Medicare Rights Center

Protecting the Poorest Americans During the Medicare Drug Transition

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EXECUTIVE SUMMARY

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 6.4 million "dual eligibles" – low-income individuals who are enrolled in both Medicare and Medicaid – will lose their Medicaid drug coverage on January 1, 2006. Each dual eligible will be transferred into one of the hundreds of new Medicare "Part D" prescription drug plans for drug coverage. Because Medicaid drug coverage ends on the first day that Medicare drug coverage begins, the transition leaves no margin for computer or human error. As a result, millions of dual eligibles could experience gaps in drug treatment during the first months of Part D. Such gaps could have catastrophic human consequences. The political consequences could include widespread perception of a failed rollout of the Medicare prescription drug benefit. If 95 percent of dual eligibles make a smooth transition in January 2006, more than 300,000 of the frailest Americans will lose access to needed medicine.

Dual eligibles have extensive health care needs, and they are among the most vulnerable men and women in both Medicare and Medicaid. Compared to other Medicare beneficiaries, dual eligibles are far more likely to be sick, from underserved ethnic backgrounds, living in rural areas, lacking high school diplomas, living in nursing homes, and very poor. Nearly a quarter live in institutions, and four in ten have a cognitive impairment.

Transitioning dual eligibles into Part D will happen in a very compressed timeframe. Most dual eligibles will be notified by mail of their random assignment into a Part D plan in late October. Between then and December 31, 2005, dual eligibles will have to learn how to navigate a complex new program and how to evaluate formularies, access drugs that may not be on plan formularies, and understand pharmacy networks as well as other features of their plans.

In general, Part D drug coverage will differ from Medicaid drug coverage in several important respects, including the specific drugs that are covered, the pharmacies that enrollees may use, copayment rules, and the availability of emergency supplies pending appeals when a plan denies coverage of a prescribed medication.

While the Centers for Medicare and Medicaid Services (CMS) has taken important steps to improve automatic enrollment processes and formulary protections, the final transition process remains inadequate to ensure a smooth transition for dual eligibles. Dual eligibles face serious risks, including falling through the cracks of complicated data exchanges between and among the Social Security Administration (SSA), CMS, plans and states; losing coverage because of formulary and pharmacy network limitations; and not understanding changes in their coverage enough to navigate the complicated new system. All patients face risks that their doctors and pharmacists will be overwhelmed by the demands of the new system in the early months of the new Part D benefit.

Congress could reduce the risks of a precarious transition strategy by extending the availability of Medicaid as backup drug coverage during a reasonable transition period to Part D. With a safety net in place, CMS, states, health advocates, drug plans and providers would have time to implement a comprehensive education and transition plan that would ensure that all dual eligibles are successfully enrolled in Part D plans; that they know how and where they can obtain necessary drugs; and that their doctors have had adequate time and information to review and, if necessary, appeal new formulary guidelines.

OVERVIEW

Under the MMA, 6.4 million "dual eligibles" (low-income individuals enrolled in both Medicare and Medicaid) will lose their Medicaid drug coverage on January 1, 2006. Each dual eligible will be transferred into one of the hundreds of new Medicare "Part D" prescription drug plans for drug coverage. Because Medicaid drug coverage ends on the first day that the new Medicare drug coverage begins, the dual eligible transition leaves literally no margin for computer errors, data glitches, postal delays, or the inevitable disruptions and confusion involved in moving millions of the frailest and poorest older and disabled adults out of one prescription drug program and into another one.

