state-based programs' continuing operations have the potential to distort the marketplace for Part D plans.

Reflecting these policy tensions, the MMA and implementing regulations provide varying and occasionally inconsistent rules on the role that state-based drug programs may (and may not) play for their Medicare enrollees. For example, state Medicaid programs are not permitted to fill in Part D coverage gaps with Federal financing, while ADAP programs are permitted to use federal funds. State Pharmacy Assistance Programs (SPAPs) like EPIC received significant subsidies from the federal government for Part D-related outreach activities, while ADAP and Medicaid received no such funding.

Within these and similar federal guidelines, many issued informally from the federal Centers for Medicare and Medicaid Services (CMS), state policy-makers have substantial discretion to decide how state programs will interface with Part D coverage. States have utilized different approaches. Some state programs have eliminated prescription drug

coverage for Medicare beneficiaries as soon as the federal Part D coverage became available. Others have tried to hold program enrollees harmless from any changes in their drug coverage by providing robust wrap-around benefits. In comparison with other states, New York's prescription drug programs have generally provided generous continuing prescription drug coverage for Medicare beneficiaries. Appendix II includes some information on policies from other states.

To complicate matters further, both federal and state policies relating to the roles of state-based pharmacy programs underwent significant changes in the early months of Part D implementation. Systems, data and enforcement problems plagued the program, putting many low-income beneficiaries at risk.[3]

In the face of a crisis, federal policymakers encouraged a more significant state role in filling drug benefit gaps. In New York, policymakers committed substantial resources to providing temporary "emergency coverage" through Medicaid for dual eligibles, which effectively provided a full formulary wrap-around.

The purpose of this paper is to examine the different ways in which three New York State programs – Medicaid, EPIC, and ADAP – are interacting with the new Medicare prescription drug benefit. The following sections compare the programs' different approaches to "wrapping around" Part D formularies and cost-sharing requirements; the extent to which the programs require or facilitate Part D participation for eligible enrollees; their outreach and education efforts related to Part D; and their efforts to mitigate disruptions in care or access as a result of the new drug coverage. The paper concludes with a series of observations and recommendations for creating a more equitable, coordinated and coherent framework that meets the needs of existing beneficiaries, realizes the value of the Part D benefit, and maximizes the impact of available state resources on vulnerable beneficiaries. The recommendations assume no significant changes or expansions in the underlying federal benefit. Some of the recommendations could be adopted under existing state program authorities; others would require new state legislation.

Overview of Benefits Provided Under Medicare Part D and State Programs in New York

Under the MMA, the Medicare prescription drug benefit is available to all Medicare beneficiaries who enroll in private prescription drug plans (PDPs) approved to offer the new drug coverage, or in Medicare Advantage plans, (MA-PDs), which offer drug coverage as well as other Medicare benefits through private managed care arrangements. For 2006, in most regions of the country, including in New York, beneficiaries have a choice of more than 40 stand-alone PDPs and dozens of MA-PDs.

The new Medicare drug benefit, though a significant expansion in Medicare coverage, has significant gaps and limitations when measured against many state prescription drug programs. The following sections describe the standard Medicare Part D benefit, comparing the program to three New York programs (Medicaid, EPIC and ADAP), specifically with regard to cost sharing requirements, formulary limitations and pharmacy networks.

Table 1: **Key Features of Part D and NYS Prescription Assistance Programs in 2006**

	Medicare Part D (No Low Income Subsidy (LIS))[4]	Medicare Part D (With Low Income Subsidy)	NYS Medicaid Pharmacy Benefit	NYS Elderly Pharmaceutical Insurance Coverage (EPIC)	NYS AIDS Drug Assistance Program (ADAP)
Eligibility	Open to everyone who qualifies for Medicare Part A or B – based on age or disability.	Medicare-eligible individuals with low incomes and assets.	Open to various populations of low income and high-needs individuals.	Open to non-Medicaid eligible seniors, with incomes below a certain threshold ($35,000 if single).	Open to HIV-positive individuals with incomes below a certain threshold ($44,000 if single).
Premiums	Vary by plan. Average $386 annually in 2006.[5]	Lower income/asset enrollees (<135% of FPL, < $6000 assets/single) pay no premiums. Those with slightly higher incomes/assets pay premiums on a sliding scale.	None	Enrollees with incomes below a certain threshold ($20,000 if single) pay an annual fee on a sliding scale. This fee ranges from $8 to $230.	None
Deductibles	Standard federal benefit has initial $250 deductible, and a gap in coverage when total drug costs are between $2,250 and $5,100.	None for most LIS enrollees. Those with slightly higher incomes/assets pay a $50 annual deductible.	None	Higher income enrollees (up to $35,000, if single) pay an annual deductible, on a sliding scale that ranges from $530 to $1,230.	None
Copayments	25% copay when total drug spending is between $250 and $2,250 and a 5% copay when total drug spending is greater than $5,100.	Sliding scale. $1 – $5 per prescription for most LIS enrollees. Higher income enrollees pay up to 15%. Copays are eliminated or limited once total spending exceeds $5,100.	$3 per prescription if brand name, $1 if generic, capped at $200 annually.	Vary from $3 to $20 per prescription, depending on total price of drug; sliding scale cap $291 – $1,160 (single).	None
Formulary	Varies by plan. Must include drugs within each therapeutic category, and all drugs in 6 special categories. Certain drug categories are excluded from coverage, including barbiturates and benzodiazepines.	Identical to standard Part D benefit.	Comprehensive	Comprehensive	Limited to approximately 500 drugs frequently required by HIV/AIDS patients.
Pharmacy Network	Varies by plan.	Identical to standard Part D benefit.	Includes most pharmacies within New York State.	Includes most pharmacies within New York State.	Includes 3,000 pharmacies statewide.

Costs to Beneficiaries

While overall, the Part D benefit lowers the costs of prescription drugs for many Medicare beneficiaries, the "standard" benefit requires substantially greater beneficiary cost-sharing than the cost-sharing required under New York's state programs. Subsidies for certain low-income beneficiaries, including all dual eligibles and many EPIC and ADAP enrollees, reduce Part D cost-sharing significantly.

Medicare Part D

The MMA's standard benefit requires significant cost-sharing for most beneficiaries, including, in 2006, premiums that average about $25/month, a $250 deductible, 25 percent coinsurance for the first $2,250 in covered drug spending, 100 percent coinsurance (or no coverage) for the next $2,850 in covered drug spending (which creates the so-called "donut hole," or "coverage gap"), and then up to 5 percent coinsurance once an individual has hit a catastrophic cap on spending. The catastrophic cap on beneficiary spending is only triggered when a Part D enrollee spends a certain amount on covered drugs out of his or her own pocket. This "true out-of-pocket" limit, or "TrOOP," means that payments made by third party payers for Part D drugs generally do not count toward helping the individual move out of the Part D coverage gap, or donut hole. Premiums, deductibles, cost-sharing, and the duration of the coverage gap are all indexed to drug spending growth, and therefore are expected to increase each year.

Many Part D plans offer alternative coverage to the Part D standard benefit, with different cost-sharing arrangements including the use of fixed copayments instead of coinsurance and reduced deductibles. However, this alternative coverage is required to be actuarially equivalent to the standard coverage. Some plans also offer "enhanced" coverage, which may include partial or total coverage in the donut hole. These plans must charge beneficiary premiums to finance these more generous benefits (except MA-PDs, which may use savings from other health care benefits).

