THE MEDICARE R_X DRUG LAW

Medicare Part D: Issues for Dual Eligibles on the Eve of Implementation

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INTRODUCTION

December 31, 2005 signifies the end of Medicaid prescription drug coverage for the more than 6 million beneficiaries of full Medicaid services who are also eligible for Medicare. Beginning January 1, 2006, these dually eligible beneficiaries will get their drugs covered through Medicare's new prescription drug benefit, known as Part D, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

This paper describes current information about the dually-eligible population and how they are treated under Part D, including policies that are unique to this population. It also describes policy issues raised for dually eligible beneficiaries both by the immediate transition from Medicaid to Medicare at the end of 2005 and by ongoing Part D implementation.

DUAL ELIGIBLES AND PART D

Part D's assistance for low-income Medicare beneficiaries is considerably more substantial than it is for higher income beneficiaries. For beneficiaries dually eligible for Medicare and Medicaid, however, the salutary aspects of this assistance may be mitigated by the loss of Medicaid coverage.

It is important to note that Medicaid coverage ends whether the dually eligible individual chooses to be in a Part D plan and whether the plan in which she is enrolled covers the drug she needs. The ending of Medicaid coverage is achieved through the law's prohibition against payment of federal financial participation to state Medicaid programs for such services.

The significance of this loss of Medicaid coverage cannot be overstated: Part D requires fewer beneficiary protections than does Medicaid. As a result, some dually eligible beneficiaries may find they have access to fewer drugs, higher copayments, no assurance of access to prescription drugs if they are unable to pay the copayment, and no assurance of coverage pending appeal.

1. Demographics and health profile of dual eligibles.

Dual eligibles are the poorest, sickest and most expensive to treat consumers of health care resources among the Medicare population. They generally require more services, use more drugs, and have poorer healthcare outcomes.

They are impoverished: over 60 percent live below the federal poverty level, and 94% live below 200% of poverty. Compared to the rest of the Medicare population, dual eligibles are disproportionately Hispanic or African-American, disproportionately women, more likely to never have been married and much more likely to be in an institution. They are less likely to have graduated from high school, more often live in rural areas, and more often live alone. Dual eligibles are more likely than non-dual eligibles to be under 65 and disabled or over 85 years old.

Dual eligibles are more likely than other Medicare beneficiaries to have diabetes and stroke, and more than twice as likely to have Alzheimer's disease. They use, on average, at least ten more prescription drugs than non-dually eligible Medicare beneficiaries.

2. Dual Eligibles as Defined by Part D.

Part D uses the term "full-benefit dual eligible" to refer to those individuals who are the subject of this paper; (in the paper, they are referred to as "dual eligibles" or "dually eligible beneficiaries"). "Full-benefit dual eligibles" are defined for most purposes in Part D as individuals who have coverage under a Part D prescription drug plan (PDP) and who are eligible for *full* Medicaid benefits under any category of a state plan. For the purpose of loss of Medicaid coverage, however, full-benefit dual eligible is defined *without* reference to being enrolled in a Part D plan.

Individuals entitled to the Qualified Medicare Beneficiary (QMB) and Specified Low-Income Beneficiary (SLMB) Programs may be "full-benefit dual eligibles" if they also receive full Medicaid services. Those with full coverage under a Medicaid research and demonstration or home and community-based services waiver are Part D dual eligibles, but not individuals receiving only prescription drug coverage under a Section 1115 Pharmacy Plus waiver. Individuals who receive Medicaid as medically needy are dual eligibles during the period when they actually receive Medicaid services.