EXAMPLE: MS. R*

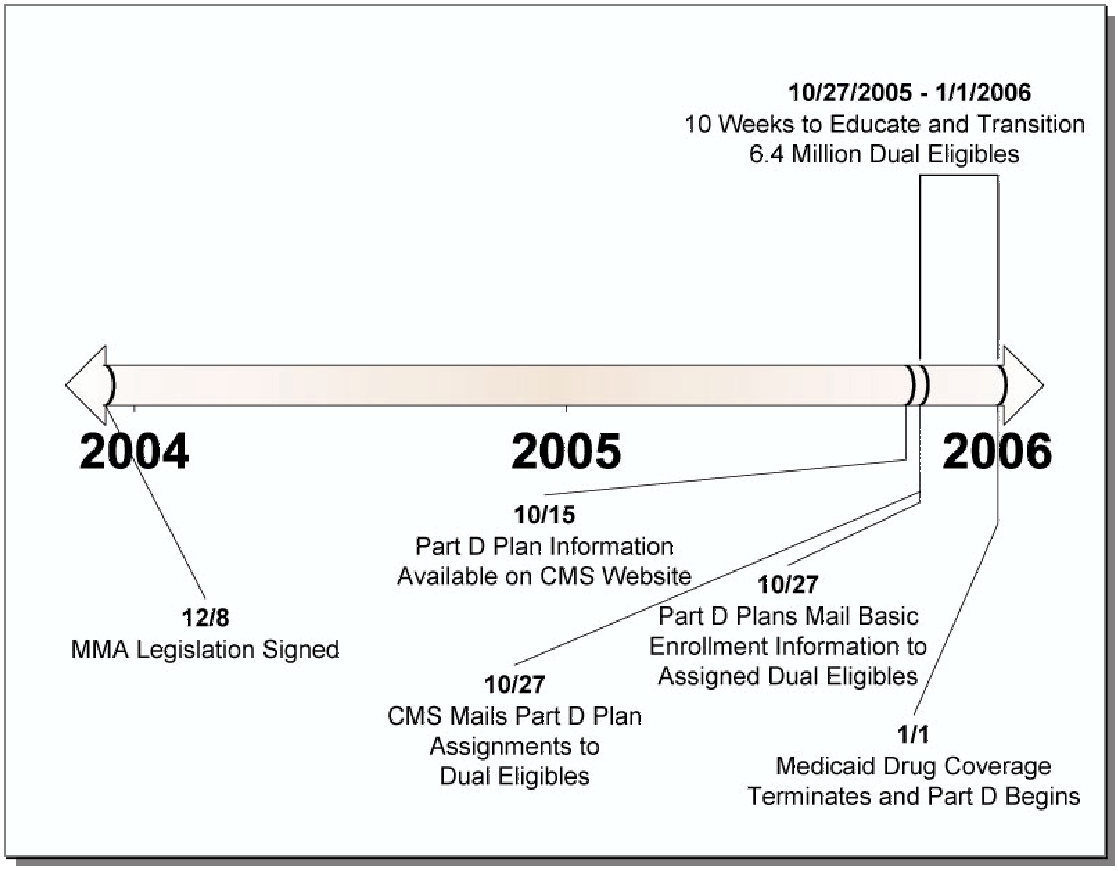
Ms. R is 33 years old and has severe physical disabilities. She is well aware of the changes in Medicaid drug coverage and has been informed that she will be automatically assigned to an appropriate plan in time to refill her prescriptions in January 2006. On December 15, she still hasn't received a new Part D card. She calls her state Medicaid office and is told not to worry, she is in their records as a dual eligible and therefore CMS must have assigned her to a plan. On January 5, she still hasn't received a card and her prescriptions are running out. She calls 1-800-Medicare. The operator tells her that she cannot give her a plan assignment, because they have no record of Ms. R as a dual eligible. They refer Ms. R back to her state Medicaid office. Ms. R calls the Medicaid office again, but the lines are busy. Ms. R arranges a ride to the Medicaid office the next day, where she waits in line for several hours. A weary Medicaid worker promises to "look into" her situation with CMS, but suggests that to be safe, Ms. R enroll in a plan and apply for the low-income subsidy on her own so that at least she can be sure of getting coverage in about a month.

As a result of this precarious transition strategy, millions of dual eligibles could experience gaps in drug treatment during the first months of the Medicare prescription drug benefit. Such gaps could have catastrophic consequences for ill and severely impaired men and women, including increased hospitalizations, disruptive behaviors, disease progression, drug resistance, and premature death. The transition also could have serious implications for the success of the overall Part D program. Dual eligibles are the very first group required to enroll in the new Medicare Part D plans. If they cannot access the drugs they need in the first months of the program, the public's confidence in the drug benefit could be undermined.

In final rules and guidance implementing the MMA, CMS recognized special concern for dual eligibles and acknowledged "the enormity of the [duals'] transition."[1] But the CMS transition strategy, though improved over time, remains inadequate to ensure that critical treatment regimens are undisturbed. While helpful, CMS' regulatory efforts to date will not avert a transition crisis.

The numbers are unavoidably daunting. Even if 95 percent of dual eligibles can make a smooth transition from Medicaid to Medicare drug coverage in January 2006, more than 300,000 of the frailest Medicare beneficiaries will lack access to needed medications on January 1, 2006.

TIMELINE: THE TRANSITION TO PART D



The short time between the publication of Part D plan details and the mandatory transition for dual eligibles concerned several state Medicaid officials who were interviewed about the transition during late July and early August 2005. As one aptly noted, "It seems like the most important information [about Part D] is coming out last."

BACKGROUND ON THE DUAL ELIGIBLES' TRANSITION UNDER THE MMA

▪ Who Are the "Dual Eligibles"?

Dual eligibles are low-income individuals who are elderly or have disabilities and are covered by both Medicare and Medicaid. In general, Medicare is the primary payor for dual eligibles for hospital stays, doctor visits, and lab services, while Medicaid pays cost-sharing for those services and currently provides primary coverage for prescription drugs and long-term care services, among others. [2] Dual eligibles have extensive health care needs, and they are among the most vulnerable and highest cost beneficiaries in both programs.[3]

The characteristics of the dual eligible population will make it particularly difficult for them to navigate the transition to new Part D drug plans. Dual eligibles are:

- *Sick* - More than 70 percent are limited in activities of daily living, and they have higher rates of Alzheimer's disease, diabetes, pulmonary disease and stroke than other people with Medicare.[4]
- *Cognitively Impaired* - Nearly 4 in 10 have a mental or cognitive impairment.[5] That means that 2.5 million dual eligibles may not be able to navigate program changes even if education and communication efforts are appropriate for an elderly population.
- *Underserved* - More than 40 percent of dual eligibles are racial/ethnic minorities, and dual eligibles are more likely to live in rural areas than other Medicare beneficiaries.[6]
- *Less Educated* - 61 percent do not have a high school diploma.[7]
- *Dependent on Prescription Drugs* - Dual eligibles are expected to fill 20 million prescriptions in January 2006.[8]
- *Institutionalized* - Almost one in four dual eligibles lives in a nursing home or other long-term care facility.[9]
- *Poor* - More than 60 percent live below the poverty level.[10]

