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OBSERVATIONS ON THE INITIAL IMPLEMENTATION OF THE MEDICARE PRESCRIPTION DRUG PROGRAM:

Perspectives of State Medicaid Directors Through a Focus Group Discussion

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This paper is based on discussions with a group of Medicaid directors who gathered to address the implementation of the Medicare Part D prescription drug coverage and its impact on state Medicaid programs. We acknowledge and thank those who took the time to participate in this discussion, and who offered feedback on an earlier version of this report. Especially, we thank Medicaid officials from California, New Jersey, Kansas, Oklahoma, West Virginia, and Wisconsin. We also thank the staff of the National Association of State Medicaid Directors who also participated in the discussion.

EXECUTIVE SUMMARY

Perhaps the most challenging aspect of the January 1, 2006 implementation of the Medicare Part D drug benefit was the transition – on a single day – of over six million low-income seniors and persons with disabilities who are enrolled in both Medicare and Medicaid ("dual eligibles") from Medicaid drug coverage to newly created Medicare Part D plans. Dual eligibles have more extensive health care and prescription drug needs than other Medicare beneficiaries, so it was critically important for the auto-enrollment process and other aspects of the transition to work smoothly to prevent gaps in coverage. Soon after Part D implementation on January 1st, however, it became clear to states and to the Centers for Medicare and Medicaid Services (CMS) at the federal level that a number of problems were making it difficult for some dual eligibles to obtain needed prescriptions.

Background on the Focus Group.

To explore the early Part D implementation for dual eligibles, the implications of future plan changes and other Part D-related issues of particular importance to states, the Kaiser Commission on Medicaid and the Uninsured (KCMU) asked Health Management Associates (HMA) to conduct a focus group. Seven state Medicaid officials, including Medicaid Directors from six states, met on March 5, 2006. Three staff members from the National Association of State Medicaid Directors (NASMD) also attended. These state officials were asked to comment on several topics relating to:

- The issues encountered by dual eligibles and states during the initial transition period;
- Ongoing challenges that could result in future coverage gaps for some dual eligibles;
- Open issues including the current status of state clawback payment obligations and other fiscal impact issues;
- Part D-related long term care and specialty pharmacy issues; and
- The key "lessons learned" thus far.

Participants were asked to speak off-the-record based on their personal experience and knowledge gained as administrators of the Medicaid program. Thus, their comments do not necessarily reflect the views of other officials within their states, nor do they necessarily represent a consensus position of the Medicaid directors who participated in the group or of NASMD.

Key Themes Identified By Medicaid Officials.

Since the passage of the Medicare Modernization Act (MMA), Medicaid officials and others have expressed concerns regarding the task of successfully transitioning dual eligibles from Medicaid prescription drug coverage to Medicare Part D. After two months of observing transition issues as they emerged, the Medicaid officials participating in the focus group identified a number of key themes, including the following:

- **Implementation problems were anticipated, but CMS was unable in some cases (i.e., due to statutory limitations), and unwilling in others to respond to issues raised in advance by states.** Despite the recommendations of Medicaid officials, beginning in 2004, that a legislative change be sought to delay or phase-in the transition of dual eligibles, the Administration remained committed to implementation in January 2006.
- **Coverage disruptions for many dual eligibles are likely to occur again in 2007.** Changes in plan options and in the low-income subsidy benchmark premium could result in the need for many dual eligibles to select or be auto-enrolled into new plans raising administrative, fiscal, and access issues similar to those encountered in January 2006.
- **System lags lead to lapses in coverage for persons enrolling or switching plans late in the month.** Part D's "batch processing" approach for establishing eligibility, auto-enrolling dual eligibles, making plan assignments, and applying reduced cost-sharing is inconsistent with the on-line, real-time, point-of-sale billing systems used by pharmacies. Batch processing lags inevitably lead to lapses in coverage or inappropriate cost-sharing charges for dual eligibles enrolling or switching plans late in the month.
- **The downward revision of the clawback amount in February 2006 was "good news" for states, but the fiscal impact remains unclear for many**. Lower clawback amounts could reduce expected costs and result in state savings faster than previously anticipated, but more evaluation is needed and each state is likely to be affected differently.
- **Prior to Part D implementation, CMS concluded that states could not be reimbursed for dual eligible prescription costs after January 1st, but later found a way to do so**. Less than a month after Part D had begun and after many states established temporary coverage programs for dual eligibles, CMS announced a Medicare demonstration plan to repay states for their Part D-related transition costs. Concerns remain, however, that the CMS process to repay state costs may not be applied consistently across all states.
- **There are a number of areas where the full impact of the Part D implementation is not yet known**. These areas include:
    - The ability of dual eligibles to meet copayment requirements (and the possible health consequences);
    - The impact on the Medicaid spend-down eligibility process;
    - Reimbursement for Part D drugs provided during a retroactive Medicaid eligibility period, and
    - Possible erosion of supplemental rebate revenues due to reduced drug claim volume.
- **Long-term care and specialty pharmacies and their patients had unique problems with Part D's start up that may persist into the future.** Problem areas identified included coverage and billing for home infusion therapy drugs and unit dose packaging,

dispensing guidelines imposed in nursing home settings and large Part D accounts receivable reported by some long-term care pharmacies.

- **The historic lack of coordination between Medicare and Medicaid hampered the implementation of policies that affected dual eligibles, especially by not fully tapping into states' experience implementing healthcare reforms.** State officials believe that Medicare could have benefited more from the experience of Medicaid. Compared to Medicare, state Medicaid programs have considerable experience bringing up new and innovative programs requiring complex system and procedural changes and also have greater knowledge and familiarity with the dual eligible population and their service needs – especially the unique needs of institutionalized beneficiaries.
- **Future healthcare legislation should provide for realistic implementation timelines and greater administrative flexibility**. When sweeping changes are made to the healthcare system, regulatory flexibility is needed to deal with unforeseen implementation problems and test possible solutions.

Conclusion

Initial implementation of Medicare Part D occurred with significant impacts on the most vulnerable of Medicare beneficiaries – those also enrolled in Medicaid. For most of these dual eligibles, the transition of prescription drug coverage from Medicaid to Medicare Part D occurred without major issues. However, given the large number of individuals – over six million – problems affecting even a small portion of the total translated into major issues. Medicaid directors were in a key position to anticipate and observe the issues as they emerged and were also best positioned to resolve some of the issues that affected dual eligibles in their states. When it became apparent in January that many individuals were unable to obtain needed prescriptions, many states quickly implemented temporary solutions to assure access until the implementation issues were solved. The actions of states were central to efforts to transition coverage from Medicaid to Medicare.

