THE HENRY J. KAISER FAMILY FOUNDATION

THE MEDICARE Rx DRUG LAW

Medicare Prescription Drug Coverage for Residents of Nursing Homes and Assisted Living Facilities: Special Problems and Concerns

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INTRODUCTION

This paper describes current information about how the new Medicare Part D Prescription Drug benefit will work for residents of nursing homes and other congregate living settings, such as assisted living facilities and board and care facilities. It identifies differing rules for residents of the nursing home and non-nursing home settings and for dually-eligible beneficiaries (persons eligible for both Medicare and Medicaid). It also describes policy issues for residents that are raised by the new drug benefit and its implementation.

PRESCRIPTION DRUG COVERAGE UNDER MEDICARE PART D

Beginning January 1, 2006, Medicare will cover prescription drugs through a new voluntary and privately-administered Part D program. This new program was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). To obtain coverage, Medicare beneficiaries must take the affirmative step of enrolling in a Medicare Part D prescription drug plan that is either a free-standing prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD).

While some Medicare beneficiaries may choose not to enroll in a Part D plan, beneficiaries who are also eligible for Medicaid (the "dual-eligibles") will have virtually no choice about participation as they will be automatically enrolled in a randomly-selected Part D plan in the Fall 2005. (Dual-eligible beneficiaries can opt out of a Part D plan and may want to opt out if they have employer coverage for prescription drugs, although subsidies for Part D coverage are available only if they enroll in a Part D plan.) Accordingly, Medicaid coverage for prescription drugs for dual-eligible persons will end on January 1, 2006.

The MMA and final regulations give PDPs and MA-PDs broad discretion to decide which specific drugs to cover ("formularies"), the strengths and dosage forms of covered drugs to include, and the types of "utilization management processes" to use. Under utilization management, plans may establish different co-payments for different drugs; "tiered pricing" distinguishes among preferred drugs, non-preferred drugs, and generic drugs. Plans may also require that beneficiaries request prior authorization for covered prescription drugs or that they try particular medications included in the plan's formulary before those prescribed by the physician ("step therapy").

Using Part D effectively will pose significant challenges for many residents of nursing homes, (including both skilled nursing facilities and nursing facilities), as well as residents of assisted living and board and care facilities. Part D requires beneficiaries to make many affirmative decisions and to take many actions. In general, to get Medicare prescription drug coverage, beneficiaries must choose among plans, enroll in a particular Part D plan, and once enrolled, pursue exceptions and appeals in order to receive prescription drugs that are medically necessary but not covered by the beneficiary's plan. These affirmative decisions will be difficult for many residents who lack capacity, either in a strict legal sense or in a practical sense, because they are confused and disoriented.

They will also be difficult for many residents who do not have family members or friends who are knowledgeable or available, or both, to assist them in making necessary choices.

1. Signing up for a Part D Plan (Enrollment)

a. All Medicare beneficiaries. All Medicare beneficiaries, including nursing home, assisted living, and board and care residents, have the right to choose and enroll in the Part D plan of their choice. The initial enrollment period runs from November 15, 2005 through May 15, 2006. For 2007 and thereafter, the annual coordinated election period runs from November 15 through December 31.

In choosing a Part D plan, beneficiaries may want to consider such factors as

- the specific drugs covered by the plan ("formulary");
- the specific strengths and dosage forms of drugs listed on the formulary;
- the utilization management tools (such as formularies, tiered cost sharing, prior authorization, and step therapy) used by the PDP;
- the transition process used by the PDP;
- the exceptions process used by the PDP; and
- whether the pharmacy they use (or that is used by their facility) participates in the PDP.

b. Dual-eligible beneficiaries. All dual-eligible beneficiaries, including those who live in nursing homes or assisted living or board and care facilities, will be automatically enrolled in a Medicare drug plan in the Fall 2005 in order to assure that they do not have a gap in prescription drug coverage when they lose Medicaid coverage for prescription drugs on January 1, 2006.