EXAMPLE: MR. H*

Mr. H is 75 years old, lives on his small Social Security check in a small town in Eastern Montana, and takes medication to control his high blood pressure and diabetes. He learns that he has been automatically enrolled in a Part D plan when he receives a plan card in October 2005. In late January, he brings the card with him when a neighbor drives him to the nearby pharmacy he has used for 40 years to refill his prescriptions. His pharmacist tells him that the pharmacy is not part of his new plan's network and he can't use his Medicaid card to buy his drugs any longer. The pharmacist tells Mr. H that a pharmacy in the next town has agreed to be in his plan's network. Because the pharmacy is 15 miles away and Mr. H can't drive, he waits until the weekend to refill his prescription when his son can drive him there. By the time his prescriptions are refilled, he has been off his medication for 6 days and is at high risk for complications.

▪ Medicare Part D and the Transition Process

Under the new Medicare Part D drug benefit, CMS will contract with private sector stand-alone drug plans or Medicare Advantage plans to offer drug coverage to Medicare beneficiaries.

Dual eligibles, who will receive low-income subsidies to pay plan premiums, deductibles, and copayments, will have the option to choose from among the plans in their regions. If they do not select Part D plans on their own, most dual eligibles will be automatically assigned and enrolled in a low- to average-cost Part D plan on a random basis by January 1, 2006, when their Medicaid prescription drug coverage will terminate. Each region will have between five and fourteen Part D plans in which dual eligibles will be randomly assigned.[11] Dual eligibles who are currently enrolled in managed care plans will be passively enrolled by their plans into related Medicare Advantage Part D plans.

EXAMPLE: MS. P*

Mr. P is 84 years old, living alone, and has early stage Alzheimer's disease and glaucoma. He receives several letters and a new drug card in the mail in October 2005, but he throws them out, mistaking the official-looking envelopes for junk mail. On January 4, 2006, he walks to his corner pharmacy and presents his Medicaid card. The pharmacist tells him that he can't accept it anymore, and asks Mr. P if he has a new card. Mr. P is angry, because his Medicaid card has always worked before. The pharmacist has a long line of customers, and the computer connection to Medicare information has been slow for the whole week. He suggests that Mr. P call 1-800-Medicare, and Mr. P goes home empty-handed. Mr. P can't remember the number when he gets home. He doesn't refill his prescriptions until his daughter takes him to the doctor in March, where she discovers that he has been off his medications for two months and his eyesight has deteriorated significantly.

Under CMS' proposed transition strategy, dual eligibles will be officially notified of changes in their prescription drug coverage through three mailed notices – two from CMS, and one from their State Medicaid program.[12] The first notice from CMS was sent to beneficiaries in May and June, 2005. It advised dual eligibles of upcoming changes but provided no specific information about their new drug coverage or about their plan choices under the Medicare Part D program. States will be sending their notices to dual eligibles over the next few months, telling them about the termination of their Medicaid coverage.

The last notice from CMS, which is expected to be sent in late October,[13] will be the first to provide any specific information to dual eligibles about their new drug coverage. That notice will tell the recipient which Part D plan she will be auto-enrolled in if she does not choose her own Part D plan. For dual eligibles not already enrolled in managed care plans, Part D plan assignments will be made at random from among low- to average-cost stand-alone prescription drug plans. Assignments will not take into account individual patients' prescription drug needs or pharmacy relationships. Part D plans to which dual eligibles have been assigned will then be required to mail basic enrollment materials, including a "Summary of Benefits," to the dual eligibles who have been assigned to them.[14] More detailed information about the plans, including lists of coverage rules, formulary lists, and pharmacy networks, will be available on the Internet and by request.

During October, November, and December, CMS plans to facilitate and encourage general outreach and education efforts around the new Medicare drug benefit by states, providers,

health plans, advocacy organizations, church groups, and others.[15] Dual eligibles will be encouraged to research drug plan options and review formularies and other changes with their doctors. And on January 1, 2006, dual eligibles will have to rely on their new Part D plans to cover their prescription drug needs.

▪ Comparing the Coverage: Medicaid vs. Medicare Part D

Part D drug coverage can be expected to differ from Medicaid coverage in several important respects. The magnitude of these differences will vary, depending on the specific rules of each state Medicaid program and each Part D plan in which dual eligibles will enroll. For some dual eligibles, coverage under Part D could be better than Medicaid drug coverage, and for others it is likely to be less comprehensive. But for virtually every single one of 6.4 million dual eligibles, drug coverage rules and procedures will change overnight at the end of 2005.

Formulary Access: Part D plans are unlikely to cover the same array of drugs as state Medicaid programs, which generally cover most FDA-approved drugs. Part D plans are allowed to have limited formularies, although they must provide nearly comprehensive coverage of six categories of drugs and they must establishes processes to provide coverage for off-formulary drugs in certain cases.[16] CMS has also required plans to implement formulary transition policies for new patients, though plans have significant flexibility to define their own policies.[17] It is expected that formulary coverage will vary, perhaps significantly, across Part D plans, so that dual eligibles in one Part D plan may have access to a particular drug that will not be available to their dual eligible neighbor who has been enrolled in a different plan. Finally, Part D plans will not cover certain drugs that are typically covered by Medicaid, including certain over-the-counter medications, prescription vitamins, and some commonly prescribed psychiatric medications such as benzodiazepines.