3. Low-Income Subsidy for Dual Eligibles

- a. **The subsidy**. Dual eligibility, as defined by Part D, entitles the beneficiary to the best subsidies available to low-income individuals. All dual eligibles, regardless of their income or resources, are entitled to the full low-income subsidy, which pays for plan premiums at or below the benchmark level, the annual deductible, nearly full coverage in the coverage gap and full coverage after the catastrophic threshold has been reached. Dually eligible beneficiaries pay co-payments according to their income level and institutional status: those in nursing facilities and certain other institutions have no co-payments and, depending on whether income is above or below the federal poverty level, others have copayments of \$1 or \$2 for generic and preferred drugs and \$3 or \$5 for non-preferred drugs.
- b. **Deemed eligibility**. Persons dually eligible for Medicare and Medicaid are deemed eligible for the full subsidy without having to apply for it. CMS began notifying them of this status in the summer of 2005; such notifications will be made on an on-going basis as individuals become dually eligible.
- c. Loss of deemed eligibility status. An individual deemed eligible for the subsidy at any point during a year will remain eligible for the subsidy for the duration of that year, regardless of a change in the status that resulted in the deeming. Thus, while a medically needy individual is not a dual eligible for purposes of Part D until she has met her spenddown, once it is met for the first time in a year, she retains full subsidy eligibility throughout that calendar year, even if she goes on and off Medicaid several times during the year. If at the end of the year she is no longer eligible for Medicaid, she will have to apply separately for, and have her eligibility determined according to the income and resource rules that apply to the low-income subsidy.

- d. **Deemed eligibility through Medicare Savings Program.** A dually eligible individual who loses eligibility for full Medicaid services might still qualify as deemed eligible for the full low-income subsidy (and thus by-pass the requirement of separate application for the subsidy) if she remains eligible for one of the three Medicare Savings Programs that allow for deemed subsidy eligibility. State Medicaid agencies are required, before terminating Medicaid coverage of any beneficiary, to determine if that individual is eligible for any other category of Medicaid offered by the State.
- e. **Medicare beneficiary becoming dually eligible.** A Medicare beneficiary who is later found eligible for Medicaid and who thus becomes dually eligible and eligible for the low-income subsidy will be subsidy eligible for the first month for which she is eligible for Medicaid. Thus, if she is entitled to retroactive Medicaid benefits for three months prior to her application for Medicaid, her subsidy would also be effective during those three months, *but only if she had been enrolled in a Part D plan during that three month period.* Plans are required to refund any payments made by such an individual that are covered by the subsidy.

4. Auto-enrollment.

Although Part D is a voluntary program, Congress required that dual eligibles who have not enrolled in a Part D plan should be automatically enrolled ("auto-enrollment") in one. CMS is responsible for auto-enrollment and, for those individuals determined to be dually eligible at any time in 2005, their auto-enrollment into a plan is to be effective January 1, 2006. Successful auto enrollment will require massive exchanges of accurate, up-to-date data between states, CMS and Part D plans.

- a. **Random assignment in benchmark premium plans.** All dual eligibles will be informed by CMS, beginning in October 2005, of the plan to which they have been assigned and of their right to choose a different plan. All individuals not enrolled in a Medicare Advantage plan will be randomly assigned among those prescription drug plans serving their geographic region for which the premium is at or below the benchmark for the region. Random assignment means there will be no effort to match individuals to plans that best serve their needs. Thus a dual eligible could be assigned to a plan whose formulary does not include some or all of her drugs or whose pharmacy network does not include her pharmacy.
- b. **Special Enrollment Periods.** To avoid being enrolled in an ill-fitting plan, a dual eligible can choose a different plan before December 31, 2005. Even if she does not make a choice by that time, she can disenroll from the plan to which she has been assigned and choose another at any time. This is because dual eligibles, unlike most other Medicare beneficiaries, have an ongoing Special Enrollment Period (SEP) that allows them to change plans at any time. Disenrollment would be effective at the end of the month in which the decision was communicated; enrollment in the new plan would be effective the first of the following month.