Table 2: **Cost Sharing Under Standard Part D Benefit**

Total Annual Drug Costs	Enrollee Share
<$250	Enrollee pays 100% (Deductible)
Between $250 and $2,250	Enrollee pays 25% copayment
Between $2,250 and $5,100	Enrollee pays 100% ("Donut Hole")
>$5,100	Enrollee pays 5% copayment (Catastrophic Coverage)

Many of the cost-sharing requirements in standard Part D coverage are eliminated for certain low-income beneficiaries through federal "Low-Income Subsidies" (LIS) or "Extra Help." For beneficiaries with limited incomes (below approximately $13,000 for individuals in 2006) and assets ($6,000, not including home or car), these low-income subsidies pay

premiums for average and low-cost "standard" plans; they eliminate plan deductibles and the donut hole; and they reduce beneficiary copayments to no more than $5 per prescription. Beneficiaries with slightly higher incomes or assets up to $10,000 per individual also receive significant assistance with standard Part D cost-sharing.

"Dual eligible" beneficiaries – those eligible for Medicare and also enrolled in Medicaid – are automatically enrolled to receive the LIS. Most other low-income beneficiaries have to apply to the Social Security Administration to receive the subsidies and then enroll in a PDP to effectuate drug coverage. Depending on state program eligibility limits, many or most SPAP and ADAP enrollees may be eligible for LIS.

New York State Programs

Cost-sharing requirements vary significantly for individuals enrolled only in New York's state prescription drug programs. Under Medicaid, cost-sharing is limited to $3 per prescription and capped at $200 per year, and providers, including pharmacies, are not permitted to withhold items or services if a Medicaid enrollee is unable to pay the copayment.

Lower-income EPIC enrollees are eligible for EPIC's "fee" plan, which requires payment of an annual income-based fee of up to $230/year for prescription drug coverage. The "deductible" plan, for enrollees with incomes over $20,000/year for an individual, requires enrollees to meet a deductible of up to about $1,200 before EPIC drug coverage is activated. EPIC covers virtually all prescription drugs once fee or deductible requirements are met, charging copayments ranging from $3 to $20 per prescription depending on the cost of the drug.

ADAP provides coverage for individuals who are HIV positive or living with AIDS and have incomes below about $44,000 (for an individual). ADAP covers the full cost of drugs and does not require copayments.

Formularies

Medicare Part D

Under Part D, private PDPs are given substantial discretion to set formularies, networks, and utilization management rules. PDPs may establish limited formularies, or lists of covered drugs, as long as there are at least two in each therapeutic category or class, and as long as they otherwise meet the formulary review requirements established in federal guidance.[6] PDPs generally are prohibited from covering "excluded drugs," however, including benzodiazepines, barbiturates, vitamins, and medicines for the symptomatic relief of cough and colds. PDPs also are encouraged to establish utilization management tools, like prior authorization, step therapy, tiered copayments and dosage limits.

Part D provides important protections to help beneficiaries obtain needed prescription drugs even if they are not on their plans' formulary or are covered on a formulary tier that requires high cost-sharing. These include appeals rights, a mandatory "transition process," and required coverage of most drugs in six special classes. A beneficiary may appeal for coverage of a drug (other than an "excluded drug,") that is not covered by his or her PDP's formulary, or is covered but is in a "non-preferred" tier with high cost-sharing. Appeals must include a doctor's supporting statement indicating why that drug is necessary or why other drugs that are covered by the PDP would either be less effective or harmful to the patient.[7] Furthermore, Part D plans are required to establish "transition policies" that guarantee short-term coverage for even non-

formulary medications that a new enrollee has been stabilized on, giving the enrollee an opportunity to seek coverage permanently through an appeals process or to discuss with a provider switching to a different medication.[8] Finally, PDPs are required to cover "substantially all" drugs in six therapeutic categories, and plans are limited in the type of utilization management techniques they can use to limit access to these drugs. The categories include antidepressants, anti-neoplastics (anti-cancer drugs), anti-retrovirals, anti-convulsants, antipsychotics, and immunosuppressants.[9]

New York State Programs

Medicaid's prescription drug benefit is very comprehensive, covering almost all FDA-approved drugs. While certain drugs are subject to "prior approval" under the state's Preferred Drug List policies, which means that providers have to seek Medicaid approval before a pharmacy can dispense the drugs, those drugs are still provided once approved.[10]

EPIC's formulary is similarly comprehensive. A very small number of drugs are excluded, including those manufactured by companies that do not participate in EPIC's rebate program and a small handful of Drug Efficacy Study and Implementation ("DESI") drugs, which were developed before 1962 and have only partial FDA approval.

ADAP provides coverage for approximately 480 drugs on its formulary, most of which are therapies or prophylaxes for symptoms and conditions that commonly afflict people who are HIV positive or living with AIDS.

Pharmacy Networks

Most PDPs use networks of pharmacies that, although they must meet access standards, are at least somewhat limited. Drugs dispensed at an out-of-network pharmacy are not eligible for Part D coverage unless there is a special reason that the beneficiary could not use an "in-network" pharmacy at the time. Medicaid, EPIC and ADAP are accepted at almost all New York State pharmacies.

New York State Programs' Interaction with Part D

Under the MMA, different kinds of state-based pharmacy programs are subject to varying rules and treatment. Between enactment of the MMA in late 2003 and implementation of the new Part D benefit in 2006, policy makers in New York have had to consider whether, and to what extent, the Medicaid, EPIC, and ADAP programs would continue to provide a prescription drug safety net for enrollees who are also Medicare beneficiaries. Initial program changes have been followed by continuing modifications well past January 2006, as each program has had to adapt quickly to changing circumstances resulting from problems with Medicare's eligibility and enrollment systems, rapidly changing mandates from federal agencies and the state legislature, and feedback from program enrollees and their advocates.

Early implementation problems with Part D have had a significant impact on enrollees, especially "dual eligibles" who were losing Medicaid coverage. Problems included pharmacies unable to identify Part D plan assignments and therefore unable to seek reimbursement for prescribed drugs; systems incorrectly identifying low income subsidy status, so individuals were being charged inappropriately high cost-sharing; inadequate implementation of transition policies and appeals processes resulting in non-coverage of needed prescription drugs; Part D plan changes not effectuated, leaving some individuals in

multiple plans and some in no plans when they exercised their rights to change; and long waits for assistance from Part D plans and Medicare help hotlines.[11]

The following section describes some of the federal statutory provisions and administrative guidance that has been provided for each category of state programs: Medicaid, SPAPs and ADAP. It then details the policies New York State's programs have arrived at within these guidelines, with particular emphasis on four major issues: wrap-around benefits, enrollment, outreach, and exchange of data.

The findings and descriptions of this section are based on interviews with senior program officials with Medicaid, EPIC, and ADAP and consumer advocates who work closely with clients to navigate the intersection of these programs with Part D; as well as direct research into federal and state policies.

Table 3: **Federal Policies Regarding State Pharmacy Programs and Medicare Part D**

	Medicaid	State Pharmacy Assistance Programs (SPAPs)	AIDS Drug Assistance Programs (ADAPs)
Part D Enrollment	Mandatory	Not Mandatory	Mandatory
Funding for Wrap-around	No federal funding is allowed, except for "excluded" drugs.[12]	N/A (state-only funded benefits)	Federal funding is allowed.
Federal Funding for Outreach	None	Received $125 million for outreach in 2004 and 2005	None
TrOOP Status	State spending on dual eligibles does not count toward TrOOP limit.[13]	SPAP spending toward copayments counts towards TrOOP limit.	ADAP spending does not count towards TrOOP limit.
Use of State Savings	Most state savings from Part D are returned to federal government through "clawback."	State programs keep any savings from participants enrolling in Part D.	State programs keep savings from participants enrolling in Part D.