EXAMPLE: MS. B*

Ms. B has schizophrenia and a dependent personality disorder and takes 8 prescription drugs per month, including an atypical antipsychotic. Ms. B receives a new Part D plan card in the mail in October 2005, and discusses it with her doctor. He has been told that a special rule ensures that all antipsychotics will be covered by all Part D plans, so he counsels her to stick with the plan she has been assigned to. Ms. B has not been doing as well recently, and her physician has decided to transition her to a different atypical antipsychotic. He gives her a few samples of a new drug and gives her a prescription for it. When Ms. B brings the card to her pharmacy to refill her old prescriptions and start the new one on January 10, 2006, her pharmacist tells her that the new antipsychotic is subject to prior authorization, and he suggests that she call her doctor immediately. Ms. B is frightened and confused. She calls her doctor but cannot explain what has happened. Ms. B's doctor has been seeing patients like Ms. B to address new formulary restrictions round-the-clock since January 1. His receptionist tells Ms. B that her doctor's first available appointment is in three days unless it is an emergency. Ms. B runs out of the samples while waiting for her appointment, and on January 12 she is hospitalized after a suicide attempt.

"Utilization management," or "cost management," tools are likely to be different under Part D than what dual eligibles have previously experienced under Medicaid. Many, but not all, Medicaid programs use prior authorization requirements on some drugs, and some states impose prescription limits. Part D plans' utilization management policies are likely to vary widely and to mirror approaches currently used by pharmaceutical benefit managers in the commercial market, where enrollees are likely to be healthier, younger,

wealthier, and more educated than dual eligibles. Many of these utilization management policies, like drug substitution or "fail first" strategies, are not typically used by Medicaid programs and may be inappropriate for dual eligibles.

Pharmacy Access: Dual eligibles enrolled in Part D are likely to face new pharmacy restrictions. In most states, dual eligibles can fill Medicaid prescriptions at most retail pharmacies in the state. Under Part D, plans will only provide prescription coverage through pharmacies in defined pharmacy networks.[18] While Part D plans' pharmacy networks have to meet certain geographic access requirements, one news report suggests that some Part D plan networks could include less than one-half of a state's pharmacies.[19] Several state Medicaid officials worried that a large number of pharmacies in their states who accepted Medicaid payment for drugs would either refuse to participate in Part D networks or would refuse to provide free delivery services, because pharmacy reimbursement under Part D is expected to be substantially lower than Medicaid reimbursement in their states.[20]

Co-payment requirements: Copayment requirements will be different for dual eligibles under Part D. Currently, many – but not all – Medicaid programs impose copayments of up to $3 per prescription. These copayments must be waived by the pharmacist, however, if the beneficiary cannot afford to pay them. Under Part D, dual eligibles not living in long-term care facilities will be subject to copayments of up to $5 per prescription in the first year, and copayments will only be waived at the pharmacists' discretion.

Appeals and Emergency Supply: Under Medicaid, dual eligibles are entitled to receive an "emergency supply" of medications while prior authorization or other appeals processes are pending, to ensure that drug treatment is not inappropriately interrupted or delayed.[21] Under Part D, plans will not be required to provide an emergency supply of medications, except to institutionalized residents.[22]

Administrative Complexity: For most dual eligibles, Medicaid drug coverage rules are uniform across the state and the coverage is generally comprehensive. Medicaid officials, social workers, advocates, and providers can learn a single set of rules and procedures to help dual eligibles who face difficulties accessing prescription drugs. Under Part D, dual eligibles in each region will be divided among five to 14 plans with different formularies, pharmacy networks, and appeal procedures. Furthermore, because Part D plans are not permitted to cover certain drugs, including benzodiazepines and prescription vitamins, some dual eligibles will have to use supplemental coverage – through Medicaid or charitable programs – to access the drugs they need.

KEY TRANSITION RISKS FOR DUAL ELIGIBLES

While CMS has taken important steps to improve automatic enrollment processes and expand formulary protections since the publication of the MMA proposed regulation, the final transition process remains inadequate to ensure that dual eligibles will not be subject to dangerous treatment disruptions during the first months of the Part D program.

- **Risk: Falling Through the Cracks of Massive and Complex Data Exchanges**

The process of moving millions of persons from 51 state administered Medicaid programs into hundreds of different Part D plans will require massive systems changes and data transfers between states, CMS, SSA and the new Part D plans. Incomplete information, inaccurate or outdated data, and/or unexpected systems errors could cause automatic assignment to fail and people to fall through the cracks. Data problems are inevitable given the immense volume that must be exchanged and updated in a very short period.

