Medicare Part D Prescription Drug Coverage for Medicare-Medicaid Enrollees in the Capitated Financial Alignment Demonstration

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The Centers for Medicare & Medicaid Services (CMS) has made two financial alignment models available to states to integrate care for beneficiaries dually eligible for Medicare and Medicaid. In the capitated Financial Alignment Demonstration, health plans will enter into three-way contracts with the state and CMS to provide coordinated and integrated Medicare and Medicaid services. Almost all of the prescription drugs in these arrangements will be provided through Medicare Part D, with payment and operational requirements that are essentially the same as those that now apply to organizations providing the Part D benefit in Medicare.

Since prescription drugs are a major element in the full package of services Medicare-Medicaid enrollees will be receiving through the demonstrations, it is important for states to understand the basic features of the Part D benefit so they can participate meaningfully in designing and implementing this element of the three-way contracts.

This technical assistance brief from the Integrated Care Resource Center (ICRC) provides basic information for states on Part D, including how beneficiaries are enrolled in Part D, how Part D drugs are paid for, what drugs are and are not covered in Part D, how drug utilization is managed in Part D, and how the Part D Medication Therapy Management Program works. The brief focuses on what states need to know about Part D in the context of the Financial Alignment Demonstrations, and is not intended to provide a comprehensive overview of Part D.

How are Medicare-Medicaid Enrollees Enrolled in Part D?

Medicare-Medicaid enrollees who qualify for full Medicaid benefits are automatically deemed eligible for the Part D low-income subsidy (LIS), which covers their Part D premiums and deductibles, and subsidizes much of their remaining Part D drug cost sharing. Those receiving premium and/or cost sharing assistance from Medicare Savings Programs – the Qualified Medicare Beneficiary (QMB) Program, Specified Low-Income Medicare Beneficiary (SLMB) Program, or Qualified Individual (QI) Program – and those only eligible for SSI cash assistance are also automatically deemed eligible for the LIS. Full-benefit Medicare-Medicaid enrollees account for about two-thirds of those receiving the LIS, and Medicare Savings Program and SSI enrollees account for another 20 percent. Medicare automatically enrolls those eligible for the LIS into stand-alone prescription drug plans (PDPs) with premiums at or below the regional average (“benchmark” or “zero-premium” plans) if they do not choose a plan on their own. If they choose a plan with a premium above the

IN BRIEF: States participating in the Centers for Medicare & Medicaid Services (CMS) capitated Financial Alignment Demonstration covering Medicare-Medicaid enrollees have questions about how the Medicare Part D prescription drug benefit works and how it will be incorporated into the capitated financial alignment demonstrations.

This technical assistance brief provides some basic information for states on Part D, including how beneficiaries are enrolled in Part D, how Part D drugs are paid for, what drugs are and are not covered in Part D, how drug utilization is managed in Part D, and how the Part D Medication Therapy Management Program works. The brief focuses on what states need to know about Part D in the context of the Financial Alignment Demonstrations, and is not intended to provide a comprehensive overview of Part D.
Health plans will be paid according to the regular Part D payment rules, with the exception that the direct subsidy will be based not on a bid submitted by each plan, but on the standardized national Part D average bid amount.

In 2011, about 36 percent of the 29 million Medicare beneficiaries enrolled in Part D were low-income individuals receiving the LIS. Out of these 10.5 million LIS enrollees, about 80 percent (8.3 million) were enrolled in stand-alone PDPs that cover only prescription drugs, and the remaining 20 percent (2.2 million) were enrolled in Medicare Advantage prescription drug plans (MA-PD plans) that cover all Medicare services. There is wide state-by-state variation in the percentage of LIS beneficiaries enrolled in MA-PD plans, ranging in 2010 from less than one percent in Alaska to more than 50 percent in Arizona.

Medicare-Medicaid enrollees who are passively enrolled in dual eligible demonstration plans will likely receive their Part D coverage from a different plan than the one in which they are now enrolled. Dual eligibles are permitted to change their Part D plan at any time during the year, and Part D rules require that enrollees who transition into Part D or from one plan to another be given a 90-day period to work out appropriate coverage arrangements under the new plan. This includes provision of temporary supplies of drugs that are not covered in the new plan’s formulary while the enrollee and the plan complete either a formulary exception to maintain the enrollee’s coverage of a non-formulary drug, or a transition to a therapeutically-equivalent covered formulary drug. The transition benefit also applies to formulary changes from year to year for enrollees remaining in the plan.