Medicaid

Before implementation of the MMA, state Medicaid programs generally provided comprehensive prescription drug coverage, as well as other health care coverage, to low-income beneficiaries. For "dual eligibles" – Medicaid beneficiaries who also are enrolled in Medicare - Medicaid helped fill the gaps of Medicare's more limited health benefits by paying Medicare cost-sharing and providing "wrap-around" coverage for services only Medicaid covers, including, until 2006, outpatient prescription drugs. Medicaid coverage is financed by both state and federal funds, with a federal matching formulary that varies by state.

Federal Medicaid Policy

Under the MMA, "dual eligibles" enrolled in both Medicare and Medicaid lost Medicaid prescription drug coverage and were enrolled

in Medicare Part D coverage as of January 1, 2006. Those dual eligibles who did not select a plan were automatically enrolled into Medicare PDPs – at random from among "benchmark" PDPs whose premiums were at or below a certain level – and to receive Low Income Subsidies.

The MMA prohibits state Medicaid programs from using federal matching funds to pay for any of dual eligibles' prescription drugs costs after January 1, 2006, with one narrow exception – federal matching funds are available for the cost of Part D excluded drugs. However, in the early weeks of Part D, it appeared that many, perhaps hundreds of thousands of dual eligibles, had fallen through the cracks of the transition and were having serious difficulties accessing needed prescription drugs.[14] After several states, including New York, authorized temporary emergency Medicaid drug coverage for dual eligibles to avert public health crises, CMS established a demonstration program that would permit federal reimbursement for emergency coverage for dual eligibles. CMS offered to repay states the costs of Medicaid coverage for dual eligibles for the period between January 1, 2006, and March 31, 2006.[15]

The MMA requires state Medicaid programs to contribute financially toward the cost of covering dual eligibles under Part D, through a controversial financing formula commonly called the "clawback." The amount of the clawback payment is based on a formula that attempts to calculate a state's potential savings from no longer having to provide outpatient prescription drug coverage to their dual eligible enrollees. New York State will be required to pay $705 million in the first year in "clawback" payments to the federal government.[16]

State Medicaid programs are not prohibited under Federal law from filling Part D gaps, including paying Part D copayments, providing coverage for off-formulary drugs, or providing coverage for drugs purchased at out-of-network pharmacies. However, the MMA framework discourages this kind of assistance. Under the statute, Medicaid programs cannot receive any federal matching funds for filling these gaps; doing so does not reduce their financial responsibilities under the "clawback;" and Medicaid's contributions do not count toward beneficiaries' TrOOP limits.

State Medicaid programs also are required under the MMA to assist the federal government in administering, the new Part D benefit. For example, state Medicaid programs are required to identify dual eligibles and individuals likely to become dual eligibles on a monthly basis and provide the information to CMS in a standardized format. While Medicaid programs may receive federal matching funds to help offset some of the administrative costs related to these tasks, these matching funds cover only a portion of the costs incurred. Medicaid programs generally do not receive any additional money from the federal government to engage in outreach, troubleshooting, advocacy, or education of dual eligibles who were transferred into Part D plans.

New York's Medicaid Program

New York's Medicaid program is administered by the state Department of Health (DOH) and in 2005, covered 4 million New Yorkers, including almost 500,000 dual eligibles. In New York State, Medicaid is financed roughly 50% by the federal government and 50% by New York State and its county governments.

"Wrap-around" Benefits

Despite federal restrictions prohibiting the use of federal Medicaid funds to supplement Part

D coverage, New York Medicaid initially planned to use state funds to provide a limited prescription drug safety net for transitioning dual eligibles.[17] On the eve of Part D implementation, New York's Medicaid program had budgeted $400 million to provide limited "wrap-around" coverage for dual eligibles who would voluntarily enroll or be automatically enrolled into Part D plans by CMS. The original wrap-around coverage consisted of the following:[18]

- Continued coverage of benzodiazepines, barbiturates, limited over-the-counter drugs that were "excluded" from Part D coverage;
- Coverage for dual eligibles of "off-formulary" drugs, AFTER submission of evidence by prescribing providers that Part D coverage had been pursued to the "coverage determination" level and rejected by the PDP,[19] and in compliance with New York's Preferred Drug List policies;
- Continued coverage with Medicaid as primary payer until the dual eligible was actually enrolled in a Part D plan.

New York was one of only a handful of states that planned to provide Medicaid coverage for dual eligibles for drugs that were not on Part D plan formularies using state-only funds.[20]

As it became clear in the first weeks of 2006 that system glitches in Part D implementation were depriving thousands of dual eligibles of access to needed prescription drugs, the legislature reversed course and, on an emergency basis, passed legislation permitting pharmacies to continue billing Medicaid for prescription drugs for dual eligibles.[21]

Initially, under emergency coverage, pharmacists could bill Medicaid without proof that the beneficiary had first tried to bill a Part D plan for that drug. By mid-February, 2006, DOH implemented a new system which required pharmacists to bill Part D plans and receive a claim denial before they could bill Medicaid.[22] State officials indicated that this new "claim denial" requirement, which streamlined the wrap-around process and allowed dual eligibles to secure coverage for their drugs at the pharmacy point of sale, would replace the "coverage determination denial" requirement initially implemented with New York's wrap-around.[23]

State officials planned to eliminate the formulary wrap-around coverage on July 1, 2006, but at the end of the 2006 legislative session, the New York legislature modified the Part D wrap-around yet again.[24] It continued the "claim denial" formulary wrap-around for New York's dual eligibles through December 31, 2006. Beginning on January 1, 2007, according to this legislation, the Medicaid wrap-around coverage will be available only for Part D "excluded" drugs and for drugs in four special categories – atypical antipsychotics; immunosuppressants for individuals who have received organ transplants; antidepressants; and anti-retrovirals used in the treatment of HIV/AIDS.

Enrollment

Consistent with federal law, New York has made enrollment in Part D plans a condition of eligibility for other Medicaid benefits for dual eligibles.[25] New York also provides extra protection not required by federal law by continuing Medicaid prescription drug coverage for dual eligible individuals who have a lag between identification as dual eligibles and actual enrollment in Part D plans.

Unlike some state Medicaid programs, however, New York does not play a role in the selection of or enrollment into Part D plans for dual eligibles. New York's dual eligibles are

automatically enrolled into Part D plans at random from among "benchmark" plans whose premiums are at or below specified levels through a federal assignment process. (Dual eligibles retain the right to switch Part D plans at any time.) As Medicaid beneficiaries become eligible for Medicare Part D, New York Medicaid does not compare their drug and pharmacy historic utilization to available Part D plan formularies and pharmacy networks or make recommendations on plan selection to individual dual eligibles – a process sometimes referred to as "intelligent random assignment," or IRA. One official explained that the Department of Health had considered doing so but was discouraged by CMS; officials also were concerned that available software to make the plan selections was not nuanced enough to ensure good plan recommendations. New York also does not facilitate the enrollment of dual eligibles into Part D plans when a dual eligible falls through the cracks of the federal auto-assignment process.

Outreach

Despite a lack of allocated funding for the purpose, Medicaid has hired four staff to focus specifically on Part D issues.[26] Medicaid has:

- sent numerous mailings to dual eligibles informing them of changes to their prescription drug coverage, to the availability of emergency Medicaid coverage, and impending changes in wrap-around coverage;
- conducted numerous presentations about Part D/Medicaid interactions;
- communicated with providers and pharmacies about changes in Medicaid coverage through existing provider newsletters and hotlines; and
- engaged in surveys and monitoring of Part D plans to determine whether plans are providing the coverage that their marketing materials and Part D regulations require.