Auto-assignment processes will require CMS:

- to obtain from states complete, up-to-date lists identifying all dual eligibles from 51 Medicaid programs;
- to obtain from the Social Security Administration complete, up-to-date mailing addresses for those dual eligibles or their designated representatives;
- to obtain from Medicare Advantage (MA) plans and Special Needs Plans (SNPs) up-to-date lists of dual eligible enrollees whom they plan to "passively enroll";
- to exclude from auto-assignment into stand-alone plans, those dual eligibles who will be "passively enrolled" into MA plans or SNPs;
- to match the millions of dual eligibles not enrolled in Medicare Advantage plans with one of the many stand-alone prescription drug plans in their regions;
- to ensure that all auto-assignments are accurately communicated to the plans, to beneficiaries or their designated representatives, and to states;
- to ensure that SNPs and MA plans properly "passively enroll" dual eligibles into their prescription drug plans;
- to receive, input, and confirm with plans and beneficiaries all disenrollments, reenrollments, and declined enrollments made before January 1, 2006; and
- to receive, input and confirm with plans and beneficiaries changes from individuals who move or change their mailing addresses or who become eligible for Medicaid after the first auto enrollment process.

An unknown number of dual eligibles have already fallen victim to one kind of "system" error related to the transition. CMS revealed in June that some of the notices sent to dual eligibles telling them about the termination of their Medicaid coverage never made it to their intended destinations – the envelopes meant to contain the notices were empty. At the time the incident occurred, CMS could not assess how many envelopes arrived empty or identify who received empty envelopes in order to provide them with another copy.[23]

LEARNING FROM THE SSI TRANSITION CRISIS: DÉJÀ VU?

This is not the first time that a federal agency has been directed to transfer millions of poor and vulnerable people from a state-administered benefit program to a federal program literally overnight. In 1974, the Social Security Administration (SSA) launched the Supplemental Security Income program, or SSI, to replace state-administered adult public assistance programs for people with disabilities. SSA was required to transfer 3.2 million Americans, half the number of people who must be transferred to the Medicare drug benefit this January.

SSA made a substantial effort to ensure a smooth transition for the millions of state welfare recipients who would be moved to the federal program. It hired 10,000 new employees, opened new offices and call centers, and gave almost every employee intensive training in SSI. On January 1, 1974, the new program was rolled out.

Things did not go well, according to an account in *OASIS*, SSA's in-house magazine. "Starting on January 2, 1974, thousands of people who had not gotten their new SSI checks began descending on the [District Offices].... SSA expected a maximum of 20,000 queries a day ... from the field. Instead, the number of queries rose sharply to as many as 60,000 per day....The [computer] overload cause the system to go 'down' several times for extensive periods during the early weeks."

"Many former State recipients got the wrong SSI payment....Others received no SSI check at all. The problem was most severe in California, with about 500,000 recipients shifting to SSI, and New York City, with about 200,000. In New York City freezing weather made matters worse for the very large crowds flocking to the city's 23 SSA offices.... Some offices had to close their doors before 10 a.m. because they already had as many people as they could handle during the entire day."

News reports describe protest rallies and blocks-long lines outside Social Security offices that required police security. By August 1974, the New York State Assembly had branded the new program a failure, citing recipients' **loss** of financial security as a result of now having to contend with "the frequently insensitive attitudes of two bureaucracies" – state and federal offices. Many lawsuits were filed, and Congressional committees held more than a dozen hearings about the difficult transition.

What caused the huge problems with the SSI transition? Did systems fail entirely? Hardly. Indeed, one report cited by SSA noted that 95 to 98 percent of the 3.2 million people shifting from to SSI rolls got their checks on time in January 1974. But tens of thousands of people didn't, starting a chain reaction of panic and protest as vulnerable people contemplated the loss of money for rent, food, and medicine.

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- **Risk: Disrupting Access to Critical Treatment Regimens**

Although detailed information about plan formularies and pharmacy networks will not be available until late October, it is virtually certain that some dual eligibles who are randomly assigned to prescription drug plans will learn on their first pharmacy visits in 2006 that their drugs are not covered at all or are subject to prior authorization. Others will find that the pharmacies they have always used are not on their plans' networks. For some, these barriers will not be difficult to overcome, but for others, they could result in dangerous treatment disruptions.

Certain statutory appeals provisions and regulatory guidance issued by CMS were intended to reduce the risk of dangerous treatment disruptions.[24] Appeals provisions permit beneficiaries to petition for coverage of medically necessary drugs even if the drugs are not on plan formularies. CMS' formulary guidance requires drug plans to provide nearly comprehensive coverage of six important categories of drugs, though prior authorization can be required for some patients. Finally, CMS' formulary transition guidance requires plans to implement "appropriate transitions processes" for new enrollees that take into account their prior drug regimens, and it "recommends" that plans provide temporary one-time transition supplies of prescribed drugs that are not on plan formularies.

EXAMPLE: MS. L*

Mrs. L is a 94-year-old widow living in a nursing home. She is randomly assigned to a Part D plan that does not have a contract with the long-term care pharmacy that services her nursing home. Her roommate is automatically assigned to a different Part D plan, and her neighbors down the hall have chosen a third Part D plan to enroll in. The overworked nursing home social worker has not yet finished a chart indicating the Part D plans that residents are assigned to, the plan rules and formularies, and the different long-term care pharmacies that must be called for prescriptions. On January 5, before the social worker had completed her chart, Mrs. L begins showing signs of a low-grade pneumonia. The doctor prescribes antibiotics before he leaves the facility that night. The nurse on duty spends several hours juggling patient needs and struggling to determine which of several new pharmacies she can call. Mrs. L's condition deteriorates while she waits for the medication, and at midnight the nurse calls for an ambulance to take Mrs. L to the hospital.

