Law and the Public's Health

IMPLEMENTING THE MEDICARE PART D PRESCRIPTION DRUG BENEFIT PROGRAM: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

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This installment of *Law and the Public's Health* examines the legal provisions of the Medicare Part D prescription drug benefit, the special legal protections for the Medicare beneficiaries who will enroll in prescription drug plans (PDPs), and the implications of the new law for public health practice and policy.

OVERVIEW OF PART D

The Part D prescription drug coverage program begins on January 1, 2006. Part D is voluntary; for an average monthly premium of $37 in 2006 (like Medicare Part B, the Part D premium rises annually), beneficiaries will be entitled to enroll in a PDP. Partial and full financial subsidies will be available for Medicare beneficiaries with modest assets and incomes below 150% of the federal poverty level.[1] Low-income subsidy enrollment will be available through local Social Security and Medicaid agency offices; no separate enrollment will be needed for Medicare beneficiaries who also receive Medicaid (i.e., dual enrollees). For dual enrollees, the program in essence is not voluntary. Medicaid drug coverage terminates for dual enrollees on January 1, 2006; in order to ensure their coverage without interruption, the Centers for Medicare & Medicaid Services (CMS) intends to "auto-enroll" all dual enrollees (i.e., automatically enroll without a separate low-income subsidy application) directly into a participating PDP. Once auto-enrolled, dual enrollees may subsequently change plans.

Enrollees will be entitled to choose between at least two private PDPs that have been certified by CMS to sell Part D coverage. Financial coverage under Part D consists of both "front end" and "catastrophic" assistance. For 2006, the dollar value of the coverage is as follows: after a $250 deductible, Medicare will pay 75% of the first $2,250 worth of covered drugs. Non-subsidized beneficiaries then must incur an additional $2,850 in out-of-pocket payments (popularly referred to as the "doughnut hole") until they hit a "stop-loss" (i.e., an out-of-pocket limit) equal to $5,100 in total expenditures for covered drugs. At this point, catastrophic coverage begins, picking up 95% of the cost of covered drugs. (All of these dollar figures are subject to upward adjustment in subsequent years.)

In terms of coverage design, PDPs can use formularies (which are a typical feature of private prescription drug coverage) that limit coverage to those drugs on the PDP's formulary list. Federal rules require a reasonable formulary design, but the rules nonetheless allow PDPs to exclude potentially numerous safe and effective drugs. In addition, PDPs can subject covered drugs to "tiered cost sharing" requirements to incentivize the purchase of less costly drugs (e.g., generic drugs or older and less expensive classes of drugs). If they believe that medical evidence justifies it, PDPs can grant exceptions to their formulary restrictions and can reduce cost sharing.

It should be evident from this thumbnail description that Part D is both complex and valuable. (For an excellent fact sheet and overview of Part D, see the Kaiser Family Foundation's materials at http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=33325). Beyond issues of design complexity, it is also evident that at several points in the program, important disputes can arise: (*1*) initial enrollment into a PDP could be rejected for some reason (e.g., beneficiary does not live in the service area) or a PDP could disenroll a member; (*2*) a PDP could deny a requested drug as excluded or require high cost sharing to incentivize the use of what may be a less suitable alternative drug; (*3*) an application for low-income assistance could be denied, or ongoing assistance could be reduced or terminated; or (*4*) the enrollee could have a complaint about some aspect of the PDP's operations (e.g., poor choice in participating pharmacies). For these reasons, it is also important to understand the procedures available under the Part D program to resolve these disputes.

Using the dispute systems offered under Part D is very important. For the more than 6 million elderly and disabled dual enrollees who will be auto-enrolled into PDPs, ensuring that they are properly enrolled and receiving appropriate coverage will be an enormous challenge that raises potentially life-and-death issues. (The program applies to all Medicare beneficiaries, even those in nursing homes, with no back-up Medicaid coverage in the event of enrollment failure.) It is also essential that beneficiaries understand Part D coverage in some detail. This is because under Part D, the $5,100 catastrophic threshold cannot be met until the enrollee's out-of-pocket limit has been reached for *covered* drugs. That is, if a drug is excluded from the formulary, a beneficiary's out-of-pocket payments for the uncovered drug do not count toward the stop-loss, no matter how great they are. (Furthermore, in general, drug assistance payments made by third parties—for example, from Veterans Affairs, health center, Indian Health Service, or the Ryan White Care Act ADAP programs—do not count toward satisfaction of the out-of-pocket stop-loss; however, payments by state pharmacy assistance program or charities would count in the case of lower-income beneficiaries, but they would need to be tracked.)