On an *ad hoc* basis, the Medicaid program also serves as an occasional conduit to the CMS regional office for beneficiary and advocate questions and complaints.[27] However, it does not provide a hotline number or otherwise publicize its troubleshooting role in communications with dual eligibles.

Coordination/Data Exchange

Before Part D implementation, Medicaid maintained significant data on dual eligibles' drug and pharmacy utilization, and it engaged in a robust utilization review program to analyze clinical effectiveness and ensure against program fraud.[28] Medicaid did not share any utilization information with Part D plans, which could have used the information to ensure compliance with CMS' formulary transition requirements for dual eligibles who were stabilized on a particular drug regimen, citing a concern that sharing the information might violate federal and state privacy laws.[29] Moreover, to date, New York Medicaid has not been able to secure access to Part D drug utilization information for its dual eligibles, though efforts are underway to seek that information voluntarily from Part D plans with the assistance of CMS.[30] Medicaid officials cited a need for the utilization information to facilitate disease management programs for dual eligibles, to do Part D plan monitoring in connection with the formulary wraparound, and for other care management purposes.

State Pharmacy Assistance Programs (EPIC)

Before the implementation of Medicare Part D, SPAPs operated in roughly half of states and generally offered prescription drug coverage to low-to-moderate income Medicare beneficiaries, or subsets of Medicare

beneficiaries, using state-only funding. The size of the programs and the generosity of the prescription benefits varied significantly among states. New York's EPIC program is the largest and one of the most comprehensive SPAPs in the nation.

Federal SPAP Policy

Unlike its treatment of Medicaid programs, the MMA contains numerous incentives for SPAPs to continue playing a role in supplementing the Part D benefit for dual enrollees. In addition to special statutory treatment, SPAPs have received additional support for continuing their role from CMS in regulations and informal guidance.

Though many SPAP programs were expected to save considerably once the Part D benefit began, the MMA does not require SPAPs to contribute to Part D coverage for SPAP enrollees – that is, there is no requirement similar to Medicaid's "clawback" requirement – nor is there any maintenance of effort policy that would require SPAPs to expand their programs to other populations or otherwise. Furthermore, SPAP contributions to supplement Part D coverage are treated preferentially – SPAP contributions to copayments, including when enrollees are in the "donut hole," count toward beneficiaries' TrOOP limits. SPAPs also were given a total of $125 million in Transitional Grant Distribution Awards in the two years prior to implementation of Part D to facilitate education and outreach to enrollees.

The MMA contains an "anti-discrimination" provision that provides that SPAPs may not steer SPAP enrollees into one or a limited number of PDPs, and CMS guidance further requires that SPAPs provide equal supplemental coverage to their enrollees, regardless of which PDP they enrolled in.[31] However, CMS has become more flexible in its interpretation of this provision over time, allowing several SPAPs to auto-enroll their participants into a limited number of PDPs and to provide wrap-around coverage or premium assistance for a limited number of PDPs.[32]

New York's EPIC Program

EPIC, New York State's SPAP, covers nearly 400,000 seniors. The program is fully state-financed and is implemented by the New York State Department of Health. Virtually all EPIC enrollees also have health coverage through Medicare, though individuals with full Medicaid benefits and those who are eligible for Medicare on the basis of disability, rather than age, are not eligible for EPIC.

As a "qualified SPAP" under the MMA, EPIC has been encouraged by the federal government to continue providing prescription benefits to Part D enrollees. Although some states elected to discontinue benefits under their SPAPs for enrollees who were eligible to enroll in Medicare Part D, EPIC continued its commitment to enrollees, promising from the outset a generous Part D wrap-around benefit.

Because of these generous wrap-around policies, EPIC enrollees generally did not experience severely impaired access to prescription drugs during the early months of the Part D benefit. And as early Part D implementation problems have slowly been addressed, EPIC has taken a more proactive role encouraging its participants to enroll in Part D and LIS.

Wrap-around

From the outset, EPIC promised to maintain at least the same level of prescription drug assistance to its enrollees, regardless of whether they enrolled in Part D.[33] For participants who choose not to enroll in a Part D plan, EPIC coverage continues essentially unchanged.[34]

For enrollees who elect to enroll in Part D, EPIC provides full wrap-around coverage. "Full wrap-around" coverage includes coverage of "off-formulary" drugs, "excluded" drugs, drugs that are subject to Part D prior authorization/utilization management tools, and drug expenses incurred while enrollees are in the "donut hole" for those who do not have LIS coverage.[35]

EPIC provides assistance with Part D copayments according to EPIC's existing schedule – the Part D required copayment is considered the "cost" of the drug to EPIC, and copayments are assessed on that basis. For example, if a drug's retail cost is $100, and an EPIC participant's Part D plan charges a $40 copayment, the beneficiary would pay $15 of that copayment and EPIC would pay $25.

EPIC requires the use of Part D coverage as primary payer for participants who have Part D coverage, but it has only recently, in August 2006, enforced the requirement that pharmacists bill Part D for drugs (for those EPIC enrollees who have Part D coverage) before billing EPIC.[36] EPIC encourages the pursuit of Part D coverage through the coverage determination process, but it provides immediate, point of sale coverage whenever Part D coverage is denied for an EPIC-covered drug.

Enrollment

EPIC encourages, but by state statute is not permitted to require, its participants to enroll in Part D plans. EPIC waives its fees for individuals who are enrolled to receive full Part D LIS, and it advertises the copayment advantages of combining EPIC and Part D coverage. However, unlike many other SPAPs, EPIC does not pay for Part D premiums for all or any subset of its enrollees.[37] Officials indicated that they had not yet determined whether paying Part D premiums and providing a formulary wraparound would be cost-effective for all EPIC participants.[38]

Legislation passed in the 2006-07 state budget authorizes EPIC to initiate a more aggressive effort to enroll low-income EPIC participants in Part D plans. As a result of that legislation, EPIC participants who may be eligible for the Part D LIS are required, as a condition of continued EPIC eligibility, to provide EPIC with information about their income and assets that is sufficient for EPIC to help complete and submit an application for LIS on participants' behalfs. For those who are approved by SSA for the full LIS subsidy, EPIC is authorized to facilitate their enrollment into a Part D plan using an "intelligent random assignment," or IRA, process. That process involves using EPIC participants' data – primarily related to drug and pharmacy utilization – and comparing it against the formularies and pharmacy networks of available "benchmark" Part D plans to select the most appropriate plan for the individual and to facilitate his/her enrollment into that plan. A key feature of the enrollment process, however, is that EPIC participants can decline or disenroll from the selected plan at any time, without any penalty.[39]

This LIS application and automatic enrollment process is currently underway for 70,000 EPIC participants.

Higher income EPIC enrollees remain free to decide whether or not to enroll in Part D plans and have no data reporting or other Part D-related requirements to stay enrolled in EPIC.