Despite the good intentions behind these provisions, it is unclear how meaningful these safeguards will be for dual eligibles, for several reasons. First, many dual eligibles will not be able to either understand or exercise their rights under these policies. Second, accessing these safeguards will often require multiple steps that cannot be taken at the point of sale (the pharmacy), but will require follow-up calls, letters and paperwork outside of the pharmacy either to obtain prior authorization for use of a drug or to prove that treatment with that drug has been ongoing. Third, many of these protections will depend on smooth communication and cooperation between vulnerable patients and their doctors, pharmacists and plans.

Indeed, even among less vulnerable populations, formulary and appeals processes can pose barriers to needed medications. A recent study of formulary processes used by Medicaid managed care plans in one state reported numerous examples of harm to patients resulting from patient confusion, communication breakdowns between plans, physicians, patients and pharmacists, and inadequate training for plan staff about patient safeguards, even though

patients' rights under Medicaid are more extensive than they will be under the Part D program.[25] One study cited by the Medicare Payment Advisory Commission (MedPAC), an independent federal body that advises Congress on Medicare issues, showed that when pharmacies rejected nonformulary prescriptions of a commercially insured group of patients, it took significant time and effort for them to get their medications. Upon learning that a prescribed drug was not covered by a patients' drug plan, pharmacists called the patients' physician directly only 40 percent of the time. Nearly 30 percent of the patients spent more than three hours of their own time trying to resolve the coverage issue over several days, making multiple calls to their doctors and their plans. And 30 percent of patients never secured coverage for a prescription drug at all; 11 percent never took any drug for their condition, another 11 percent paid for the prescribed drug out of their own pockets, and 8 percent bought an over-the-counter medication instead.[26]

- **Risk: Failures of Communication and Education**

One of the biggest challenges regarding autoenrollment will be educating dual eligibles on how to navigate a complex new pharmacy system involving dozens of competing prescription drug plans, each with different formularies and coverage rules and with limited pharmacy networks. In order to ensure continuity of prescription coverage, by January 1, 2006, every dual eligible (or family member, caseworker, or caregiver) will have to know and understand:

- that her Medicaid card will not work at a drugstore anymore;
- which Part D plan she is assigned to, and how to prove her enrollment;[27]
- the consequences of enrolling in a Part D plan, (for example, whether it will reduce benefits available through retiree coverage);
- the consequences of disenrollment from her plan, (including the loss of all drug coverage and the risk of future penalties);
- which pharmacies she can use to fill prescriptions;
- which of her drugs are on the new plan formulary;
- what to do if a drug she takes is not on the plan formulary;
- what to do if a drug she takes is subject to prior authorization or a step-therapy requirement;
- what her co-payments will be at the pharmacy.

Furthermore, to ensure the most appropriate coverage available, each one of the 6.4 million dual eligibles should have assistance in evaluating all of the available plan options in the twelve weeks between the publication of Part D plan information and the end of Medicaid coverage.

According to the MedPAC, an independent federal body that advises Congress on Medicare issues, ensuring a smooth transition between private-sector drug plans takes a minimum of six, and preferably nine, months, with much of the time necessary to do enrollee education.[28] Adequate education requires several interventions for each consumer, including repeated information, through multiple channels and in multiple formats, about the change in coverage as well as personalized education and counseling to help people make informed plan choices.

Educating dual eligibles will be far more difficult than educating private-sector plan enrollees. State experience with automatic enrollment of dual eligibles into mandatory managed care demonstrates that this group is extremely difficult to reach and educate.[29] Many have low literacy or limited English proficiency, and four in ten have some form of mental or cognitive impairment. MedPAC reported that mainstream health counseling organizations were not well-equipped to effectively reach hard-to-reach groups such as those in nursing homes, younger beneficiaries with disabilities, and members of racial and ethnic minorities who face linguistic, cultural, and educational barriers[30] – all populations that are disproportionately represented among dual eligibles.

State Medicaid officials interviewed about the transition of dual eligibles into Part D put concerns about beneficiary education and communications high on their list of worries. All noted concern about whether mail-only contacts would be adequate to educate dual eligibles about changes in their drug coverage, pointing out that some would never reach the recipients, and others will be ignored or not understood because of language or literacy barriers. Gene Gessow, Iowa's Medicaid Director, noted that "[y]ou can't tell people once in a letter or put it up on a website and expect them to understand it." All of the officials noted that CMS had encouraged states do much of the outreach to dual eligibles, without providing them additional money, information, or control over the transition process.[31]

- **Risk: Disruptions to Health Care Delivery**

Changing procedures and rules for millions of individuals on one day is likely to result in short-term disruptions to the entire care delivery system. Notwithstanding CMS' best intentions to prepare health care providers for the change, there is little evidence that doctors, community health providers, nursing homes or pharmacists are ready for what they will face between October 2005 and January 2006. Physicians who treat large numbers of Medicare patients, especially Part D's first enrollees, the dual eligibles, will face a daunting spike in their workloads. According to a recent poll, 38 percent of seniors planned to turn to a physician to

STATE MEDICAID OFFICIALS VOICE CONCERN ABOUT THE DUAL ELIGIBLES' TRANSITION

During interviews conducted in early August 2005, Medicaid officials from Pennsylvania, Utah, Iowa, New Mexico and Alabama voiced serious concerns about transitioning their dual eligible enrollees into Medicare prescription drug plans. Several praised CMS' hard work and acknowledged that CMS officials were doing the best they could with the huge task presented to them. Nonetheless, the officials also noted that CMS had left it to the states to do a lot of the outreach to dual eligibles and worried that they did not have adequate resources or time to ensure a smooth transition. The officials raised a number of specific concerns during the interviews, including duals "falling through the cracks" and not understanding how to get their drugs; the sufficiency of Part D formularies and pharmacy networks; that the providers in their states were not prepared to help their patients understand the new program; and the increased costs and suffering that disruptions in drug treatment could bring about.