A key message that emerged from the discussions with Medicaid directors is the need to continue to focus on the interaction between Medicaid and Medicare Part D, and to address the key system and coordination issues that remain. In particular, attention should be directed to potential disruptions that could occur in January 2007 when new Part D contracts and recalculated benchmarks for the low-income subsidy take effect. Also, the dual eligible population is constantly changing, with individuals attaining dual eligible status each day. Focus is needed on issues of initial enrollment and transition from Medicaid to Medicare and on the inherent system lags that can make it impossible for Part D plans to know when an individual is a dual eligible and entitled to lower copayments and waiver of premiums. Finally and significantly, state officials remain concerned about their financial obligation under the clawback.

INTRODUCTION

Perhaps the most challenging aspect of the January 1, 2006 implementation of the Medicare Part D drug benefit was the transition – on a single day – of over six million low-income seniors and persons with disabilities who are enrolled in both Medicare and Medicaid ("dual eligibles") from Medicaid drug coverage to newly created Medicare Part D plans. Part D was a welcome new benefit for many Medicare beneficiaries who did not previously have access to prescription drug coverage. However, most dual eligibles switched to an unfamiliar, new private Part D plan, selected for them through a random, automatic enrollment process. Even if they exercised their option to affirmatively select a plan, many dual eligibles found themselves in a plan that imposed greater copayments and more restrictive formularies than existed under their previous Medicaid coverage.

Dual eligibles have more extensive health care and prescription drug needs than other Medicare beneficiaries, so it was critically important for the auto-enrollment process and other aspects of the transition to work smoothly to prevent gaps in coverage. Soon after Part D implementation on January 1st, however, it became clear to states and to the Centers for Medicare and Medicaid Services (CMS) at the federal level that a number of problems were making it difficult for some dual eligibles to obtain needed prescriptions. Since that time, CMS has taken a number of corrective actions and many states also implemented temporary programs to assure that dual eligibles obtained needed medications during the transition period.[1] CMS even took the unusual step of creating a Medicare demonstration program to repay states for the costs of their temporary programs.

> *"While considerable progress has been made, change of this magnitude in such a short time span is bound to encounter some difficulties. CMS is very concerned about anyone who has experienced problems in obtaining their medicines. We make no excuses for the problems. They are important, they are ours to solve, and we are finding and fixing them."*
>
> *-- Dr. Mark McClellan, Testimony before House Energy and Commerce Subcommittee on Health, March 1, 2006.*

To explore the early Part D implementation for dual eligibles, the implications of future plan changes and other Part D-related issues of particular importance to states, the Kaiser Commission on Medicaid and the Uninsured (KCMU) asked Health Management Associates (HMA) to conduct a focus group of state Medicaid officials on March 5, 2006 – the third such focus group since the passage of the Medicare Modernization Act (MMA) that added the new Part D benefit to the Medicare program. The earlier two focus groups were conducted prior to Part D implementation in November 2004 and November 2005.[2]

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[1] *See* Vernon Smith, Kathleen Gifford, Sandy Kramer and Linda Elam, *The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation, Results from a 50-State Snapshot*, Kaiser Commission on Medicaid and the Uninsured, February 2006, Publication No. 7467.

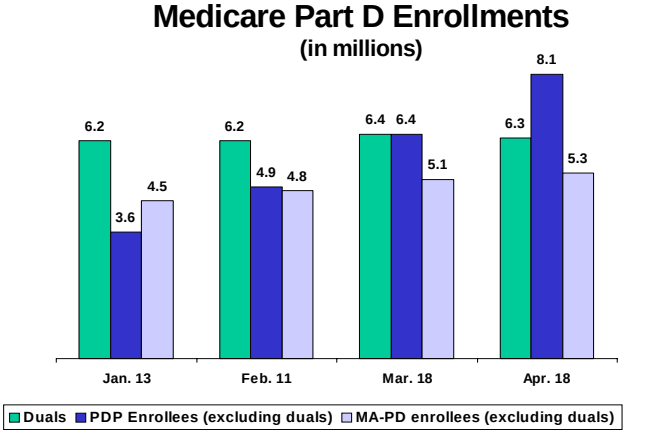
[2] Vernon Smith, Kathleen Gifford and Sandy Kramer, *Implications of the Medicare Modernization Act for States: Observations from a Focus Group Discussion with Medicaid Directors*, Kaiser Commission on Medicaid and the Uninsured, January 2005, Publication No. 7428, and Vernon Smith, Kathleen Gifford, Sandy Kramer and Linda Elam, *A Medicaid Perspective on Part D Implementation; The Medicare Prescription Drug Program, Findings from a Focus Group Discussion with Medicaid Directors*, Kaiser Commission on Medicaid and the Uninsured, December 2005, Publication No. 7447.

BACKGROUND ON THE FOCUS GROUP

To discuss the Part D implementation for dual eligibles and other Part D-related implications for Medicaid beneficiaries and state Medicaid programs, HMA convened a focus group on March 5, 2006 with seven Medicaid officials, including Medicaid directors from six states. Three staff members from the National Association of State Medicaid Directors (NASMD) also attended. Participating Medicaid directors were members of the Executive Committee of NASMD and therefore represented leaders among Medicaid officials from states across the country with diverse administrative approaches for their Medicaid prescription drug programs. The seven state participants were from California, New Jersey, Kansas, Oklahoma, West Virginia, and Wisconsin. Dual eligibles from these states represent nearly 23 percent of the dual eligibles across the nation.[3] Participants were asked to speak off-the-record based on their personal experience and knowledge gained as administrators of the Medicaid program. Thus, their comments do not necessarily reflect the views of other officials within their states, nor do they necessarily represent a consensus position of the Medicaid directors who participated in the group or of NASMD.

Since January, the Department of Health and Human Services (HHS) has reported monthly on the status of Part D enrollments. As of April 18, 2006, HHS announced that 19.7 million beneficiaries[4] were receiving Medicare prescription drug coverage, including 6.3 million dual eligibles (with 500,000 in Medicare Advantage plans with Part D coverage (MA-PDs) and the remaining in stand-alone plans (PDPs)). (Figure 1)

Figure 1



SOURCE: HHS Press Releases dated January 17, 2006, February 22, 2006, March 23, 2006 and April 20, 2006.