Auto-enrollment for dual-eligible beneficiaries may be made only to PDPs whose monthly beneficiary premium for a standard benefit plan does not exceed the Part D low-income premium subsidy amount; the premium amounts vary among regions of the country and range from $23.25 to $36.39. If more than one plan offers a standard benefit with a premium meeting this definition, beneficiaries will be randomly enrolled in one of them.

Auto-enrollment will not take into account whether the PDP includes in its formulary the specific prescription drugs (or the strengths and dosages of the prescription drugs) that the beneficiary takes. Auto-enrollment will also not take into account whether the long-term care pharmacy used by the nursing home, assisted living, or board and care facility participates in the PDP to which the beneficiary is assigned.

c. Disenrolling from Part D. Unlike most Medicare beneficiaries, who are generally contractually bound for a year to the PDP they choose, dually-eligible beneficiaries and those eligible for a Medicare Savings Program (where Medicaid pays Medicare premiums) may disenroll from a PDP at any time. Beneficiaries who are auto-enrolled in a plan that does not work well for them – because, for example, it does not cover the

prescription drugs they need and take – may disenroll and re-enroll in a different plan, identified through the factors listed above.

Individuals who move into, reside in, or move out of a nursing home have a special enrollment period (SEP) during which they may change Part D plans. The SEP is available to all nursing home residents, regardless of income. An SEP is available to assisted living and board and care residents only if they are dually-eligible for Medicare and Medicaid; private-pay residents may not change their Part D plan when they move in or out of an assisted living or board and care facility.

If beneficiaries choose or are auto-enrolled in a plan that does not cover all of the prescription drugs that they need, they may go without such medications, seek exceptions or file appeals, or both, as described below, or pay privately.

2. Transition process

In many instances, beneficiaries may choose (or may be placed in) plans with drug formularies that do not include all of the prescription drugs that the beneficiary is taking. Under the Medicare prescription drug benefit, a Part D sponsor must "provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary." Although the regulations provide no additional requirements, sub-regulatory guidance issued by the Centers for Medicare & Medicaid Services (CMS) suggests that PDPs provide special transition periods of up to 90 to 180 days for nursing home residents. Later guidance added a requirement that Part D plans cover an emergency supply of non-formulary Part D drugs for nursing home residents as part of the transition process. This requirement does not apply to assisted living or board and care residents.

During the transition period, the PDP will pay for any non-formulary drug the resident is taking. CMS anticipates that the beneficiary will change drugs or file for an exception or appeal during the transition period. CMS guidance suggests, alternatively, that a PDP may choose to call all nursing home enrollees before the drug benefit becomes effective in January 2006 to discuss the drugs they take and to suggest that they take others, instead, that are on the plan's formulary.

CMS' guidance does not suggest that PDPs provide any special transition period for assisted living or board and care residents. The general 30-day transition period suggested by CMS guidance for all Medicare beneficiaries applies. Like nursing home residents, assisted living or board and care residents may be called by their Part D plan in advance, with suggestions that they change to a drug that is covered by the plan.

After the initial transition to Part D in January 2006, transitions will occur on an ongoing basis as individuals qualify for Medicare and Part D and as beneficiaries move into nursing homes, assisted living facilities, and other long-term care facilities.

3. The Exceptions Process

The MMA requires that all PDPs establish an exceptions process that Medicare beneficiaries may use under various circumstances to try to persuade the plan to provide them with a prescription drug that is not otherwise available to plan members. A beneficiary, for example, may use the exceptions process to try to get coverage for a necessary non-formulary drug or for coverage for particular strengths or dosages of necessary prescription drugs or to get exemptions from tiered cost-sharing requirements.

Not all of these reasons are applicable to all residents of long-term care institutions. While residents of nursing homes, assisted living, and board and care facilities may use the exceptions process to get coverage of non-formulary drugs, the tiered cost-sharing issue is relevant only to nursing home residents who are not dually-eligible for Medicare and Medicaid and to assisted living and board and care residents. Dually-eligible nursing home residents do not have any cost-sharing obligations under Part D.