But despite their worries, all noted that to some extent their hands were tied. None of the officials' states had budgeted for any kind of contingency plan to ensure that dual eligibles get their medications if the Part D transition does not go smoothly. Said one, "Somebody is going to fall through the cracks, and even though they are a Medicaid beneficiary … we can't do anything."

help them navigate the Medicare prescription drug benefit.[32] Physicians will be asked:

- to advise patients on plan selection;
- to review new formularies for dozens of different plans;
- to review patient charts and provide new prescriptions to conform to new plan formularies;
- to respond to patient requests and pharmacist calls about the need for prior authorization, supportive statements for appeals and expedited reviews, or revisions in prescription ordering.

Nurses, aides, social workers and physicians working in nursing homes will face particularly challenging circumstances. Because automatic enrollment of dual eligibles must be done on a random basis among available plans, patients in a single nursing home are likely to be enrolled in dozens of different Part D plans, with different formularies, coverage rules, and even different long-term care pharmacy providers. Nursing homes will have to track the plan assignments, coverage rules, and support exceptions and appeals requests for a great many of their residents. Although CMS has required Part D plans to provide one-time "emergency supplies" of drugs for patients in nursing homes, this will not reduce the administrative burdens on nursing home caregivers.

Pharmacists may also be overwhelmed in January, as confused dual eligibles seek personal assistance from front-line providers to explain the new Part D plan rules, to listen to complaints about the loss of familiar coverage, and to research the Part D plan assignments of those who have not been adequately informed of changes. Some will have to turn loyal customers away to pharmacies in their plan networks. Pharmacy crowds could have serious clinical consequences, as well, as the risk of medication errors has been shown to increase when pharmacists are busiest.[33]

The consequences of these health system stresses could be severe. One Medicaid official predicted that the transition to Part D would involve "three to six months of hard work, confusion, and lines at the pharmacy and doctors' offices. Hopefully people won't give up, fall through the cracks, and not get the medicine they need, but some of that will probably happen."[34]

PROPOSED SOLUTION

To ensure the successful, timely implementation of the MMA and the safe and smooth transition of dual eligibles, Congress should extend the availability of Medicaid as backup drug coverage during a reasonable transition period to Part D. In order to ensure that states do not bear additional costs, Congress should provide full federal financing for Medicaid backup costs or reduce states' "clawback" contributions by the amount of state spending on backup Medicaid. With a Medicaid safety net in place to ensure that treatment regimens are not disrupted, CMS, states, health advocates, drug plans and providers would have time to implement a comprehensive education and transition plan that would ensure that dual eligibles are all covered by Part D; that they know how and where they can obtain necessary drugs; and that their doctors have had adequate time and information to thoroughly review new formularies and ensure that any treatment modifications or appeals procedures will work for these very vulnerable patients.

The costs associated with such an approach would not be significant in the context of the Part D program, especially because any transition safety net would be a temporary, time-limited arrangement. Indeed, if the Part D transition is smooth and dual eligibles are able to access the medicines they need through their new plans, the costs for backup Medicaid would be very low. If Medicaid coverage were accessed unnecessarily, states could be required to try to recoup any Medicaid spending from the responsible Part D plans. Finally, overall costs to Medicare and Medicaid would certainly be reduced if dual eligibles were able to avoid hospitalizations or emergency room treatment due to disruptions in drug treatment.

Investing in this kind of targeted safety net will minimize the dangerous transition challenges for millions of the most vulnerable Americans, and offers the best opportunity for a safe and smooth transition to the new Medicare drug benefit.

ENDNOTES

* Because the Part D program has not yet begun, no one has experience with a transition yet. These are hypothetical examples that do not reflect individuals' actual experience.

[1] Centers for Medicare and Medicaid Services (CMS) Guidance, "*A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Prescription Drug Coverage – May 2, 2005*," found at http://www.cms.hhs.gov/medicarereform/strategyforduals.pdf (hereinafter "*CMS Dual Eligibles Transition Guidance*").

[2] There are approximately 7.5 million people who have Medicare coverage and receive some coverage from Medicaid. For about one million of them who are enrolled in "Medicare Savings Programs," Medicaid coverage is limited to paying Medicare cost-sharing. Approximately 6.4 million dual eligibles are "full benefit dual eligibles" who are entitled to full Medicaid benefits in addition to their Medicare benefits.

[3] Kaiser Commission on Medicaid and the Uninsured, "*Dual Eligibles: Medicaid's Role in Filling Medicare's Gaps*," March 2004.