How are Part D Drugs Paid For?

In general, Part D drugs are paid for through a combination of beneficiary premiums and cost sharing, and federal subsidies. The base beneficiary premium in 2013 is $31.17. Monthly premiums vary widely by plan and type of coverage. As noted earlier, the Medicare LIS covers Part D premiums and deductibles for Medicare-Medicaid enrollees who are deemed eligible for the LIS, so their only payments for Part D are their required copayments (discussed below) and any premium they choose to pay if they enroll in a plan with a premium above the benchmark level.

Medicare pays three major types of subsidy to Part D plan sponsors:

- **Direct subsidy**, which is based on plan bids and is adjusted for the risk of individual enrollees, and accounted for an estimated 34 percent of Medicare’s total $59 billion federal Part D subsidy in 2011;
- **Reinsurance**, which covers 80 percent of drug spending above an enrollee’s annual out-of-pocket threshold, and accounted for about 22 percent of the Part D federal subsidy in 2011; and
- **LIS**, which covers expected cost sharing and premiums for low-income beneficiaries, and accounted for an estimated 38 percent of the federal subsidy in 2011.

A retiree drug subsidy accounted for the remaining seven percent of the federal Part D subsidy in 2011. These direct and reinsurance subsidies combined cover 74.5 percent of the cost of basic Part D benefits, on average, and the remainder of the cost is covered by beneficiary premiums. In addition to these subsidies, Medicare establishes symmetric risk corridors separately for each Part D plan to limit a plan’s overall losses or profits.

The amounts Medicare pays to Part D plans each year are based on an annual bidding process as well as on a reconciliation after the year ends based on actual experience.

Health plans participating in the capitated Financial Alignment Demonstrations will be paid according to the regular Part D payment rules, with the exception that the direct subsidy will be based not on a bid submitted by each plan, but on the standardized national Part D average bid amount. This national average bid
amount, which was $79.64 for 2013, will be risk adjusted according to the same rules that apply for all other Part D plans. Because demonstration plans will not be submitting bids for either Medicare medical benefits (Parts A and B) or for prescription drug benefits under Part D, CMS will set a monthly payment amount for LIS and the reinsurance payments, both of which are reconciled based on actual expenditures after the payment year is over.

Part D plans are widely available in every state, although the number of zero-premium benchmark plans available to Medicare-Medicaid enrollees is more limited. In 2013, 1,031 PDPs are being offered across the 34 PDP regions nationwide, and beneficiaries in each state have a choice of at least 23 stand-alone PDPs and multiple MA-PD plans. Only 331 of these PDPs are benchmark plans available for LIS enrollment, however, a one percent increase from 2012.

**What Drugs Are and Are Not Covered by Part D?**

Part D may cover prescription drugs that both meet certain conditions and are included on CMS approved formularies (or are treated as if included on formularies as the result of approved exceptions and appeals processes). In general, Part D drugs must be products approved by and properly listed with the federal Food and Drug Administration (FDA), as well as prescribed for medical indications cited in approved FDA product labeling or for certain off-label uses supported by specific compendia. In addition, Part D drugs cannot be otherwise coverable under Medicare Parts A or B as they are dispensed or administered.

Part D plans’ 2011 formularies included, on average, 84 percent of all available drugs, well in excess of CMS’ minimum requirements. Of the 200 drugs most commonly used by dual eligibles in 2012, Part D plan formularies covered, on average, 96 percent of the drugs eligible for Part D coverage. While CMS is prohibited by federal law from mandating a national formulary for Part D, CMS has the authority to ensure that Part D plan formularies do not substantially discourage enrollment by certain Part D individuals, especially those who may have predictably high prescription drug costs. CMS conducts a rigorous review of all Part D plan formularies each year to ensure appropriate access to drugs and to avoid discrimination against beneficiaries with certain conditions.

**Protected Classes**

Part D formularies currently must include “all or substantially all” drugs in the following six “protected classes:”

- Antidepressants;
- Antipsychotics;
- Anticonvulsants (for treatment of epileptic seizures and bipolar disorder);
- Antiretrovirals (for treatment of HIV/AIDS);
- Antineoplastics (for treatment of cancer); and
- Immunosuppressants (for protection against organ transplant rejection).