Only plans providing standard or actuarially equivalent to standard coverage will be included in the pool for random assignment, even if plans offering enhanced benefits do so with a premium at or below the benchmark. Similarly, the premium subsidy will only be available for standard coverage; a beneficiary cannot get full subsidy coverage for a premium for an enhanced plan, even if the amount is below the benchmark.

c. **Medicare Advantage Plans.** Individuals enrolled in a Medicare Advantage plan will be auto-enrolled in a Medicare Advantage Prescription Drug plan (MA-PD) offered by their MA plan, even if the only MA-PD offered has a premium above the benchmark (i.e., subsidized) amount. In this case, the dually-eligible individual is responsible for the difference. CMS does not address the question of how a person who is dually-eligible could pay for the unsubsidized premium amount; one strategy is to avoid the payment by disenrolling from the MA plan altogether, thus returning to Original Medicare Parts A and B, and then to enroll in a free-standing PDP.

5. Nursing Facility Residents and other institutionalized individuals

About one in five dual eligibles resides in a nursing facility or other institution. These individuals have additional challenges and benefits with respect to Part D. For example, when they are randomly assigned to a Part D plan, they have no assurance that the plan will include in its network the long-term care pharmacy that is used by the facility in which they reside, although all plans are required to include some long-term pharmacies in their networks. Residents, many of whom have cognitive impairments, may not have the ability to review their assigned plan or to choose another, yet may not have a designated authorized representative or even a family member to assist them.

- a. Paying for non-Part D or non-formulary drugs. Dually eligible nursing facility residents have no co-payment for drugs included on their plan's formulary, regardless of which tier the drug may be on. For drugs not on the formulary, they can seek an exception through the required plan process and *unlike other non-institutionalized Medicare beneficiaries, including other dual eligibles*, they are entitled to have the plan provide them non-formulary drugs during the exceptions process. Dually eligible residents who are unsuccessful in appealing the non-coverage of their drug can also pay for it through the incurred medical expense deduction allowed for them before they pay their share of cost under Medicaid to the nursing home. Finally, nursing home residents are protected from being denied prescription drugs by provisions of the nursing home reform law that require facilities to provide all services required by the resident's comprehensive assessment, regardless of the availability of Medicare or Medicaid payment.
- b. Some protections do not apply in assisted living and personal care homes. The protections described above for residents of long term care facilities generally do not apply to residents of board and care or assisted living facilities, even though such residents may be virtually identical in their needs to long term care facility residents. The incurred medical expenses deduction for non-covered drugs might be available to such residents if they are required by Medicaid to pay a share of cost.

6. Transitions

Every plan must have a process to address the needs of new enrollees who are using medications not included on the plan's formulary; dual eligibles who are auto enrolled into a plan are explicitly identified as a population needing attention. The plans have flexibility in the design of their processes; most of CMS' guidance is suggestive rather than prescriptive. For example, CMS recommends, but does not require, that plans consider filling a temporary one-time supply of the non-formulary medication: 30 days for those in the community, 90-180 days for residents of long-term care facilities taking

multiple medications. As noted above, the guidance does *require* that plans provided non-formulary drugs to long-term care facility residents during the exceptions process, but such a supply would not be available to one who had not known to seek an exception.

During the initial transition from Medicaid to Medicare, dual eligibles could also be protected by having their state Medicaid program provide them with a 90-day supply of drugs for the period January through March. CMS has assured states that they can receive federal financial participation for such coverage, but states are not required to provide it.

7. Formulary issues.

While issues related to plan formulary do not have a unique impact on dual eligibles, they do have a special relevance for a number of reasons. First, dual eligibles are higher users of prescription drugs than other Medicare beneficiaries. Because of the multitude and complexity of their health conditions, some of their drugs may be on the highest copayment tier of their plan's formulary. Currently, under Medicaid, some states have no co-payment for prescription drugs; where co-payments are required, Medicaid beneficiaries cannot be denied prescription drugs for failure to pay the co-payment. Moreover, they are entitled to a temporary supply pending a request for prior authorization and to aid paid pending appeal of a cut off of services. These protections are generally not available under Part D.