Outreach

Under the MMA, EPIC received $34 million from the federal government before January 1, 2006, to engage in outreach and education about Part D. Some of the money went to community-based organizations and other

partners to do outreach work; some went to county-based Health Insurance Information Counseling and Assistance Programs (HIICAP) to increase their capacity to do counseling around Part D; and a significant portion was spent on an extensive media/advertising campaign around the benefits of combining Part D and EPIC. There is no more significant federal grant money available for Part D outreach activities. EPIC also has had a hotline, and its staffing nearly tripled with the implementation of Part D. EPIC participants receive troubleshooting assistance through the hotline, but they cannot obtain any assistance pursuing Part D coverage determinations or appeals.[40]

Coordination/Drug Data Exchange

EPIC receives information about its participants' Part D-covered drug utilization for each drug purchase in which EPIC pays a portion of the cost-sharing. However, it has not been able to obtain access to all of its participants' Part D drug utilization data, although CMS has "encouraged" plans to share that information. Furthermore, because EPIC's contributions toward Part D cost-sharing count toward the calculation of an enrollee's out-of-pocket costs, EPIC's payments for drugs for Part D enrollees should be captured by a federal "TrOOP Facilitator" and the information automatically shared with Part D plans. However, when an individual enrolled in a Part D plan uses EPIC coverage only for the purchase of a particular drug, the drug data is not shared with the Part D plan. As a result, neither EPIC nor the Part D plans are receiving full information about the drug purchases of their joint enrollees. If it could secure access to full utilization data, EPIC would use it to facilitate the "intelligent random assignment" process and to do drug utilization review and Part D plan monitoring.[41]

AIDS Drug Assistance Programs

AIDS Drug Assistance Programs (ADAPs) provide HIV-positive individuals who lack insurance coverage with access to prescription drugs, commonly prescribed for individuals with HIV or AIDS. The programs are primarily financed with federal funds, with state funds providing some additional support.[42]

Federal ADAP Policy

Under the MMA and the statute governing ADAP funding, ADAPs are permitted to use federal funds to fill Part D coverage gaps for dual program enrollees. The federal agency overseeing ADAPs requires enrollment of Medicare beneficiaries into Part D as a condition of eligibility for ADAP. However, the MMA does not permit ADAP contributions to count toward enrollees' "TrOOP" calculation,[43] and no federal funds have been provided to support outreach or other activities related to Part D implementation.

New York's ADAP Program

Approximately 10% of the 16,000 people enrolled in New York's ADAP are also eligible for Medicare Part D. ADAP's small size has allowed it to take a more flexible and individualized approach towards this group. As a result, ADAP has largely prevented disruptions in prescription drug access, while assisting the vast majority of eligible enrollees transition to Part D.

Wrap-around

ADAP has provided wrap-around coverage to all of its beneficiaries, whether or not they have enrolled in Part D. This wrap-around includes:

- Coverage of ADAP-covered drugs that are "off-formulary" or "excluded" by Part D and coverage of ADAP-covered

anti-virals when Part D plans require prior authorization;[44]

- Payment of copays for ADAP eligible drugs;
- Coverage for ADAP eligible drugs within the initial Part D deductible (up to $250) and the "donut hole." However, as noted above, ADAP payments (of copayments or deductibles) do not count towards beneficiaries' TrOOP limits. Thus, an ADAP beneficiary would have to spend $3,600 out-of-pocket on non-ADAP covered drugs in order to qualify for "catastrophic coverage" under Part D.[45]

New York's ADAP also receives rebates from drug manufacturers on Part D covered drugs for which ADAP pays the beneficiary cost-sharing amount.[46] Through this mechanism, the cost to ADAP of its wrap-around policies is significantly reduced.

As a general rule, ADAP does not automatically assist enrollees with Part D premiums. However, some Part D recipients may qualify for the ADAP Plus Insurance Coverage (APIC), which offers assistance with health insurance premiums when they exceed 4% of the beneficiary's income.

Enrollment

As noted above, federal guidelines require that eligible ADAP participants enroll in Part D as a condition of their continued eligibility for ADAP.[47] The only exception is for those who have other "creditable" prescription drug coverage. Enrollment in Part D is the responsibility of the ADAP-enrolled beneficiary. Unlike in EPIC and Medicaid, there is no facilitated or automatic enrollment by either the state or federal governments.

Despite this, the vast majority of eligible ADAP recipients have enrolled in Part D. Of the estimated 1,600 Medicare-eligible ADAP beneficiaries, approximately 90% have enrolled. Of the remaining 10%, it is estimated that half already have creditable private coverage (and thus are not required to enroll in Part D), leaving only 5% in danger of losing ADAP eligibility. However, as noted above, ADAP has yet to suspend coverage for this group – instead, it continues to offer them support and assistance in enrolling in Part D.[48]

Outreach

Although ADAP does not have specific funding or staff dedicated to outreach and education on Part D, it has nonetheless made significant efforts to provide beneficiaries with information needed to navigate the transition. Outreach was conducted through letters to affected beneficiaries, periodic updates on the ADAP website, numerous staff presentations to providers and beneficiaries, and ADAP's hotline, which saw a significant up-tick in volume during the first weeks of Part D implementation. ADAP made a particular effort to provide information on the LIS to qualifying beneficiaries.[49]

Coordination/Drug Data Exchange

Since ADAP continues to pay the Part D copays for drugs on its formulary, it continues to have access to most, but not all, claims data for its beneficiaries. One exception is for enrollees who are eligible for the LIS and have reached the catastrophic coverage level ($5,100) and are thus no longer required to pay copays. Thus far, ADAP has neither shared with nor received any claims data from individual Part D plans.

Observations and Recommendations

New York is fortunate to have robust state programs that have helped fill prescription drug coverage gaps for vulnerable Medicare beneficiaries. However, limited and at times conflicting federal guidance, as well as fragmented state policy-making, has resulted in a lack of coherence across the three programs. The following observations and recommendations offer strategies for a more coordinated, efficient and equitable approach to New York's pharmacy programs.

Continuing Part D Wrap-around Coverage

During the first year of Part D implementation, New York's pharmacy assistance programs played a critical role in providing wrap-around coverage that facilitated access to prescription drugs for vulnerable populations who were at risk of falling through the cracks of the new Part D benefit. EPIC's and ADAP's generous wrap-around policies and Medicaid's extended emergency coverage, once implemented, minimized problems for Medicare beneficiaries enrolled in those programs during the implementation period.

Although the past few months have seen significant progress in Part D operations and a reduction in reported enrollee problems in New York, it remains difficult to determine how much of the improvement is attributable to temporarily liberalized state wrap-around policies. EPIC and ADAP officials have moved cautiously, in the interest of beneficiary protection, to vigorously enforce certain program requirements – like the requirement that a pharmacy attempt to bill Part D for drugs before seeking reimbursement from the state program – and Medicaid's complete formulary wrap-around has effectively been extended through the end of 2006. Thus the extent to which Part D operational problems have been resolved will not be entirely clear for at least several months.

Furthermore, the same state wrap-around policies may have blunted the impact on prescription drug access of Part D's significant cost-sharing requirements and complicated utilization and formulary controls for the most vulnerable Medicare beneficiaries. Wrap-around benefits will continue to be vitally important for these beneficiaries.

Finally, each program is likely to experience some savings from Part D implementation over time that could contribute to the funding of continued wraparound coverage.

Recommendation: Unless there is a significant expansion in Part D coverage, state-based pharmacy assistance programs can and should continue to play a critical role filling in the many Part D gaps for vulnerable populations with significant prescription drug needs. Specifically, dual eligibles enrolled in Medicaid and Medicare continue to need formulary wrap-around coverage to ensure appropriate access to needed prescription drugs, and ADAP and EPIC enrollees continue to need formulary wrap-around coverage and, for those not eligible for Part D's low-income subsidies, cost-sharing assistance.