Although the PDP must grant an exception "whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary," each PDP establishes its own procedures for making that determination. In all instances, the rules require that a resident'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. It is up to each PDP to decide whether it will require written statements and written follow-up information from the physician. A burdensome process will discourage physicians from filing, or supporting a beneficiary's request, for an exception.

4. The Appeals Process

a. Notice and appeal rights. If an exception for a medically necessary prescription drug is denied, a beneficiary may pursue the various levels of administrative appeal and, if necessary, judicial review. The appeals process may also be used to address other "coverage determinations," such as a plan's decision that a prescription drug is not medically necessary, cannot be filled for the amount specified, or cannot be filled at the time requested.

CMS guidance assumes that, if the PDP provides a sufficiently lengthy transition period, the appeals process may be completed during this period. If the appeal is not completed during the transition period, CMS acknowledges that the beneficiary may have a "coverage gap" – a period of time when the beneficiary has no prescription drug coverage. If the beneficiary loses the appeal, the beneficiary must either change to a covered drug or pay for the uncovered drug completely out-of-pocket. These choices apply to all beneficiaries, whether they are dually-eligible or eligible only for Medicare and whether they live in a nursing home, assisted living facility, or board and care facility.

The PDP is responsible for providing notice of appeal rights when an unfavorable coverage determination, including denial of an exception, is made. PDPs must make

arrangements with their network pharmacies to either post or hand out a general notice telling plan enrollees to call the plan to get a coverage determination that will explain appeal rights. A beneficiary must contact the PDP in order to get more information and to pursue an appeal if the pharmacy says the plan will not pay for a drug.

b. Steps in the appeals process are:

- A standard **redetermination** by the Part D plan, or an expedited redetermination when a more rapid decision is needed;
- A **reconsideration** by an Independent Review Entity
- A **hearing** before an Administrative Law Judge (ALJ) if the amount in controversy meets the threshold requirements established annually by the Secretary;
- **Medicare Appeals Council review**; and
- **Judicial review** of a final CMS decision if the amount in controversy meets the threshold requirements established annually by the Secretary.

5. Coverage of non-covered prescription drugs and over-the-counter drugs

The MMA explicitly prohibits PDP and MA-PD coverage of over-the-counter drugs; specified categories of drugs that are optional under Medicaid, but commonly used by long-term care residents, including benzodiazipenes, barbituates, and drugs for weight-loss or weight-gain; and drugs that could be covered by Parts A or B, even if the beneficiary does not have Parts A or B. Beneficiaries in a Part A stay in a skilled nursing facility, however, will continue to have their prescription and over-the-counter drugs covered by Part A.

a. Over-the-counter drugs. Over-the-counter drugs are covered by the daily rate paid to skilled nursing facilities by Medicare Part A and to nursing facilities by Medicaid. The Nursing Home Reform Law requires that any over-the-counter drugs needed and used by a resident must be provided by the nursing facility, without charge to the resident.

Private-pay nursing home residents and assisted living and board and care residents need to look to state law and their admissions contracts to determine whether they must pay for over-the-counter drugs.

b. Part D-excluded drugs. While the MMA explicitly excludes certain drugs from coverage under Part D, dually-eligible residents of nursing homes and assisted living and board and care facilities may be able to rely on one of several Medicaid and state funding mechanisms to pay for some or all of the drugs. While Medicaid mechanisms are not available to private-pay residents, low-income residents of nursing homes or assisted living and board and care facilities may qualify for assistance under a State Pharmaceutical Assistance Program.

c. Medicaid. The state can cover Part D-excluded drugs under its Medicaid program and continue to receive federal funds. However, Medicaid will *not* pay for a prescription drug that a beneficiary needs if the drug is covered under Medicare but excluded from the formulary of beneficiary's PDP.