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[3] *Medicare Release State-by-State Prescription Drug Enrollment Figures*, CMS Medicare Fact Sheet, January 19, 2006.

[4] *30 Million Medicare Beneficiaries Now Receiving Prescription Drug Coverage*, CMS Press Release, April 20, 2006, accessed at http://www.hhs.gov/news/press/2006pres/20060420.html.

This report focuses on the transition of the 6.3 million dual eligibles, primarily based on Medicaid officials' comments on several topics including:[5]

- The issues encountered by dual eligibles and states during the initial transition period;
- Ongoing challenges that could result in future coverage gaps for some dual eligibles;
- Open issues including the current status of state clawback payment obligations and other fiscal impact issues;
- Part D-related long term care and specialty pharmacy issues; and
- The key "lessons learned" thus far.

ISSUES ENCOUNTERED DURING INITIAL TRANSITION PERIOD

Background

Since the passage of the MMA in 2003, Medicaid officials and others have expressed concerns regarding the task of successfully transitioning more than six million dual eligibles from Medicaid prescription drug coverage to Medicare Part D. For example, in the pre-implementation focus groups held on November 16, 2004 and November 6, 2005, Medicaid officials acknowledged the extensive efforts taken by CMS to ensure a successful transition, but nevertheless expressed concern that a significant number of dual eligibles would likely "fall through the cracks" and be left without drug coverage after December 31, 2005.

Observations of Focus Group Participants

- **Implementation problems were anticipated, but CMS was unable in some cases (i.e., due to statutory limitations), and unwilling in others, to respond to issues raised in advance by states.** According to focus group participants, state Medicaid officials began suggesting to CMS in 2004 that the transition of dual eligibles to Part D be delayed or phased-in over time to assure there were no lapses in coverage. State Medicaid officials indicated they offered to go to Congress with CMS officials to seek a legislative delay or phase-in, if necessary, but the Administration decided to not pursue any legislative changes and move forward with the January 1, 2006 implementation date.
- **States predicted that data discrepancies would cause implementation difficulties, but had limited control over Part D implementation and therefore were not in a position to prevent those difficulties from occurring.** In the months leading up to implementation, state officials found that in some cases persons identified as dual eligibles in state data file submissions to CMS could not be matched by CMS against its Medicare eligibles database due to technical data file discrepancies. As a result, these

[5] Federal Part D policies and procedures have continued to evolve rapidly since the focus group was held on March 5, 2006. This report incorporates a number of those policy developments that relate to comments made by focus group participants.

individuals could not be auto-enrolled into Part D plans by CMS. Medicaid officials commented that some CMS officials erroneously believed that bad Medicaid data from the states caused the discrepancies. One participant noted, however, that CMS officials working on data issues in her state recently came to the conclusion that in fact it was not the Medicaid data that was at fault. This realization was described as "a wake-up call" for officials on the necessity to work collaboratively.

- **The Part D State Issues Workgroup served to identify and minimize many but not all transition problems.** State officials offered their expertise a number of times to help CMS plan for a successful transition of the dual eligibles. Beginning in August 2004, officials from CMS, the Social Security Administration and state Medicaid programs began working together in the "State Issues Workgroup" for the purpose of identifying and resolving issues relating to the successful transition of dual eligibles to Part D coverage. Bi-monthly all-state conference calls with CMS officials were also convened for this purpose. One focus group member commented on the value of these efforts:

  > *"What might have happened if we hadn't had some of the workgroups and brought up some of these issues? Some of these things would have never been addressed."*

  Despite these joint planning efforts, one Medicaid Director observed that a regional CMS official had recently commented (post-implementation): "We wish we would have better understood the issues with the duals."

ONGOING CHALLENGES

At the time of the focus group, the initial transition period was nearly over and a number of improvements had been made. For example, CMS was continuing to work on matching data files with the states and focus group participants generally agreed that the data returned to states in February was "definitely much better," although still not totally correct. Despite progress in data matching and improvements in other areas, several issues remain unresolved and focus group participants expressed concern that dual eligibles will continue to face future Part D transitions that are likely to result in significant problems for some.

Key Issues Remaining, as Identified by Focus Group Participants

> *"If you think that PDPs have sent them all their letters that 'your drug is not on our formulary', you'd be wrong. And if you think that [for] the letters that did go out that the consumers would actually have had a chance to get that taken care of, you'd also be wrong."*

- **As of early March 2006 (the time of the focus group), participants predicted that significant problems would likely occur when the formulary transition period ended (after March 31, 2006), and as CMS worked to correct erroneous plan assignments.**

  End of formulary transition period. Part D plans have lists of preferred drugs (called formularies). CMS asked that each plan provide transition mechanisms that address the needs of new enrollees who are using drugs not covered on its formulary prior

to enrollment. Part D plans originally agreed to offer 30 days of emergency coverage for non-formulary drugs for new enrollees and in some cases a longer supply for institutionalized individuals. To help ensure smooth transitions to drugs that are covered and allow beneficiaries more time to work with prescribers, in February CMS extended the transitional period and asked all Part D plans to continue to cover non-formulary drugs through March 31, 2006. This extension applies only to individuals enrolled during the first three months of the Part D benefit. Some Medicaid officials expressed concern that beneficiaries had not received adequate notice of this change and would face difficulties obtaining needed prescriptions in April.[6]

Termination of duplicate plan enrollments. According to Dr. Mark McClellan, CMS Administrator, well over one million Medicare beneficiaries were enrolled in more than one Part D plan.[7] At the time the focus group was held, one participant expressed concern that additional disruptions in access to needed prescriptions would occur when dual eligibles enrolled in two plans were terminated from one of the plans (although the number of dual eligibles that would be affected was unknown). Beneficiaries may not know which plan has been terminated and are likely to be confused if they receive a notice of termination. In late March, the *New York Times* reported that beneficiaries enrolled in two plans that had only accessed benefits from one of the plans would be dropped from the other plan without notice. Approximately 500,000 other beneficiaries were sent notices on March 27, 2006, indicating that if they took no action, they would be disenrolled from their original plan, but would retain coverage under the second plan.[8]

Dual eligibles are being enrolled in Part D plans not operating in their state. The CMS auto-assignment process is based on beneficiary addresses from the Social Security Administration, which in some cases are not the actual beneficiary's address, but that of their responsible party. As a result, state officials have found that auto-assignments are being made to Part D plans not operating in a dual eligible's state of residence.