Part D plan formularies can be considerably more restrictive than Medicaid's; oversight of the generally broad discretion left to the plans is limited to the Secretary's role in disapproving a plan that may likely "substantially discourage enrollment by certain Part D eligible individuals. . ." A dually eligible beneficiary might be taking a drug or drugs for which she was able to get Medicaid coverage, but that might not appear on any of the formularies of plans having the benchmark-level premium that gives her a full subsidy, or that may be removed from the plan's formulary after she has joined. Plans are permitted to change their formularies during a plan year upon 60-days notice to those affected by the change. Although dual eligibles, unlike most other Medicare beneficiaries, can change plans in that circumstance, they might not find another plan that covers all their drugs at the benchmark premium amount.

Plans must have an exceptions process to allow enrollees to seek coverage of a non-formulary drug, reinstated coverage of a drug removed from the formulary, and reduction of the drug's cost-sharing from a higher tier to a lower tier, but, with the exception of institutionalized individuals, beneficiaries are generally not entitled to an emergency supply of the drug pending the outcome of the process.

While plans have broad discretion in formulary design, CMS has required them to include "all or substantially all" of the drugs in the categories of antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS. For some of these drugs, plans will still be permitted to use utilization management tools such as step therapy and prior authorization for individuals starting on such drugs after enrolling in the plan, but not for those who are stabilized on them at the time of enrollment. Plans are, in fact, using such tools.

- 8. Drugs not covered by Medicare or by the Part D plan.
- a. **Drugs Excluded from Part D by definition.** Medicaid may continue to cover, for dual eligibles, drugs that are excluded from Part D coverage. States will receive federal financial participation for such coverage, but it is not required to be provided by States.
- b. **Drugs excluded because they can be covered by Parts A or B.** In addition to drugs for which coverage is excluded from Part D, certain drugs will not be paid for by Part D if they are covered by Parts A or B. This will be true even if the particular beneficiary using the drug does not have coverage under that Part of Medicare. Some state Medicaid programs do not automatically pay Part A premiums for very low income dual eligibles who are not entitled to premium-free Part A, even though they are required by law to do so. Also, some states do not pay Part B premiums for slightly higher income individuals, especially those for whose payment they cannot receive federal financial participation. Thus, a dual eligible might be lacking either Part A or Part B and would not be able to get Part D coverage for certain drugs for that reason.
- c. **Drugs not on the plan formulary.** Each plan is required to have for a particular strength or dosage of a drug that is on the formulary, or for a change in the cost-sharing tier on which the drug appears. Challenges to the tier on which a drug appears would not be relevant to dually-eligible residents of nursing facilities, since they do not have to pay co-payments for their drugs.

To seek an exception, the beneficiary's physician must provide an oral or written statement that all of the covered drugs on any tier of the formulary would either not be as effective for the beneficiary as the requested drug or would have adverse effects on the beneficiary, or both. Each plan decides the details of this process; there are no standard mandatory requirements across all Medicare contracted plans.

Only residents of long-term care facilities are entitled to a temporary supply of their drug while their exception is pending. Dual eligibles residing in other settings are not similarly protected, including those covered under home and community-based waivers, although such protection currently exists under Medicaid when a state requires prior authorization for drug coverage.

- d. Other means of paying for non-covered drugs. What happens if the state Medicaid program will not cover Part D excluded drugs, or if the beneficiary is denied Part D coverage because her drug is covered under Part A and she does not have Part A, or her effort to get an exception to the plan's formulary fails? Several payment options may be available, but it must be understood that payments for drugs that are not on the plan's formulary will not count toward meeting the out-of-pocket maximum that triggers catastrophic coverage under Part D.
- i. **Medically needy spenddown.** Individuals with incomes too high to qualify for Medicaid under one of their state's categories of eligibility may qualify as medically needy due to having high medical expenses. To get Medicaid coverage, they must have incurred medical expenditures that reduce their income to the state's "medically needy income level." The total of these expenditures is referred to as their "spenddown." Expenditures on non-covered drugs would qualify toward meeting a spenddown.