A state may choose to pay for drugs that are not covered by a beneficiary's PDP using state-only funds, not federal funds.

d. Assistance through Medicaid's "Incurred Medical Expense Deduction." Payment for non-formulary or otherwise non-covered drugs may be possible through Medicaid's incurred medical expense deduction. Under this deduction, federal Medicaid law allows residents of nursing homes and assisted living and board and care facilities to deduct from their "share of cost" – i.e., the amount of money that they must contribute to the cost of their long-term care – out-of-pocket costs of medical services that are recognized by state law but not covered by the Medicaid state plan. If a resident has income that is contributed to the resident's share of cost in the nursing home or assisted living or board and care facility, the resident may be able to use some of that income, under the incurred medical expense deduction, to pay for prescription drugs that are not covered by the Part D plan. A resident might use the incurred medical expense deduction while engaged in the exceptions or appeals process or, if those failed, to pay for drugs that are not covered by the resident's Part D plan. The resident might also use some of this income to purchase a more comprehensive Part D plan – a PDP providing "enhanced alternative coverage" – that includes a larger number of prescription drugs in its formulary.

The incurred medical expense deduction is available to a resident only if the resident has some income, such as Social Security or a private pension, that the resident uses to contribute to the cost of the nursing home or assisted living or board and care facility. If the resident's only income is SSI, the resident has no additional income to protect and cannot use this deduction. Many board and care residents have only SSI and cannot use the incurred medical expense deduction.

e. State Pharmaceutical Assistance Programs. Many states have State Pharmaceutical Assistance Programs (SPAPs). These programs provide different amounts and types of assistance with drug costs for low-income older people or people with disabilities or both. An SPAP may cover drugs excluded from Part D and non-formulary drugs and may pay co-payments that are required under Part D. SPAPs are funded exclusively from state sources.

6. The Nursing Home Reform Law and the Medicare Prescription Drug Benefit

The Nursing Home Reform Law (the Reform Law) mandates that *all* services, including pharmaceutical services, be provided to a resident when required by the resident's comprehensive assessment and care plan, regardless of the availability of Medicare or Medicaid payment for the service. In other words, even if a nursing home resident's PDP does not include the prescription drug (or particular dosage form) required by the resident, and even if the state Medicaid program and SPAP do not cover the drug, and

even if the resident has no income to use to pay for the drug under the incurred medical expense deduction, the nursing facility is required to provide the drug, without charge, if it is included in the resident's care plan.

Under the Reform Law, CMS provides extensive guidance on prescription drugs for nursing home residents. It identifies medications that should generally not be taken by older people and it recognizes the dangers of changing medications that older people have successfully used over time.

A provision of the Reform Law, called drug regimen review, specifically requires that a licensed pharmacist review *all* the drugs taken by each nursing home resident at least monthly, and more often, if necessary, to determine if the resident is receiving a potentially inappropriate drug, as defined by CMS guidelines. The pharmacist must report "any irregularities" to the attending physician and director of nursing. Federal law requires nursing homes to act on the pharmacists' reports. The MMA establishes a medication therapy management program (MTMP) to review drug usage of Medicare beneficiaries who have multiple chronic diseases, take multiple Part D drugs, and incur high annual costs for Part D-covered drugs. Since many nursing home and assisted living and board and care facility residents meet these criteria, a large portion of the beneficiaries reviewed under MTMP are expected to be nursing home, assisted living, and board and care residents.

The Nursing Home Reform Law does not apply to assisted living and board and care facilities and residents. Assisted living and board and care facilities are not obligated to assure that residents receive medically necessary prescription drugs nor do they generally have consultant pharmacists review residents' total drug regimens.