Section 3307 of the 2010 Affordable Care Act (ACA) requires CMS to establish criteria for identifying protected categories and classes of drugs that are of “clinical concern,” and provides that every drug in such a category or class must be included in Part D formularies until CMS makes a specific exemption. The ACA also provides that the existing CMS guidance on protected classes remains in effect until it is modified, which it has not been as of early 2013.

**Drugs Excluded by Statute from Part D**

The following types of drugs are currently excluded by statute from Part D coverage, but they must be provided to dual eligibles by state Medicaid programs if they are covered for other Medicaid beneficiaries in the state:

- Barbiturates, when used in the treatment of conditions other than epilepsy, cancer, or a chronic mental health disorder;
States may find that the benefit management tools used by specific Part D plans are more or less stringent than those used in the state’s Medicaid program.

- Nonprescription (over-the-counter) medications;
- Prescription vitamins and minerals (not including prenatal vitamins and fluoride preparations);
- Drugs used for anorexia, weight loss, or weight gain;
- Drugs that promote fertility;
- Drugs used for treatment of sexual or erectile dysfunction;
- Drugs used for cosmetic purposes or hair growth;
- Drugs used for symptomatic relief of coughs or colds; and
- Drugs for which the manufacturer requires that associated tests or monitoring services be purchased exclusively from the manufacturer.

Starting in 2014, barbiturates must be covered under Part D for all indications. When these drugs are covered by Part D, they cannot be covered by Medicaid for Medicare enrollees.15

**How is Drug Utilization Managed in Part D?**

Part D plans are permitted to use formulary management tools like prior authorization, step therapy, and quantity limits as long as they are consistent with “existing best practices.” In making this determination, CMS looks to current industry standards as well as appropriate guidelines from expert organizations. CMS also looks to the use of such standards by existing drug sponsors that are widely used by seniors and people with disabilities.16

In 2011, approximately 30 percent of drugs in Part D plans were subject to some form of utilization management, with prior authorization and quantity limits being much more common (applying to 15 to 20 percent of drugs) than step therapy, which applied to only 2 percent of drugs in the average plan.17 States may therefore find that the benefit management tools used by specific Part D plans are more or less stringent than those used in the state’s Medicaid program. State Medicaid programs vary, for example, in the stringency of the prior authorization procedures that are used in both fee-for-service and capitated managed care settings, and states also vary in their uses of step therapy and quantity limits.18 State requirements regarding use of these drug utilization tools by Medicaid managed care plans also vary from state to state, and CMS generally does not seek to impose uniform standards on states for Medicaid.19

**Beneficiary Cost Sharing**

Beneficiary cost sharing in Part D is substantially more limited for Medicare-Medicaid enrollees than it is for other Medicare beneficiaries, so this benefit management tool is quite limited for these Part D beneficiaries.20 For full dual eligibles, there are no premiums and no deductibles. Copayments vary based on beneficiaries’ income level and whether they are institutionalized or receive home- and community-based waiver services (HCBS). There are no copayments for full dual eligibles who are institutionalized or who are receiving HCBS. For all other full dual eligibles, copayments (for 2013) are limited to $1.15 to $2.65 for generic drugs and $3.50 to $6.60 for brand name drugs, depending on income level. There are no copayments after total drug spending reaches $6733.75.21 CMS announced in September 2012 that Part D cost sharing for dual eligibles in the Financial Alignment Demonstration could be reduced or eliminated under specified circumstances.22 The Part D copayment amounts are larger than the $0.65 to $3.65 permitted in Medicaid and, unlike in Medicaid, pharmacists can deny Part D services if the copayments are not made.23

**How Does the Part D Medication Therapy Management Program Work?**

Part D sponsors are required to establish a medication therapy management (MTM) program that is designed to ensure that Part D drugs “are appropriately used to optimize therapeutic outcomes through improved medication use,” and “reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries.”24 Sponsors must submit an
MTM program description to CMS annually for review and approval.

We provide here a high-level overview of the Part D MTM program for contract year 2013. CMS has prepared a ten-page fact sheet on MTM programs in 2012 that provides additional background. There is substantially more detail, along with a discussion of how the Part D MTM program fits into capitated Financial Alignment Demonstration contracts, in an April 10, 2012 CMS memo to all Part D sponsors.

Beneficiaries targeted for MTM include enrollees in the plan who meet all of the following requirements:

- Have multiple chronic diseases, with three diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;
- Take multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and
- Are likely to incur annual Part D drug costs of $3,144 or more.