"It's actually not too soon to start thinking about next January. They are re-bidding all of these [Part D] contracts and they are going either to reduce or just change who are the benchmark plans. Then next January there's going to be a wholesale switching problem."

- **In January 2007, coverage disruptions for many dual eligibles are likely to occur again when the 2007 Part D contracts take effect.** Focus group participants noted that when the Part D plan contracts are re-procured for 2007, there are bound to be changes in the number of participating companies and their plan options[9] and in the calculation of the low-income

[6] Since the focus group discussion, CMS notified Part D plans of the need to inform beneficiaries about the change and ensure beneficiaries do not face delays because appeals have not been resolved. CMS further stated that plans that cannot resolve appeal or exception requests without delays should provide beneficiaries with a temporary medication supply. *Transition Fact Sheet*, Friday March 31, 2006 accessed at www.cms.hhs.gov.
[7] Robert Pear, *"Retirees on 2 Drug Plans Must Make Choice,"* The New York Times, March 28, 2006.
[8] Ibid.
[9] On April 3, 2006, CMS released PDP instructions for the 2007 contract year indicating that CMS will review bids and announce successful applicants by September 2006. The instructions noted that, pursuant to 42 CFR 423.512, CMS may terminate PDP contracts with fewer than 5,000 enrollees (1,500 for non-urban areas). CMS also signaled

subsidy benchmark premium. Because the MMA only authorizes CMS to fully subsidize Part D premiums for dual eligibles enrolled in Part D plans with premiums falling at or below that benchmark, a change in the benchmark could result in the need for many dual eligibles to select or be auto-enrolled into new plans to avoid having to pay excess premium amounts over the benchmark.[10] Focus group participants expressed concerns that CMS had not built in enough time to carry out this process and that the disenrollment of dual eligibles from existing plans and reenrollment into new plans would raise administrative and fiscal issues similar to those encountered in January 2006.

- **System lags lead to lapses in coverage for persons enrolling or switching plans late in the month.** Part D processes for establishing eligibility, auto-enrolling dual eligibles, making plan assignments, and applying reduced cost-sharing do not happen in real time and instead rely on a sequence of "batch" processes with built-in time lags (Figure 2). Medicaid officials noted that this batch processing approach is not consistent with the on-line, real-time, point-of-sale billing systems used by pharmacies. These systems allow pharmacies nearly instantaneous access to an individual's eligibility for a particular prescription plan and to the plan's drug coverages, cost sharing, and utilization controls – all before a prescription is dispensed. No other healthcare service covered by Medicare has such sophisticated data processing and billing capabilities.

  The current Part D batch transfer of crucial enrollment data with its inherent processing lags inevitably causes erroneous messages to pharmacies working in a real-time environment. For example, dual eligibles may not appear to be enrolled in Part D for a period of time after plan assignments have in fact been made. Persons enrolling or switching plans late in the month will be particularly vulnerable to these lapses in coverage or inappropriate cost-sharing charges. One official described another situation that would result in incorrect cost-sharing amounts because of the batch process:

  > *"Every time a person changes plans, they lose 15 days of low-income subsidy [reduced cost sharing] and that's built into the structure. If you call the plan later in the month and say I want to enroll in the plan, the plan does not know you're low-income… They send off a transaction to CMS saying I'm enrolling John Smith… and 15 days later they get a transaction back that says this person is entitled to low-income subsidies. They may post that right away or they may wait a week to post it. Meanwhile, you're paying too high of copays. That happens any time anybody changes, including the first of month."*

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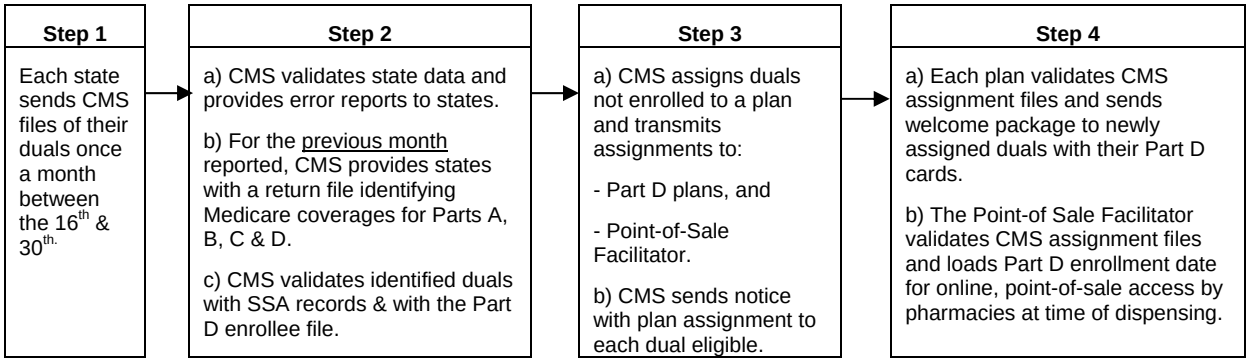
its intention to simplify plan offerings by advising PDP sponsors that each of their plans should represent a "meaningful variation" and further stated that more than two bids in a region from a sponsoring organization "would not provide meaningful variation, unless one of the bids is an enhanced alternative plan that provides coverage in the coverage gap." *Instructions for 2007 Contract Year*, CMS Memorandum to Medicare Prescription Drug Plan (PDP) Sponsors from Cynthia G. Tudor, April 3, 2006, accessed at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2007PDPCallLetter.pdf.

[10] The 2007 contract year instructions state that a dual eligible currently enrolled in a plan whose 2007 premium exceeds the 2007 benchmark premium could be reassigned by the plan's sponsor to another of the sponsor's plans with a premium at or below the benchmark in the same service area. If the PDP sponsor does not offer another PDP in the same service area with a premium at or below the benchmark, CMS will randomly auto-assign these dual eligibles to qualifying plans. CMS further noted that more details on the auto-enrollment process will be provided "as soon as possible." Ibid.

Figure 2: Key Batch Processing Steps Supporting Dual Eligible Enrollments into Part D*



* Specific timeframes are not available to evaluate the time that passes between each step. However, the Part D batch processes (with their monthly cycles) lag significantly behind the real-time, online data systems used in pharmacies.

Similar issues historically existed for dual eligibles before Part D, but Medicaid programs typically paid the claims and reconciled those issues on the back end after prescriptions had been dispensed. The process was streamlined because pharmacies were familiar with a state's Medicaid coverage requirements. This is not as viable under Medicare Part D with its multiple plans operating in a state – each with a different formulary and utilization controls.