7. Policy Issues

While information about Part D is extensive, many information gaps remain and many questions remain unanswered. The policy implications of these questions are significant.

a. Who has authority to act on behalf of a nursing home, assisted living, or board and care facility resident? Many residents of nursing homes and assisted living and board and care facilities have cognitive impairments that make it impossible for them, as a practical matter, to make decisions about their Part D plans. The Part D rules and informal guidance allow an "authorized representative," defined as a person who has legal authority under state law to act on the beneficiary's behalf, to assist a beneficiary in enrolling in a Part D plan; authorized representatives and the prescribing physician may pursue exceptions and appeals on the beneficiary's behalf. Most long-term care residents, however, have not been adjudicated incompetent and do not have court-appointed guardians. Many residents do not have a surrogate decision-maker authorized by state law to act on their behalf.

Some, but not all, states have laws that authorize surrogate decision-makers to make health care decisions for incapacitated individuals. In some states with health care

surrogacy laws, health care proxy decision-makers may not enroll a person in an insurance plan, since such enrollment is not considered a health care decision. If Part D is viewed in these states as an insurance program, surrogate decision-makers will not be able to enroll or disenroll beneficiaries.

National nursing home trade associations contend that their member facilities cannot and should not make health care decisions for their residents. State long-term care ombudsmen and State Health Insurance Programs have been advised that their employees and volunteers are not decision-makers for beneficiaries and cannot make Part D enrollment and disenrollment decisions or pursue exceptions and appeals on beneficiaries' behalf.

The result may be that many residents who are unable to make decisions on their own will have no one to help them or to act on their behalf in making Part D decisions. There is no easy or obvious answer to this enormous problem, which is exacerbated by the presumption that Medicare beneficiaries will need to take many kinds of affirmative steps – choosing plans, changing plans, pursuing exceptions and appeals – in order to assure access to all medically necessary drugs.

A beneficiary who is unable to enroll affirmatively in a Part D plan and has no one to act on his or her behalf may not be enrolled in Part D unless dually-eligible for Medicare and Medicaid and auto-enrolled. If a beneficiary or someone legally acting on his or her behalf does not file for an exception or an appeal, the beneficiary's prescribed medications will be changed to those covered by the PDP, whether or not the plan's formulary includes the drugs that are medically appropriate for that beneficiary.

b. How will beneficiaries and their surrogate decision-makers be informed of methods for getting prescription drugs that are not covered by their PDP or MA-PD? As noted above, various Medicaid and state programs may cover prescription drugs that are excluded, by statute or PDP formulary, from coverage by a resident's Part D plan. These programs are not self-implementing, but require affirmative action on the part of the beneficiary to take effect. It is not clear who will advise beneficiaries and their surrogate decision-makers about these methods and how to exercise them. If a beneficiary is unable to act independently and has no surrogate decision-maker, the beneficiary will be unable to use these alternative programs to get medically necessary prescription drugs.

Moreover, even if beneficiaries are knowledgeable about these alternative programs and willing to use them, their state may not have created such programs. States are not obligated to have State Pharmaceutical Assistance Programs. States' incurred medical expense deduction program may be inconsistent with the requirements of federal law, or inadequate, as a practical matter, to deal with residents' changing prescription drug needs. While some states may revise their programs to make them more comprehensive and workable, in other instances, in other states, litigation will be necessary just to get a program put in place.

c. How will differences between Part D and the Nursing Home Reform Law be resolved and by whom? Although the Nursing Home Reform Law offers broad protection to nursing home residents to assure that they receive all care and services they need, regardless of the availability of payment, its provisions are not self-executing. Someone must have the ability and authority to enforce the mandates on behalf of individual residents.

Potential conflicts between the Reform Law and Part D, in such areas as drug regimen review and medication therapy management programs, also need to be resolved. Whose decision about the appropriateness of medications for a particular resident will prevail, the consultant pharmacist's or the plan's MTMP? CMS' guidance simply advises PDPs that they will need to resolve any "disparity" between the two federal laws.

d. How will assisted living and board and care residents get covered and non-covered prescription drugs? While there is an interest in reversing the "institutional bias" and in providing care at home and in settings other than conventional nursing homes – such as independent and assisted living facilities – the MMA provides greater protections to those who live in nursing homes.