Part D plan sponsors must offer a minimum level of MTM services to each beneficiary enrolled in the program that includes all of the following:

- Interventions for both beneficiaries and prescribers;
- An annual comprehensive medication review (CMR), with written summaries in CMS’ standardized format. The beneficiary’s CMR must include an interactive person-to-person or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. If a beneficiary is offered the annual CMR and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the CMR with the beneficiary’s prescriber, caregiver, or other authorized individual; and
- Quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary.

Cognitively Impaired Beneficiaries

While providers are required to offer a CMR to all beneficiaries, regardless of setting, in the event the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, CMS recommends that the pharmacist or qualified provider reach out to the beneficiary’s prescriber, caregiver, or other authorized individual, such as the beneficiary’s health care proxy or legal guardian, to take part in the beneficiary’s CMR. However, in the event the MTM provider is unable to identify another individual who is able to participate in the CMR, and a CMR cannot be performed, sponsors are still required to perform TMRs at least quarterly with follow-up interventions when necessary and to perform prescriber interventions.

Residents in Long-Term Care Settings

In the past CMS has not required Part D plans to offer CMRs for residents of nursing facilities or other long-term care (LTC) facilities, but they were still required to perform quarterly medication reviews and other interventions targeted to the beneficiaries’ prescribers. Starting in 2013, Part D plans must offer CMRs to LTC facility residents. CMS recommends that plan sponsors coordinate with the facility’s LTC consultant pharmacist and/or the beneficiaries’ prescriber, caregiver, or authorized representative to determine whether the beneficiary is cognitively impaired and cannot accept the offer to participate. CMS also encourages plan sponsors to coordinate with the LTC consulting pharmacist in order to address potentially conflicting medication recommendations.

Opportunities for States

As Medicare-Medicaid enrollees are enrolled in demonstration plans that make Part D benefits available as part of a fully integrated benefit package, states will have expanded opportunities to work with Part
D plans to improve the care of Medicare-Medicaid enrollees. States and demonstration plans will be better able to obtain current and reliable information on enrollees’ prescription drug use for care coordination purposes, and there will be enhanced opportunities to make prescription drug use more effective and beneficial for enrollees, and more cost-effective for plans and payers.

More Information on Medicare Part D


ABOUT THE INTEGRATED CARE RESOURCE CENTER

The Integrated Care Resource Center is a national initiative of the Centers for Medicare & Medicaid Services to help states improve the quality and cost-effectiveness of care for Medicaid’s high-need, high-cost beneficiaries. The state technical assistance activities provided within the Integrated Care Resource Center are coordinated by Mathematica Policy Research and the Center for Health Care Strategies. For more information, visit www.integratedcareresourcecenter.com.

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Endnotes

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5. Summer, et al., op.cit., Appendix Table 1, p. 24.

6. CMS. Medicare Prescription Drug Manual, Chapter 6 – Part D Drugs and Formulary Requirements, Section 30.4 – Transition.


15. Total Medicaid expenditures in 2009 for benzodiazepines for dual eligibles were $70 million, and for barbiturates were $3.1 million. See Table D.13 in the Statistical Compendium on Medicaid Pharmacy Use and Reimbursement in 2009, prepared for CMS by Mathematica Policy Research. Total Medicaid expenditures for dual eligibles for all drugs excluded by statute from Part D in 2009 were $204 million, 0.9 percent of the $22 billion in total Medicaid expenditures for all prescription drugs in that year (Table N.1 in the Statistical Compendium).

16. CMS. Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2.


20. MedPAC has expressed concern about the high level of Part D LIS spending that has resulted from the current limits on beneficiary cost sharing, and has recommended that Congress give the Secretary of DHHS authority to modify the current cost sharing to encourage greater use of generic drugs and other cost-effective alternatives. MedPAC, Report to the Congress, March 2012, pp. 352-366.


23. For state-by-state detail on Medicaid beneficiary cost sharing for prescription drugs, see Appendix B on p. 21 in V. Smith, et al. “Managing Medicaid Pharmacy Benefits.”

24. 42 CFR Section 423.153(d).


27. The 2013 MTM annual cost threshold is $3,144. In accordance with 42 CFR Sections 423.153(d) and 423.104(d)(5)(iv), the threshold is increased each year by a percentage equal to the prior year’s increase in national per capita expenditures for Part D drugs.