Additional comments on system response lags:

"At the very best, under their current structure, the earliest the State would hear back once they submitted [files] on the 30th of month …is the 25th of the next month of the plan that the person gets. That's assuming that everything goes perfectly, which isn't going to happen. There is an inherent flaw there. And that doesn't mean the person has a card or the plan knows that the person's there."

"This is a batch process working slowly in an online world."

- **To eliminate the inevitable coverage gaps resulting from the current lags in system response times, focus group participants recommended that CMS consider implementing a temporary fee-for-service "holding area" for new dually eligible Part D enrollees.** In states with mandatory risk-based Medicaid managed care, it is common practice to temporarily cover a new Medicaid beneficiary in the fee-for-service delivery system until the beneficiary's managed care plan assignment becomes effective. This avoids any lapses in coverage. Medicaid officials suggested that CMS should consider using such an approach for dual eligibles in Part D, although a statutory change might be needed to do so.

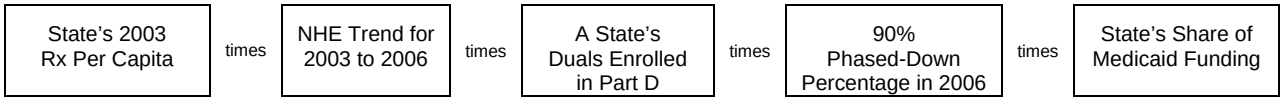
FISCAL ISSUES

Background

States are a significant source of financing for Medicare Part D. According to the Congressional Budget Office, states collectively will contribute (via the "clawback" discussed below) $3.8 billion in federal fiscal year 2006, $7.0 billion in federal fiscal year 2007 (the first full fiscal year of Part D implementation), and $7.7 billion in 2008. This amount is projected to grow each year by nine to ten percent, reaching $15.5 billion in 2016. Over the ten years ending in 2016, states are projected to contribute a total of $107.6 billion.[11]

The MMA requires each state to submit monthly to the federal government its "state phased-down contribution," also known as the clawback. This payment in theory reflects a percentage of the amount a state would have spent on dual eligible drug coverage if the MMA had not been enacted. For 2006 it is calculated based on a state-specific *per capita amount* for 2003 determined by identifying the number of enrollee-months for full-benefit duals eligibles, drug expenditures for Part D covered drugs for these individuals, actual (not incurred) manufacturer rebates received during 2003, and other technical adjustments. Each state's 2003 per capita amount is then projected forward to 2006 using the same national trend factor based on National Health Expenditure (NHE) Projections.[12] The resulting amount for each state is then discounted by ten percent for 2006. The discount is gradually increased over ten years to 25 percent. The discount remains constant thereafter, and the clawback obligation is never phased out. A state must pay the discounted per capita amount monthly for each of the state's dual eligibles enrolled in Part D.

The Clawback Formula for 2006



In October 2005, CMS provided each state with 2006 clawback amounts. These amounts were revised downward in February 2006 after CMS incorporated into the clawback calculation the January 2006 National Health Expenditures Projections (which were lower for drug spending than the prior year's estimates). With this modification, CMS announced that state contributions nationally would be lower than originally estimated.[13]

The MMA also prohibits states from receiving federal Medicaid funding for Part D covered prescriptions dispensed to dual eligibles. Many states, however, implemented temporary

[11] Congressional Budget Office, Medicare Baseline, March 2006.
[12] The *National Health Care Expenditure (NHE) Projections* is published annually by the Office of the Actuary at CMS. Historical estimates are calculated along with projected future spending for various healthcare services including prescription drugs. After 2006, the clawback will be indexed to growth in actual Part D spending.
[13] As a new version of the NHE Projections is issued, updates occur to previously reported values. To illustrate, for 2003 to 2006 the "Per Capita Amount" trend in Prescription Drug Expenditures declined from 36.2% as reported in 2003 to 22.4% as reported in the 2006 version of the NHE Projections used for the clawback calculation.

coverage programs to ensure dual eligibles access to needed prescription drugs immediately following Part D implementation.[14] Acknowledging the difficulties some dual eligibles were facing and state actions to aid their transition, CMS announced a new Medicare demonstration project to reimburse states for dual eligible prescriptions and for administrative costs related to the transition to Part D. Forty-six states were approved for this demonstration.[15]

Observations of Focus Group Participants

- **The downward revision of the clawback amount in February 2006 was "good news" for states, but the fiscal impact remains unclear for many**. Participants acknowledged "the good news – we have [lower] re-calculated rates." Optimistic about this recalculation, one state official commented that the lower amounts could reduce expected costs and result in savings faster than previously anticipated, but that savings still might not occur in 2006. Officials cautioned, however, that more evaluation would be needed and that each state would be affected differently. State officials also continued to express frustration with the general concept of the clawback, noting that states are mandated to pay for a federal benefit over which they have no control and that is run by numerous private Part D plans with which they have little interaction.
- **At the time of the focus group, no state had yet been billed for the clawback and it was uncertain when payments would begin.** In the fall of 2005, CMS advised states to expect their first clawback billing by January 10th and that payment would be due by February 1st with a 25-day grace period before interest penalties would be applied.[16] However, as of the discussion on March 5, 2006, CMS had not issued the first billing to any state. It was uncertain when the monthly billings would begin and whether or how states would be required to make "catch up" payments once the billings commenced. Most states begin new state fiscal years in July and would therefore find it very difficult to accommodate "extra" catch-up payments assessed after June 30 in their state fiscal year 2007 budgets. One director commented that he did not yet know how to budget for the clawback for state fiscal year 2007.[17]
- **At the time of the focus group, reduced prescription volume resulting from the dual eligibles transitioning to Part D had not impacted state supplemental rebates from drug manufacturers.** Prior to Part D implementation, approximately half of all Medicaid drug expenditures were for dual eligibles. Some states have been concerned that Part D

[14] Thirty-seven states implemented temporary coverage programs to ensure needed prescriptions were received by dual eligibles transitioning to Part D. Source: For more information concerning the states undertaking these programs, see V. Smith et al, *The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation, Results from a 50-State Snapshot,* Kaiser Commission on Medicaid and the Uninsured, February 2006, Publication No. 7467.

[15] *Fact Sheet State Reimbursement for Medicare Part D Transition,* issued by CMS on January 24, 2006.

[16] All State conference call with CMS held September 19, 2005.