- ii. **Incurred medical expense deduction.** Individuals in nursing facilities and, depending on the state, possibly those receiving long-term care services in a home or community based setting, may deduct from the income they pay to the service provider (their share of cost) expenses for medical equipment, supplies and services recognized by state law but not covered by Medicaid. This deduction is required by federal law but is little known about in many states and may not even have been implemented in others. Non-covered drugs could be paid for out of pocket by utilizing the incurred medical expense deduction.
- iii. State Pharmaceutical Assistance Programs (SPAPs). Many states currently operate programs to assist Medicare beneficiaries who have no other coverage to pay for prescription drugs. These programs generally have income limits that would make most Medicaid beneficiaries eligible. They have, however, traditionally excluded Medicaid beneficiaries from eligibility, because they have had drug coverage under Medicaid. Since such coverage will not be available beginning January 1, 2006, it is possible that dual eligibles could qualify for SPAP assistance to pay for some or all of the out-of-pocket costs incurred. The availability of such assistance depends on each state's new program design in relationship to Part D, including whether it will include Medicaid beneficiaries and whether it will pay for non-covered drugs excluded for the various reasons described.
- iv. **Nursing Home Reform Law.** As discussed earlier, the federal Nursing Home Reform Law, which applies to skilled nursing facilities and nursing facilities, requires that facilities provide over-the-counter drugs, which are excluded from Part D coverage, as part of the daily Medicare and Medicaid reimbursement rates. Moreover, the reform law requires that facilities provide *all* drugs required by a resident's plan of care, regardless of whether Medicare or Medicaid will pay for them.
- v. **Enrollment in Parts A and B.** Agreements with CMS allow states to pay Medicare Parts A and B premiums for their dually eligible population. Not all states pay such premiums for all beneficiaries, but if they did so, dually eligible beneficiaries would be assured that drugs covered by those Parts of Medicare would be paid for, since they will be excluded from Part D plan payment.

9. Policy Issues

a. States, the federal government and plans must be able to give and receive accurate information about dual eligibles and the plans in which they are enrolled by the January 1, 2006 deadline. To assure that all dual eligibles are, in fact, enrolled in a Part D plan by January 1, state Medicaid programs, CMS, Part D plans and, in some instances, State Pharmaceutical Assistance Programs will need perfect data and problem-free data transfers relating to 6.4 million individuals in 51 jurisdictions. CMS must: 1) have complete and up-to-date names and addresses, 2) match those 6.4 million individuals with appropriate plans in their respective regions, 3) ensure that all assignments are accurately communicated to plans and to beneficiaries 4) have the ability quickly to reverse enrollment information in those situations where a dually eligible beneficiary chooses a different plan from the one to which she was assigned. Recent research on data matches from one state identified more than 20,000 disparities in dual eligible identification between CMS and the state.