Inequities in Coverage and State Assistance

Implementation of Part D wrap-around policies in New York state programs has created new inequities in the prescription drug coverage available to various needy populations. Most strikingly, as of January 2007, Medicaid-Medicare dual eligibles will have less comprehensive prescription drug formulary coverage than their counterparts in EPIC, even

though the former group is typically needier. While this and other inequities are exacerbated or encouraged by inconsistent federal policies, none are compelled by them.

Under New York's Medicaid program, non-Medicare eligible beneficiaries have access to a comprehensive formulary and are liable for no more than $200 in copayments in a calendar year, including copayments for prescription drugs. In contrast, under Part D, dual eligibles are liable for copayments of up to $5 per prescription in 2006, with no annual limits, and starting in 2007, also will be subject to Part D plans' more limited formularies and their utilization management rules.

EPIC beneficiaries enrolled in Part D also have access to a more expansive formulary than do dual eligibles. EPIC's wrap-around benefit ensures immediate coverage and access to "off-formulary" drugs and drugs that are subject to PDP prior authorization. Moreover, this wrap-around benefit is funded entirely by the state.

ADAP beneficiaries who also are enrolled in Part D have their cost-sharing covered, whether or not they are enrolled to receive Part D's low-income subsidies, while dual eligibles do not.

In short, ADAP and EPIC have policies in place to ensure that their enrollees have at least as comprehensive drug coverage after the implementation of Part D as they did before. Medicaid beneficiaries, on the other hand, will face significant reductions from their comprehensive pharmacy benefit in January 2007.

State policy with respect to wrap-around and cost-sharing assistance is rooted in the unique history and purpose of each safety net program as well as federal incentives and restrictions with respect to how those programs interact with Part D. Nonetheless, Part D has created a new imperative for New York policy-makers to re-evaluate wrap-around and cost-sharing assistance for dual eligibles, who are some of the lowest-income New Yorkers.

Recommendation: New York State should study and implement policies to address equity issues for dual eligibles. Policies that could be considered include continuing the full Medicaid wraparound; imposing a state-funded cap on dual eligibles' out-of-pocket Part D copayments; and permitting Part D cost-sharing to apply toward the Medicaid out-of-pocket cap, among others. Policy-makers could also consider automatically enrolling dual eligibles into EPIC for their wraparound drug coverage, as some other states have done, in order to take advantage of the TrOOP eligibility of EPIC's cost-sharing contributions and to maximize administrative efficiencies.

Program Coordination and Collaboration

New York State has not articulated a common purpose or goals for how its pharmacy programs should interact with Medicare Part D. As a result, there is relatively little coordination among the Medicaid, EPIC and ADAP programs and no coherent state policy with respect to maximizing the benefits of Part D and ensuring access to drug coverage for New York's most vulnerable Medicare beneficiaries. Lacking a coherent policy framework, the state's three pharmacy assistance programs have tackled complex implementation and program management issues largely independent of one another.

While Medicaid, EPIC and ADAP serve different populations and are subject to different federal requirements, necessitating differentiated policy in some cases, there are areas of Part D management that would lend themselves to collaborative coordination and

oversight. Such areas include development of a central, statewide resource to serve as a clearinghouse for Part D information, help resolve Part D enrollees' problems, and assist with Part D appeals. No such resource currently exists at the federal or state levels. Of the three state-based programs, only EPIC currently has a hotline for its beneficiaries enrolled in Part D. Medicaid directs dual eligibles who have difficulties accessing drug referrals to the CMS regional office or directly to Part D plans, but on an *ad hoc*, rather than a systematic basis.[50] None of the three programs helps enrollees navigate the complex coverage appeals process. While advocates and state program officials agree that the total absence of a centralized appeals assistance function resulted in more beneficiary confusion, reduced Part D coverage, and greater wrap-around/emergency coverage outlays, the absence of long-term funding and an administrative structure for Part D coverage maximization activities at the state level remains a significant barrier to its development.

Similarly, each state program has been left to do Part D outreach and education on its own, and only EPIC has received substantial federal funding. All of the programs have had to rely heavily on pharmacists to help beneficiaries, with mixed success; according to advocates, pharmacists themselves are not always clear on the latest rules and program interactions.

Each pharmacy assistance program also has an interest in and conducts some activity related to monitoring PDP performance and overall Part D program operations – functions that are well suited to consolidation and centralization.

Recommendation: New York State officials should provide for better coordination among EPIC, Medicaid, and ADAP programs on key program management and monitoring issues in Part D including:

- Creating a centralized resource for enrollees to use for Part D appeals information and assistance;
- Monitoring of Part D plans and the overall implementation of the Part D benefit;
- Sharing best practices, including approaches to facilitating enrollment into Part D plans; and
- Where relevant, negotiating/communicating with CMS about coordinated state-based initiatives.

PDP Selection Assistance/Intelligent Assignment

Despite widespread agreement that some Part D plans are better suited than others for Medicare beneficiaries who are also eligible for Medicaid, EPIC or ADAP, the state's three prescription drug assistance programs have divergent and, in general, insufficient practices with respect to assigning or assisting their beneficiaries in selecting the "best" Part D plan for their needs.

EPIC is the only state program that is supporting "intelligent" selection of Part D plans, but only for its low-income enrollees. EPIC will assign LIS enrollees to particular plans, with an opt-out option, using software that considers each enrollee's pharmacy usage and drug utilization. EPIC's assignment logic also assigns spouses to the same plan whenever possible.

Neither New York Medicaid nor the ADAP program provides Part D enrollment assistance or assignment for their beneficiaries. New York's dual eligibles are therefore assigned to

Part D plans at random through the federal process, as are ADAP enrollees who are enrolled to receive LIS. Medicaid had earlier explored and rejected using an IRA software program similar to that used by EPIC that would notify dual eligibles of PDPs best suited to their needs. Medicaid program officials have indicated that this approach may be reconsidered in the future for particular sub-populations or new dual eligibles. In the meantime, Medicaid program officials believe beneficiaries are afforded some protection in that they are able to switch PDPs at any time, and they noted that dual eligibles were indeed voluntarily moving to plans with more comprehensive formulary coverage.

ADAP has not considered using IRA software to provide systematic recommendations to enrollees about Part D plans.

Recommendation: New York's pharmacy assistance programs should collaborate to select and implement IRA systems to recommend or assign new Medicare Part D enrollees to Part D plans that best meet their needs based at least on drug and pharmacy utilization. Care should be taken to ensure that the process is completed in such a way that beneficiaries retain the ability to opt out of the recommended Part D plan and to make their own plan selection.

Mandatory Part D Enrollment for EPIC Beneficiaries

In accordance with federal rules, both Medicaid and ADAP require enrollment in Part D or the existence of other creditable prescription drug coverage for all eligible program participants. The programs have different enforcement approaches: dual eligibles are automatically cut from Medicaid drug coverage and enrolled in Part D plans almost as soon as they are eligible, while ADAP enrollees have some time to add Part D coverage before losing ADAP benefits.

EPIC encourages dual enrollment through advertising, some fee incentives, and a passive enrollment process for low-income enrollees only, but it permits all participants to continue with EPIC-only coverage if they choose to do so. As a result, prescription drug coverage for thousands of EPIC enrollees is funded through state-only dollars, rather than through a combination of federally funded Part D coverage with EPIC as a wrap-around. EPIC's current approach could forfeit millions of dollars in state savings each year.