[4] Kaiser Family Foundation (KFF), Medicare Chart Book 2005. The statistics cited in the Kaiser Chart book apply to full dual eligibles as well as the approximately 1.1 million enrolled in Medicare and one of the Medicare Savings Programs.

[5] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: New Approaches in Medicare*, June, 2004, Ch. 3. (Hereinafter "MedPAC June 2004 Report".) The statistics cited in the MedPAC report apply to full dual eligibles and those enrolled in the Medicare Savings Programs.

[6] Id.

[7] Kaiser Family Foundation, Medicare Chart Book 2005.

[8] Kaiser Family Foundation estimate.

[9] Kaiser Family Foundation, Medicare Chart Book 2005. The proportion of "full dual eligibles" who live in nursing homes is probably somewhat higher.

[10] Id. The proportion of "full dual eligibles" with income below the federal poverty line is probably significantly higher.

[11] Centers for Medicare and Medicaid Services (CMS), "*Premium Options Limited Income and Resources Table*," August 29, 2005, found at http://www.cms.hhs.gov/medicarereform/premiumoptionslis%20table.pdf.

[12] CMS Dual Eligibles Transition Guidance; Centers for Medicare and Medicaid Services, "*Direct Mailings to Beneficiaries for Part D Communications and Outreach, Last Updated May 18, 2005*," found at http://www.cms.hhs.gov/partnerships/news/mma/externalmailing5-18-05.pdf.

[13] Centers for Medicare and Medicaid Services, "*Direct Mailings to Beneficiaries for Part D Communication and Outreach, Last Updated May 18, 2005,"* found at http://www.cms.hhs.gov/partnerships/news/mma/externalmailing5-18-05.pdf.

[14] Centers for Medicare and Medicaid Services, "*PDP Guidance: Eligibility, Enrollment and Disenrollment*," at 31-32, found at http://www.cms.hhs.gov/pdps/PDP_enrollmentguidance+exhibits_FINAL_8-29-05.pdf.

[15] CMS Dual Eligibles Transition Guidance. After January 1, 2006, dual eligibles will be allowed to switch plans at any time, effective the first day of the following month.

[16] Centers for Medicare and Medicaid Services, "*Modernization Act Final Guidelines – Formularies,"* found at http://www.cms.hhs.gov/pdps/FormularyGuidance.pdf. (Hereinafter "*CMS Formulary Guidance*".)

[17] Centers for Medicare and Medicaid Services, "*Information for Part D Sponsors on Requirements for a Transition Process*," March 16, 2005, found at http://www.cms.hhs.gov/pdps/transition_process.pdf. (Hereinafter "*CMS Formulary Transition Guidance*".)

[18] Part D plans will be required to cover purchases at out-of-network pharmacies in emergency cases, but coverage will only come in the form of reimbursement and will not be available at the point of sale. 70 Fed. Reg. 4194, 4268 (January 28, 2005) (Centers for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Final Rule, Preamble).

[19] Inside CMS, "*PBM: CMS OKs Tight Formularies; Retail Networks Best Access Minimum*," July 28, 2005.

[20] Interview with Carolyn Ingram, Director, New Mexico Medical Assistance Division, August 4, 2005; Interview with State Medicaid Official, August 1, 2005.

[21] Sara Rosenbaum, "*Grievance and appeals procedures: An analysis of the MMA and proposed regulations*." Kaiser Family Foundation, 2004.

[22] CMS does require plans to develop "transition policies" that could include provision of a one-time refill of otherwise uncovered medications. *CMS Formulary Transition Guidance*.

[23] CMS email to MMA_States listserv, June 7, 2005, on file; Julie Rovner, June 7, 2005 report at http://www.npr.org.

[24] CMS Formulary Guidance; CMS Formulary Transition Guidance.

[25] Gene Bishop, "*One State's Medicaid Managed Care Formulary Operations: A Look at Pennsylvania, 2001-2002*," Kaiser Commission on Medicaid and the Uninsured, March 2005.
[26] Cox, E., R. Henderson, and B. Motheral "*Health Plan Member Experience with Point-of-Service Prescription Step Therapy*," Journal of Managed Care, Pharmacy, July/August 2004 (Vol. 10, No. 4): 291-298.
[27] CMS officials have indicated that pharmacists will have online access to information about the plan assignment of every Medicare beneficiary, and that pharmacists will be able to help confused dual eligibles determine in which Part D plans they are enrolled. CMS will not require or pay pharmacists or plans to provide this assistance, however.
[28] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: New Approaches in Medicare*, Ch. 1, June, 2004.
[29] Kaiser Commission on Medicaid and the Uninsured, *The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans*, (Jensen, R.), January 2005.
[30] Medicare Payment Assessment Commission, *Report to the Congress: Issues in a Modernized Medicare Program*, Ch. 1, June 2005.
[31] Interview with Gene Gessow, Iowa Medicaid Director, July 29, 2005.
[32] 30% of seniors are likely to turn to a pharmacist, and 38% to a doctor, for help navigating the new Medicare benefit. Kaiser Family Foundation, *Health Poll Report Survey: Selected Findings on the Medicare Drug Law*, 2005.
[33] Phillips, D., Jarvinen, J., and Phillips, R. "*A Spike in Fatal Medication Errors at the Beginning of Each Month*," Pharmacotherapy 2005: 25(1).
[34] Interview with State Medicaid Official, August 1, 2005.

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