[17] On April 13, 2006, CMS sent letters to each state billing them for the January, February and March clawback amounts. While the payment for March enrollments was due May 1 (with a 25-day grace period before interest penalties are applied), CMS gave states the option of paying the combined amount of the January and February bills with the March payment or making eight equal payments from May to December 2006. *"Issue Brief 06-21, States Receive Clawback Bills,"* Federal Funds Information for States, April 19, 2006.

implementation would reduce Medicaid's drug market share and "purchasing power," which might result in lower supplemental manufacturer rebates. At the March 5 discussion, however, Medicaid officials reported no impact yet on their supplemental rebate contracts, although they acknowledged that some erosion could occur later. State officials generally believed that a state's ability to negotiate with manufacturers is not only about volume, but also the ability to move market share within the remaining Medicaid population. It was further noted that the relative mix of drugs paid by one state Medicaid program had changed since the dual eligibles were transitioned to Part D, and classes previously ignored are now being pursued in preferred drug initiatives.

> *"It's all about market share and the ability to move market share."*
>
> *"We are very aggressively pursuing [drug] categories that we have historically left alone, [but are] now rising to the top of what's left…"*

- **Prior to Part D implementation, CMS concluded that states could not be reimbursed for dual eligible prescription costs after January 1st, but later found a way to do so**. Early in the development of Part D, states urged CMS to slow or phase-in the dual eligible transition and to allow Medicaid to continue to pay for dual eligible prescriptions on a temporary basis when necessary to preserve access. CMS concluded that this was not permitted by the MMA. Less than a month after Part D had begun, however, CMS indicated state payments for dual eligible prescriptions were indeed a necessary accommodation and announced a Medicare demonstration plan to repay states. One participant observed that "state reimbursement has been the safety net for a period of time – but that time is limited." State officials said the last date included in the demonstration plan was March 8, although six states with significant problems were given extensions until the end of March 2006. Medicaid officials expressed concern that the CMS process to repay state costs during the transition period was discretionary and may not be applied consistently across all states.

OTHER OPEN ISSUES

Background

It is still too soon to tell what many of the Part D impacts will be. However, state officials discussed specific issues that could pose difficult challenges in the future. High on this list are issues dealing with patient cost-sharing and the inter-relationship between Part D and Medicaid eligibility for the medically needy.

Copayments. Dual eligibles residing in institutional settings (such as a nursing home) are not subject to Part D copayments (after they have spent a continuous, full calendar month in an institution).[18] Part D copayments for other dual eligibles depend upon their income. For 2006, the copayment levels are $1

HHS Poverty Guidelines Federal Poverty Limit (FPL) for 2006		
Family Size	100% of FPL	
	Monthly	Annual
1	$ 817	$9,800
2	$1,100	$13,200

Federal Register, Vol. 71. No. 15, January 24, 2006, pp. 3848-3849.

[18] Question and Answer ID 6224, last updated February 6, 2006, available at www.cms.hhs.gov

(generics) and $3 (brands) for individuals with incomes under 100 percent of the federal poverty level (FPL) and $2 (generics) and $5 (brands) for those with incomes over 100 percent FPL.[19] These amounts are higher than those imposed by some state Medicaid programs. For example, this was the case among four states represented in the focus group discussion: California ($1), New Jersey ($2), Oklahoma ($1-$2), and West Virginia ($0.50 - $3) have Medicaid copayments lower than those imposed under Part D.[20]

Medicaid Spend-Down. Individuals eligible for Medicaid under "medically needy" programs have high medical expenses and are permitted to "spend-down" income that would otherwise exceed Medicaid thresholds to attain eligibility. Thus, incurred healthcare expenses (including prescription drugs) are deducted from income to calculate an adjusted income amount. When the adjusted income amount falls below the state's income eligibility limit, the individual qualifies for Medicaid. (Aged, blind and disabled enrollees in Section 209(b)[21] states may also "spend-down" excess income to qualify for Medicaid.) Once enrolled in Medicaid, the individual is deemed eligible for Part D's low-income subsidy and for Part D copayments between $1 and $5 for the remainder of the calendar year.[22] One consequence of the Medicare Part D coverage for prescription drugs is that individuals may not attain Medicaid coverage through the spend-down for other healthcare services as quickly as they did before Part D began.

Also, institutionalized Medicaid enrollees may have "patient-pay amounts." Unlike spend-down, these individuals are approved for Medicaid, but must pay a specified amount (the patient-pay) to the facility where they reside. Medicaid covers the remaining costs. States may allow "offsets" that reduce the patient-pay amount when an individual pays for non-covered healthcare services such as drugs not covered by Medicaid, Medicare Part D, or commercial insurance, or for Part D copayments.[23]

Observations of Medicaid Officials

- **The ability of dual eligibles to meet copayment requirements remains a concern**. While nursing home residents do not pay ongoing copayments, other dual eligibles with similar health care needs, such as participants in home and community-based services (HCBS) waivers and persons in residential care facilities, are required to pay copayments and have very limited means to do so. One official stated, "For someone on SSI in a

[19] The Office of the Actuary from CMS announced that the 2007 amounts would be $1 (generics) and $3.10 (brands) for incomes under 100 percent FPL and $2.15 (generics) and $5.35 (brands) for others. *Medicare Part Benefit Parameters for Standard Benefit: Annual Adjustments for 2007*, accessed at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/2007_Part_D_Parameter_Update.pdf.
[20] Medicaid Prescription Reimbursement Information by State, Quarter Ending December 2005, available at www.cms.hhs.gov under Medicaid Drug Rebate Program.
[21] Section 209(b) states are states that use more restrictive eligibility requirements than those in effect under the federal SSI program.
[22] Question and Answer ID 4039, last updated February 6, 2006, available at www.cms.hhs.gov
[23] For example, CMS has clarified that Part D copayments are allowable offsets which reduce the amount a dual eligible must contribute towards the cost of care provided by his or her facility and that state Medicaid payments to the facility will increase by the amount of the offset for non-covered services. Question and Answer ID 7042, last updated April 20, 2006, available at www.cms.hhs.gov

residential care facility, we leave him monthly $75 spending money for everything. If an individual is getting a large number of drug products, he doesn't end up with a lot of cash left." The longer term health outcome implications for this population (e.g., the potential for increased rates of hospitalization or institutionalization) are still unknown.