1. Medicaid residents. CMS' regulations do not include assisted living or board and care facilities in the definition of "institution." As a consequence, unlike dually-eligible nursing home residents, *all* assisted living and board and care residents have cost-sharing obligations for their Part D-covered prescription drugs. While approximately 90% of assisted living facility residents pay privately for their stay, the other 10% receive home and community-based waivers under the Medicaid program that help pay for their stays. Most board and care residents rely on Medicaid.

Under Medicaid rules, Medicaid beneficiaries are required to pay nearly all their income, except for a small amount for personal needs, for their care. Despite the absence of income, they are required by CMS to pay co-payments for their Part D-covered drugs ($1 or $2 for generic or preferred drugs; $3 or $5 for other drugs). Paying co-payments may be literally impossible. Unless dually-eligible assisted living and board and care residents are able to use the incurred medical expense deduction, they will not have any money to pay co-payments for even their Part D-covered prescription drugs. They will get non-covered drugs only by using the incurred medical expense deduction or their states' prescription assistance program, if their state has one that includes them.

2. Private pay residents. Private-pay assisted living and board and care residents may have a special enrollment period when they move into their facility if the facility is located outside the PDP's region. If they stay in the same PDP region, they are not permitted to change plans. The pharmacies covered by their Part D plans may not be used by their facility or may not provide drugs in the format required by their facility. Only dually-eligible assisted living and board and care residents can always change their Part D plan when they move in to the facility.

e. Future Part D issues for residents. Although most public attention has focused on the transition to Part D in January 2006, other issues will become more visible after Part D is in place. One issue involves the delay in enrollment in Part D plans, particularly for the large group of Medicare beneficiaries who become eligible for Medicaid for the first time when they enter a nursing home. Since beneficiaries' enrollment in a Part D plan does not become effective until, at the earliest, the month following application or auto-enrollment and since Part D does not include retroactive entitlement, as Medicaid does, there will be a coverage gap. How will these dually-eligible residents' prescription drugs be paid for during the gap? Will facilities refuse to admit people who are not already enrolled in a Part D plan? Will they refuse to admit people who are not already enrolled in a Part D plan that includes the facility's pharmacy? Will facilities discriminate, more broadly, against people who do not have guardians or other surrogate decision-makers to enroll and disenroll them and to make Part D exceptions and appeals decisions on their behalf? Will they discriminate against people who do not have someone to pay for prescription drugs during the coverage gap? Will they require that residents pay, or have someone else pay, for residents' prescription drugs during the period before their Part D plan becomes effective? Who will enforce nursing facilities' obligation under the Nursing Home Reform Law to provide residents with prescription drugs, whether or not there is a source of payment for them?

CONCLUSION

The complexities of Part D are intensified for nursing home and assisted living and board and care residents. Many questions remain about how and whether residents will be able to get the prescription drugs they need.

AUTHORITIES

Medicare Modernization Act, 42 U.S.C. ''1395w-101 et seq.

MMA regulations, 70 Fed. Reg. 4193 (Jan. 28, 2005), adding 442 C.F.R. Part 423.

Nursing Home Reform Law, 42 U.S.C. ''1395i-3(a)-(h), 1396r(a)-(h), Medicare and Medicaid, respectively.

Medicaid incurred medical expense deduction, 42 U.S.C. '1396a(a)(17)

Post-eligibility financial requirements for the categorically needy
42 C.F.R. '435.725(c)(4)(i), (ii) (institutionalized individuals in SSI states)
42 C.F.R. '435.726(c)(4)(i), (ii) (individuals receiving home and community-based services under a waiver)
42 C.F.R. '435.733(c)(4)(i), (ii) (institutionalized individuals in states using more restrictive requirements than SSI)
42 C.F.R. '435.735(c)(4)(i), (ii) (individuals receiving home and community-based services under a waiver)

Post-eligibility financial requirements for the medically needy
42 C.F.R. ' 435.832(c)(4)(i), (ii) (institutionalized individuals)

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