- h. Dual eligibles must be informed of their loss of Medicaid coverage, the Part D plan into which they have been auto-enrolled and other plans they might choose instead before December 31. Dual eligibles will not be able to use their Medicaid card to get prescription drugs starting January 1. And, unlike other Medicare beneficiaries who have until May 15, 2006 to choose a Part D plan, dual eligibles have only from November 15 to December 31, 2005 to both choose and understand how to use their plan, if they want to avoid coverage gaps beginning January 2006. Because they are generally older, frailer, less educated and use far more drugs than other Medicare beneficiaries, they are more likely to need individual assistance in navigating the world of Part D. Even if the plan into which they are auto-enrolled turns out to be right for them, they will still need help in understanding its formulary, seeking exceptions for excluded drugs and generally knowing how to make the plan work for them. If the plan is not right for them, they will have to figure that out and review the other benchmark plans available to them. Many dual eligibles live alone and/or have cognitive impairments and may not have an "authorized representative" or family member to help them enroll. Experience with enrolling dual eligibles in state Medicaid managed care programs and in the Medicare discount drug card is that this population is challenging to engage and enroll, especially in such a short time frame.
- c. The healthcare infrastructure must be able to respond to the short term pressures of the transition of 6.4 million people from coverage through a single state Medicaid system to coverage through myriad Part D plans operating in any given region. Plans that do not offer full coverage of all current drugs as part of their transition plan must prepare for several thousand requests for coverage determinations and appeals; pharmacists will be inundated with requests for assistance and requests for waivers of co-payment requirements as dual eligibles first confront their changed circumstances when they try to fill a prescription; physicians will be faced with requests from patients to provide evidence to support an exception to plans' formulary exclusions.
- d. Dual eligibles must be provided with the means to pay for costs they incur for prescription drugs and with information about what means are available. Dual eligibles will have drug costs under Part D that they do not currently have under Medicaid. First, all non-institutionalized dual eligibles can be charged co-payments from \$1 to \$5; at least some state Medicaid programs have no co-payments for current drug coverage. Moreover, even where co-payments exist, beneficiaries cannot be denied needed drugs for failure to pay the co-payment. Such protection does not exist in Part D. Pharmacies have discretion, but are not required, to waive co-payments on an individual basis.

Second, dual eligibles, like all other Medicare beneficiaries, will have to pay full cost for out-of-pocket for drugs not included on their plan's formulary. With the exception of institutionalized individuals, they will have to pay pending a coverage determination to include their drug on the formulary. This is true even of drugs initially on the formulary, but subsequently removed. In Medicaid, states must provide a 72 hour supply of a drug for which the state is requiring prior authorization and, while Medicaid programs can have preferred drug lists, unlike Part D plans, they cannot have closed formularies.

Third, dual eligibles enrolled in a Medicare Advantage (MA) plan will be auto enrolled into their MA plan's prescription drug plan (MA-PD), even if its premium is above the

benchmark for full premium subsidy. This means that some dual eligibles will have to pay a portion of a premium for drug coverage, something they have not had to do under Medicaid.

Individuals with a medically needy spenddown can use the costs they incur under Part D to meet their spenddown.

Those dual eligibles receiving long-term care services who are required to pay most of their income to the service provider (institution or community-based provider) can deduct their Part D costs from the amount they pay to the provider, but this is a process that is often little known in states and may be difficult to utilize.

Individuals in skilled nursing facilities and nursing facilities are protected, at least for the uncovered drugs, by the federal nursing home reform law that requires nursing facilities to provide all drugs required by a plan of care, regardless of whether Medicare or Medicaid will pay for them. This provision, too, is little known to beneficiaries who would probably require assistance from officials to enforce it.

Dual eligibles might also be eligible for assistance from their State Pharmaceutical Assistance Program, in those states that intend to continue their programs, but it is currently unclear exactly what states will do and whether they will allow dual eligibles, traditionally excluded from such programs, to enroll.

CONCLUSION

The most immediate policy issues affecting dual eligibles concern the transition from Medicaid to Medicare coverage for prescription drugs on January 1, 2006. This single day transition of 6.4 million of the sickest, frailest and most vulnerable individuals using our health care system portends disaster without significant safeguards in place to address systems and human errors that are bound to occur.

After the initial transition, ongoing issues for dual eligibles center on how to pay for costs incurred under Part D and how to get the information they need to enroll in and disenroll from a plan and to seek coverage determinations for non-covered drugs. These issues demand significant resources to educate dual eligibles as to potential payment sources for their uncovered drugs and to provide individualized counseling and assistance to help the dual eligible population navigate this major new program.

RESOURCES

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (signed November 3, 2003).

Andrea Cohen, "6.4 Million at Risk: Protecting the Poorest Americans During the Medicare Drug Transition." Published by Medicare Rights Center (2005).

Milligan, Charles, Center for Health Program Development and Management, University of Maryland, presentation to the National Health Policy Forum, July 12, 2005.



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