One Medicaid Director pointed out that states would end up being effectively responsible for Part D copayments for persons on HCBS waivers as they would count as allowable medical expenses (and be applied to patient-pay amounts) thereby causing the state to pay more for other services. This director commented that it is very difficult to sort out the impacts for the states and dual eligibles. Another state was monitoring the ability of dual eligibles to pay copayments as part of the state's budget process and other participants noted that their states were considering paying Part D copayments for dual eligibles.

- **The full impact of Part D on the Medicaid spend-down eligibility process remains to be seen.** Once an individual meets the spend-down, he is to be auto-enrolled in Part D. However, because the individual will not incur prescription drug costs after Part D enrollment, he may have difficulty meeting his spend-down amounts for subsequent months and may not attain Medicaid eligibility for other healthcare services. Several state officials stated that the interaction between spend-down eligibility and Part D was a particular concern for residents in their psychiatric facilities.

  A dual eligible attaining Medicaid eligibility through the spend-down process could incur a net financial loss as a result of Part D enrollment if he previously met his spend-down requirement by "incurring" drug expenses, but not actually paying for them out-of-pocket. One director noted that drug payments for dual eligibles previously made by the AIDS Drug Assistance Program (ADAP) had counted as "incurred" health care expense for purposes of spend-down, even though these drug costs were not actually paid by the beneficiary. He noted that a large number of ADAP enrollees in his state were unable to access Medicaid for other heath care costs now that their AIDS drugs were covered under Part D and could no longer be counted for spend-down. Officials indicated that spend-down was an important issue and that it is likely to take three to six months before they could begin to evaluate the full impact.

- **The fiscal impact on states and dual eligibles relating to Part D drugs provided during a retroactive Medicaid eligibility period is unknown.** When an individual submits an application for Medicaid coverage, the effective date of that coverage may be "retroactive" and apply to already incurred healthcare expenses. Similarly, Medicare also approves retroactive coverage, particularly for disabled individuals. At the time of the discussion, CMS had not yet answered the question of how to account for retroactive Medicaid eligibility periods for auto-enrolled individuals who had not enrolled in Part D before they became Medicaid eligible. Subsequently, CMS acknowledged the potential for gaps in prescription drug coverage and changed its policy so that the effective date of Part D auto-enrollment for a full-benefit dual eligible would be "the first day of the month of Medicaid eligibility or January 1, 2006, whichever is later." The logistics of

> *"We don't know how it's going to work. If they get retroactive Medicaid, do they get a* [Part D] *drug benefit?"*

how drug costs incurred during the retroactive period would be reimbursed were not addressed in the new guidance.[24]

- **Measurement and evaluation of Part D impacts are important.** State officials applauded CMS efforts to evaluate Part D (e.g., CMS efforts to monitor plan performance, Medicare Call Center metrics, etc.). They cautioned, however, that appropriate measures are needed for evaluation. For example, evaluation metrics should focus not only on how quickly phone inquiries are answered by Part D helpdesks, but on whether the answer provided to the beneficiary was correct.

PART D-RELATED SPECIALTY AND LONG TERM CARE PHARMACY ISSUES

Background

Within the prescription delivery system, there are specialty pharmacies that provide infusion therapy in an individual's home and pharmacies that primarily serve individuals in long- term care institutions, such as nursing homes and state mental health institutions. These pharmacies and the beneficiaries receiving their services had unique issues with Part D start up that may persist into the future.

Observations of Group Participants

- **Specialty pharmacies had problems with coverage and billing for home infusion drugs**. Many infusion therapy drugs were not covered by some Part D plans. This created a significant issue that affected individuals and specialty pharmacies in several states. One state that did not implement a temporary payment program for dual eligibles had to assign Medicaid staff to handle these complaints on a case-by-case basis. Another state with "bundled" rates for infusion therapy drugs and supplies reported that pharmacies were being required to split their billings with the drug component sent to Part D and supplies to Medicare Part B and Medicaid.[25] The result was extra work and confusion.

> *"The companies* [home infusion pharmacies] *didn't want to "un-bundle."*
>
> *"If you're not a registered Part B pharmacy, then you can't charge. One of the first issues was how to get all those Part D pharmacies registered as Part B pharmacies, so they can bill both*."

- **Long-term care pharmacies and the beneficiaries they serve encountered a number of Part D-related issues and problems, including the following**.

[24] Anthony J. Culotta, Acting Director, Medicare Enrollment and Appeals Group, *Updated Guidance – Changes to Effective Date and PDP Notice Requirements for Auto-Enrollment and Facilitated Enrollment*, CMS Memorandum to Medicare Prescription Drug Plans (PDPs), March 17, 2006

[25] After the focus group discussion, CMS clarified that states still have the option to bundle Medicaid payment for home infusion and pay a single fee to cover the drug, supplies, and other services. The entire payment is this situation is still eligible for federal Medicaid funding. CMS Dear State Medicaid Director Letter (SMDL #06-004), issued March 17, 2006

Incorrect premium assessments billed to dual eligibles. One Medicaid official noted, "We're getting a lot of complaints in the last week about premiums being assessed" for dual eligibles residing in nursing homes. There were reports that some individuals in a State Pharmaceutical Assistance Program (who are also eligible for Part D low-income premium subsidies like dual eligibles) did not pay these erroneous premium billings and were being terminated from their plans for non-payment. Officials expected this same scenario could also happen to dual eligibles.

Non-coverage of unit dose packaging for beneficiaries in residential care homes. Unit dose packaging systems are often used in nursing homes, group homes, and some HCBS waiver settings. Each dose of medication is dispensed in individual packages and labeled with patient identifiers and administration instructions. This technique streamlines administration procedures for facility staff and reduces medication errors.[26] Unit dose packaging also can provide savings, since it allows unused medications to be returned to a pharmacy's inventory if a beneficiary is admitted to the hospital, dies, or is switched to another product. At least one state Medicaid program that pays for unit dose packaging for patients in HCBS waiver settings was advised by pharmacies that none of the Part D plans would do so.

Problems with dispensing guidelines that are significantly different than Medicaid. In one state some Part D plans were mandating a 5-day supply limit on each prescription instead of the 30-days allowed in the state Medicaid program. This change significantly increased the workload of nursing home staff and their pharmacies.

Reports from some long-term care pharmacies of large Part D accounts receivables. One state official stated:

> *"Long-term care pharmacies have been floating a lot of receivables … Early on one pharmacy had a half million in receivables [from Part D plans]. It won't be until they finally get paid that they'll actually see how claims are adjudicated and that they will begin to understand the impact of the new Part D policies."*

Participants also noted that more than one state provided advances to long-term care pharmacies to lessen cash flow problems during the initial stages of the Part D transition.