Recommendation: Policymakers should seriously consider making Part D enrollment an eligibility requirement for EPIC, at least for subsets of the EPIC population for whom this would be cost-effective, so that Part D is the primary payer for prescription drugs with EPIC coverage as a wrap-around. Features of this proposal would include EPIC paying Part D premiums for those beneficiaries who do not qualify for full LIS and providing waivers for beneficiaries with other credible coverage or for whom dual enrollment would disadvantage other benefits. Further, EPIC should continue negotiating with CMS to limit the plans for which it would pay premiums and auto-assign enrollees. Savings generated through EPIC beneficiaries enrolling in Part D could be used for expanding EPIC eligibility to disabled Medicare beneficiaries or for other purposes.

Coordinated Utilization Review and Management

Despite shared concerns among State program officials and consumer advocates regarding prescription drug management and PDP

quality, New York's prescription drug programs have not taken an active role in accessing/sharing data or utilization review and management for their beneficiaries enrolled in Part D plans. No state program has access to all enrollees' Part D prescription utilization data, though the Medicaid program is actively seeking such data now. Likewise, because of Part D's coverage gaps, PDPs do not have complete information regarding beneficiaries' drug utilization, and there is a common perception that Part D plans' utilization review programs are weak.

Recommendation: State policymakers, including Medicaid, EPIC and ADAP program officials, should refocus and coordinate efforts to collect and analyze prescription drug data to monitor quality of care provided to Part D beneficiaries and positively influence PDP medication therapy management programs. This would include aggressively negotiating for access to all prescription drug utilization data for state program beneficiaries and implementation of drug utilization review programs to enhance the quality of program enrollees' prescription coverage.

Conclusion

In 2006, New York's state-based pharmacy assistance programs provided some of the nation's most generous wrap-around and emergency coverage for enrollees who are also eligible for the new Medicare prescription drug benefit. Nonetheless, these programs' policies on Part D remain fragmented and inconsistent. As Part D start-up problems gradually diminish, state officials are faced with the task of modifying and finalizing their long-term policies towards Part D. In so doing, opportunities exist for these programs to improve beneficiaries' access and quality of care, while simultaneously making the programs more efficient and equitable.

Appendix I: Part D Implementation Policies of New York State Pharmacy Programs

Program	Enrollment in Part D				Wrap-around/Formulary Issues		Outreach and Education Policies		Data Exchange	Initial Program Savings	
	How Many Part D beneficiaries?	Mandate Part D enrollment?	Facilitated enrollment?	Pay Part D premiums?	Program covers beneficiary cost-sharing?	Comprehensive formulary wrap?	Program received designated federal or state outreach funding?	Help line for Part D issues including assisting in appeals?	Is the program receiving Part D claims data,?	Anticipated initial savings from Part D?	Plans for savings?
Medicaid	531,820 (about 12.5% of all beneficiaries) as of June 2006.[1]	Yes	Yes, random auto-assignment by CMS	No, LIS pays up to benchmark premium amount	No, LIS pays a portion and the beneficiary pays up to $5.	No, not after 1/1/07[2]	No	No	No, but have requested data	No, Medicaid paid for comprehensive wrap and clawback payment.	N/A
EPIC	162,000 (about 44% of all beneficiaries) as of July 2006.[3]	No	Yes, intelligent random assignment for full LIS beneficiaries	No, LIS pays up to benchmark premium amount for low income enrollees	Yes, EPIC pays a portion and the beneficiary pays a portion.	Yes	Yes	Help line but no appeals assistance	Yes, when EPIC pays cost-sharing	Yes, $120 million in '06	Back into program costs
ADAP	About 1,600 eligibles (about 10% of all beneficiaries) as of June 2006.[4]	Yes	No	Yes[5]	Yes, if the drug is on ADAP's formulary.	Yes for drugs on ADAP's formulary	No	No	Yes, when ADAP pays cost-sharing	Yes, $800 per year for a typical beneficiary and $6,000 per year for LIS-enrolled beneficiary.	Back into program costs

[1] Data are from CMS' State Enrollment in Prescription Drug Plans, Nov. 15 – June 1, 2006.
[2] Currently the Medicaid program provides a comprehensive wrap for all non-covered drugs, though prior approval may be required for some. However, as of January 1, 2007, Medicaid will pay only for certain Part D excluded drugs and drugs in four special categories if they are not covered by a Part D plan.
[3] National Conference of State Legislatures, *State Pharmaceutical Assistance Programs in 2006: Helping to Make Medicare Part D Easier and More Affordable*, updated October 16, 2006; Interview with EPIC Program Official, July 21, 2006.
[4] Interview with ADAP Official, July 25, 2006.
[5] ADAP will pay Part D premiums through its APIC program if the sum of the Part B and Part D premiums is greater than 4% of beneficiary's gross income.

Appendix II: Selected Part D Policies from Other States

A. State Pharmacy Assistance Programs (SPAPs): Part D Enrollment Policies[6]

- Limiting the Number of Plans
    - At least two state SPAPs (IL and SC) have selectively contracted with a limited number of Part D plans for their participants to enroll and receive SPAP benefits.
- Auto-Assignment
    - Some state SPAPs used an auto-assignment process for their enrollees. Some states auto-assigned all of their SPAP members (IL, MA, and VT); while others (IN) only auto-assigned their LIS eligible enrollees.
- Intelligent Random Assignment (IRA)
    - Several state SPAPs (including CT, ME, NV, and NJ) used IRA for all their enrollees to recommend the Part D plan that best matched their needs. New York utilized IRA only for its LIS eligible enrollees.

B. State Pharmacy Assistance Programs (SPAPs): Eligibility Expansions[7]

In 2005, several states enacted legislation to utilize savings from Part D implementation by expanding their SPAP programs to include individuals other than the low-income elderly:

- Arkansas expanded eligibility to 350% of FPL regardless of age
- Illinois expanded eligibility to all residents to 300% FPL regardless of age
- Maryland expanded eligibility to the uninsured to 175% FPL regardless of age
- Montana expanded eligibility to the uninsured or those who have exhausted benefits to 250% FPL regardless of age
- New Mexico has expanded eligibility to the uninsured with no income limit regardless of age
- Oklahoma has expanded eligibility to the uninsured with no income limit regardless of age.

C. Medicaid: Cost Sharing Policies[8]

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[6] Interviews with State officials, June 2006.
[7] Cauchi, Richard and Donna Folkemer, National Conference of State Legislatures, "SPAPs & Medicare Part D: A 2006 State Update," Presentation to the NSCL Spring Forum, Washington, D.C., April 7, 2006.
[8] Fox, Kimberly and Linda Schofield, *The Pharmacy Coverage Safety Net: Variations in State Responses to Supplement Medicare Part D*, University of Southern Maine, Muskie School of Public Service, February

- In six states (CT, HI, ME, MA, NH, and NJ), the Medicaid program pays the Part D copayments for full-benefit dual eligibles.
- In three states (ME, MO, and NV), the SPAPs cover all or a portion of the Part D copayments for dual eligibles.

2006; Centers for Medicare and Medicaid Services, Part D Coordination of Benefits Guidance, July 1, 2005.

Appendix III: State Officials, Advocates, and Experts Interviewed

Edo Banach
General Counsel
Medicare Rights Center

Valerie J. Bogart
Director, Evelyn Frank Legal Resources Program
Selfhelp Community Services, Inc.