- **State developmental disability center residents reported difficulties enrolling into a Part D plan**. In one center 89 residents could not get enrolled in any plan. It was reported to that state's Medicaid director that "[e]ven though CMS tells them they're in a plan… they [center staff] call that plan and they're not enrolled."

LESSONS LEARNED

- **The historic lack of coordination between Medicare and Medicaid hampered the implementation of policies that affected dual eligibles, especially by not fully tapping into states' experience implementing healthcare reforms.** State officials

[26] *A Study of Long-Term Care Pharmacy Dispensing Costs, Legislative Budget and Finance Committee Pennsylvania General Assembly*, December 2000, accessed at www.ltcpa.org on May 2, 2006

complimented the Medicare staff and their dedication implementing Part D. However, some participants thought Medicare could have better utilized the experience of Medicaid. State Medicaid programs have considerable experience bringing up new and innovative programs requiring complex system and procedural changes. Medicaid programs believe they have great knowledge and familiarity with the dual eligible population and their service needs – especially the unique needs of institutionalized beneficiaries. Medicaid officials expressed frustration that their expertise and experience was not given more consideration, given that the most complex aspect of Part D implementation involved dual eligibles. Participants also observed that significant federal and state resources were spent transitioning the over six million dual eligibles, all of whom already had a prescription drug benefit under Medicaid. One commenter reflected that "CMS can say that 'we had a rough start, but at least it was better than what they had before' - but that was not true for the dual eligibles." Medicaid officials believed that a smoother transition for dual eligibles would have occurred if greater weight had been given to their voices. Those in this discussion clearly believed, as one participant summarized, that "the silos between Medicaid and Medicare have to be broken down."

- **Future healthcare legislation should provide for realistic implementation timelines and greater administrative flexibility**. Implementation of Part D required sweeping changes to the healthcare system. In such situations the authorizing legislation needs to provide enough regulatory authority to allow the implementing agency latitude and flexibility to make pragmatic decisions. Based on their own experience implementing complex system changes at the state level, state officials recalled that from the beginning they had communicated serious concerns about the short timeframe to transition dual eligibles to Part D. They advocated a phase-in, so that unforeseen implementation problems could be identified along with testing possible solutions. CMS could not entertain such a recommendation – even if they agreed with it – because of the constraints of the MMA. CMS could only respond: "We can't change this – it's in the statute."

- **Switching from Medicaid to Part D highlighted for many providers Medicaid's efficiency and the comprehensiveness of the Medicaid prescription drug benefit.** Pharmacies had come to rely on Medicaid programs that pay pharmacies typically within a week. Pharmacies have expressed concern that Part D plans provide slower payments to them.[27] In several instances, healthcare providers had complimented the state Medicaid program publicly, acknowledging that it has run well, has paid claims promptly and has provided a comprehensive benefit. Even Medicaid's preferred drug lists, prior authorization requirements and dose limits were seen as common sense options accepted by the health care community.

> *"In a very public way, [healthcare providers told us] we wish we could be back to the days of Medicaid – this was January 2nd."*

[27] Robert Pear, "*Pharmacists Say Drug Plan Threatens Their Income,"* The New York Times, March, 13, 2006; "*Pharmacists' Group Says Medicare Drug Benefit Driving Smaller Pharmacies Out of Business,"* CQ Healthbeat, March 30, 2006.

- **The Part D impacts for dual eligibles will not be isolated to the January 2006 rollout of the program**. As Medicare beneficiaries become eligible for Medicaid, they will face many of the same issues that were encountered when Part D first began. Also, similar challenges are likely to occur as the new 2007 contract year begins. Changes in plan options and in the low-income subsidy amount for the 2007 contract year could result in the need for many dual eligibles to select or be auto-enrolled into new plans. The numbers of individuals will not reach the magnitude of those of during January 2006, but the issues and the impacts on the individuals will remain quite similar.

CONCLUSION

Initial implementation of Medicare Part D occurred with significant impacts on the most vulnerable of Medicare beneficiaries – those also enrolled in Medicaid. For most of these dual eligibles, the transition of prescription drug coverage from Medicaid to Medicare Part D occurred without major issues. However, for the more than six million people whose demographic and medical characteristics make them the most vulnerable group enrolled in Medicare, problems affecting even a small portion of the total translated into major issues. Many of the initial problems related to major system issues that are difficult to resolve quickly.

Medicaid directors were in a key position to anticipate and observe the issues as they emerged and were also best positioned to resolve some of the issues that affected dual eligibles in their states. The purpose of this report has been to present their perspectives on those issues with the experience of the first two months of Part D implementation fresh in their minds.

Many issues, which arose in the first weeks of implementation, were anticipated by both state and federal officials. State officials were confident they did all they could to assist CMS, but problems still arose that threatened the availability of prescription drugs for persons who previously had the security of Medicaid coverage. When it became apparent that many individuals were unable to obtain needed prescriptions, many states quickly implemented temporary solutions to assure access until the implementation issues were solved. The actions of states were central to efforts to transition coverage from Medicaid to Medicare.

Medicaid officials are aware that all issues have not been fully resolved. At the time of the focus group, some individuals remained enrolled in two plans, or were enrolled in an out-of-state plan, for example. However, many significant issues of the first weeks of implementation seemed to have been addressed successfully. Now, the focus turns to the future, with attention directed to potential disruptions that could occur in January 2007 when re-procured Part D contracts and recalculated benchmarks for the low-income subsidy take effect. In addition, there are inherent system lags that can make it impossible for Part D plans to know when an individual is a dual eligible and entitled to lower copayments and waiver of premiums. Finally and significantly, state officials remain concerned about their financial obligation under the clawback.

A key message that emerged from the discussions with Medicaid directors is the need to continue to focus on the interaction between Medicaid and Medicare Part D, and to address the key system and coordination issues that remain. With the urgency to focus on implementation, federal officials may not have given the views and input of state Medicaid officials the consideration that would have assisted initial implementation. State officials indicated they remain interested in assisting with issues that remain. The dual eligible population is constantly changing, with individuals attaining dual eligible status each day. Focus is needed on issues of initial enrollment and transition from Medicaid to Medicare to avoid the possibility of future dual eligibles losing coverage for prescription drugs as occurred in the initial implementation of Part D.

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