Trilby de Jung
Health Law Attorney
Empire Justice Center

Marilyn Desmond
Assistant Director, Division of Policy Program and Guidance
Office of Medicaid Management
New York State Department of Health

Linda Jones
Director, Bureau of Pharmacy Policy and Operations
Office of Medicaid Management
New York State Department of Health

Julie Naglieri
Director, NYS EPIC Program
New York State Department of Health

Greg Otten
Coordinator of Client Advocacy
Gay Men's Health Crisis (GMHC)

Enzo Pastore
Director of Public Policy
Center for Independence of the Disabled, NY (CIDNY)

Christine Rivera
Director, HIV/Uninsured Programs
New York State Department of Health

Mark Scherzer, Esq.
Legislative Counsel
New Yorkers for Accessible Health Coverage

Denise Soffel
Senior Policy Analyst
Community Service Society of New York (CSSNY)

Endnotes

[1] Kaiser Family Foundation, *Kaiser Health Poll Report Survey: Seniors' Early Experiences With Their New Medicare Drug Plans*, June 2006.
[2] Although Medicaid and ADAP receive significant federal financing and are subject to federal requirements, we use the term "state-based prescription drug programs" (or "state programs") to refer to them and to EPIC because state policymakers retain significant discretion to design and implement the programs within federally imposed parameters.
[3] Pear, Robert, "Rules of Medicare Drug Plans Slow Access to Benefits," *New York Times*, February 14, 2006; Pear, Robert, "Rolls Growing For Drug Plan As Problems Continue," *New York Times*, January 18, 2006.
[4] All cost-sharing figures for Part D are for 2006. They are indexed and will thus increase in future years.
[5] Kaiser Family Foundation, *The Medicare Prescription Drug Benefit: Fact Sheet*, June 2006.
[6] Centers for Medicare and Medicaid Services, Formulary Guidance, available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp.
[7] Centers for Medicare and Medicaid Services, Prescription Drug Benefit Manual, Chapter 18: Part D Enrollee Grievances, Coverage Determinations, and Appeals, Revision 2, June 22, 2006.
[8] Centers for Medicare and Medicaid Services, Information for Part D Sponsors on Requirements for a Transition Process, March 16, 2005; Centers for Medicare and Medicaid Services, Transition Process Requirements for Part D Sponsors, April 2006.
[9] Centers for Medicare and Medicaid Services, Clarification Formulary Review – "All or Substantially All." Available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf.
[10] New York State Dept. of Health, Medicaid Update, Vol. 21, No. 6, June 2006.
[11] Kaiser Family Foundation, *The Transition of Dual Eligibles to Medicare Part D Prescription Coverage: State Actions During Implementation*, Feb. 2006; Kaiser Family Foundation, *Early Experiences of Medicare Beneficiaries in Prescription Drug Plans: Insights from Medicare State Health Insurance Assistance Program (SHIP) Directors*, August 2006; Interview with Medicaid official, April 17, 2006.
[12] Due to Part D start-up problems, CMS ultimately offered states a one-time reimbursement for wrap-around emergency coverage that more than 30 states, including New York, opted to provide during the first few months of Part D implementation.
[13] Dual eligibles are automatically enrolled to receive LIS, so they do not have a donut hole or gap in coverage. However, dual eligibles' cost-sharing is eliminated once they hit the TrOOP limit.
[14] Kaiser Family Foundation, *The Transition of Dual Eligibles to Medicare Part D Prescription Coverage: State Actions During Implementation*, Feb. 2006.
[15] "Medicare Pays States $232.2 Million for Duals SNAFUs, But Issues Remain," *Inside CMS*, July 13, 2006.
[16] Kaiser Family Foundation, *An Update on the Clawback: Revised Health Spending Data Change State Financial Obligation for the New Medicare Drug Benefit*, March 2006.
[17] New York State Dept. of Health, Medicaid Update – Special Edition, Vol. 20, No. 14, December 2005.
[18] Ibid.
[19] Seeking a coverage determination from a Part D plan requires contacting the plan outside of the pharmacy, usually in coordination with the prescribing physician who provides support for the patient's need for a particular drug, and waiting up to 72 hours for a response from the plan (or 24 hours if the enrollee's condition requires expedited decisionmaking). A "claim denial," on the other hand, is obtained electronically by a pharmacist while the Part D enrollee is in the pharmacy.
[20] Fox, Kimberly and Linda Schofield, *The Pharmacy Coverage Safety Net: Variations in State Responses to Supplement Medicare Part D*, University of Southern Maine, Muskie School of Public Service, February 2006.
[21] New York State Dept. of Health, Medicaid Update, Vol. 21, No. 2, February 2006.
[22] New York State Dept. of Health, Update on Temporary Medicaid Drug Coverage for Duals, February 10, 2006.
[23] New York State Dept. of Health, Medicaid Update – Special Edition, June 2006.
[24] New York State Dept. of Health, Medicaid Update, Vol. 21, No. 6, July 2006.
[25] Interview with Medicaid Official, April 17, 2006. There is an exception for dual eligibles who have employer coverage that could be jeopardized if they enroll in Part D.
[26] Interview with Medicaid Official, April, 17, 2006.
[27] Ibid.
[28] 18 NYCRR 512.4; Interview with Medicaid Official, April 17, 2006.
[29] Interview with Medicaid Official, October 23, 2006.
[30] Interview with Medicaid Official, April 17, 2006; Interview with Medicaid Official, October 23, 2006.
[31] Section 1860D-23(b)(2) of the MMA; see 70 Fed. Reg. 4194, 4222 (January 28, 2005).
[32] Fox, Kimberly and Linda Schofield, *The Pharmacy Coverage Safety Net: Variations in State Responses to Supplement Medicare Part D*, University of Southern Maine, Muskie School of Public Service, February 2006; Centers for Medicare and Medicaid Services, Part D Coordination of Benefits Guidance, July 1, 2005.

[33] New York State Dept. of Health, EPIC Provider Bulletin, No. 05-01, December 2005.
[34] This approach was possible in part because benefits for both its "fee" and "deductible" plans were determined to be at least actuarially equivalent to Part D coverage, meaning that EPIC was "creditable" coverage and enrollees would not be subject to a Part D late enrollment penalty if they later enrolled in a PDP.
[35] New York State Dept. of Health, EPIC Provider Bulletin, No. 05-01, December 2005.
[36] Interview with EPIC Official, October 19, 2006.
[37] New York State Dept. of Health, EPIC Provider Bulletin, No. 05-01, December 2005.
[38] Interview with EPIC Official, October 19, 2006.
[39] New York State Division of Budget, 2006-07 New York State Enacted Budget Report, p. 45; Interview with EPIC Official, April 17, 2006.
[40] Interview with EPIC Official, April 17, 2006.
[41] Interview with EPIC Official, October 19, 2006.
[42] Kaiser Family Foundation, *HIV/AIDS Policy Fact Sheet: AIDS Drug Assistance Programs (ADAPs)*, March 2006.
[43] Centers for Medicare and Medicaid Services, Part D Co-ordination of Benefits Guidance, July 1, 2005.
[44] In both cases, pharmacists are expected to first attempt to bill Part D and then, if this fails, to bill ADAP.
[45] New York State Department of Health, Frequently Asked Questions – Medicare Part D and ADAP, Jun. 1, 2006.
[46] Interview with ADAP official, April 17, 2006.
[47] "Should ADAPs require clients who are Medicare-eligible to participate in the Medicare Prescription Drug Benefit (Part D)?" Q&A on HRSA website citing CARE Act section 2617(b)(6)(F), available at http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/home.php.
[48] Interview with ADAP Official, April 17, 2006.
[49] Ibid.
[50] Medicaid officials did monitor Part D plans' coverage policies and customer service in the aggregate, but it did not have a system to assist individual dual eligibles with particular coverage problems.