PROCEDURAL PROTECTIONS AVAILABLE UNDER THE FINAL RULES

The final rules provide certain procedural protections, including dispute of denial of PDP enrollment or coverage. The rules also address low-income subsidies.

Disputing a denial of PDP enrollment

The final regulations do not establish a formal procedure to resolve disputes involving enrollment denials by PDPs. Instead, CMS indicates that it will monitor the procedures used by PDPs to handle disputes involving the denial of enrollment into the plan.[2]

Coverage denials

Part D provides procedural protections when coverage is denied or high cost sharing is imposed. Appeals of coverage denials are possible for disputes involving "coverage determinations." The final regulations define the term "coverage determination" as (*1*) a decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy, or the Part D plan sponsor determines that the drug is otherwise excludable as not "medically necessary;" (*2*) failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee; (*3*) a decision concerning an exceptions requests; and (*4*) a decision on cost-sharing amounts. (Other disputes, such as complaints about the lack of sufficient PDP network pharmacies, are resolved through separate and less formal "grievance" procedures.)

The final regulations clarify that a pharmacy's failure to fill a prescription when it is presented (i.e., a "point-of-sale transaction") is *not* a coverage determination triggering appeals rights. Thus, the most common means by which most beneficiaries will discover that coverage is not available (i.e., by presenting a prescription and learning from the pharmacist that the transaction did not go through) does not qualify as a coverage determination. Beneficiaries who fail to get their prescriptions filled as a covered benefit will need to make a separate and formal "request for coverage." (Additional information concerning coverage requests can be found at http://www.medicare.gov/medicarereform/default.asp.)

The final rules establish 72 hours for standard coverage determinations and 24 hours for expedited coverage determinations if the prescribing physician indicates that the standard 72-hour timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.[3] Once a coverage determination falling into the above categories is received, beneficiaries can request a redetermination of a denial, again with fast-track decision-making if the appeal follows an expedited determination. PDP sponsors must make redeterminations not later than seven calendar days from the date of receipt of a request for a standard redetermination, and within 24 hours of the request for an expedited redetermination.[4]

Submission of medical evidence on appeal does not mean an automatic "win." The final regulations preserve considerable PDP sponsor discretion to deny requests for exceptions to tiered cost sharing and formulary limits, even where the beneficiary submits written evidence from the prescribing physician satisfying the medical necessity standard applicable to such requests under the law.[5] Thus, even when a physician provides evidence that a particular prescription is medically necessary, the plan is not bound by the physician's assessment, but rather can substitute its own judgment. Finally, the final regulations permit PDP sponsors to refuse to provide any exceptions process to tiered cost sharing structures for "very high cost and unique items, such as genomic and biotech products," but does not define these terms.

Low-income subsidies

As noted, Medicare law entitles low-income persons who are determined to be "subsidy-eligible individuals" to subsidies for premiums and cost sharing if they are "determined to" meet the eligibility requirements for subsidies.[6] A subsidy-eligible person is an individual who "is enrolled in" a PDP, has family income below 150% of the federal poverty level, and meets the law's resources requirements (defined as three times the Supplemental Security Income [SSI] standard or a permissible alternative under the law).[6] Certain beneficiaries are automatically "determined to be" eligible for full subsidies without a separate application: (*1*) "full benefit" dual enrollees (Medicare beneficiaries who also receive full Medicaid coverage—typically elderly and disabled persons who receive SSI or who are residents of nursing homes; (*2*) low-income Medicare beneficiaries who receive partial Medicaid coverage for premiums and cost sharing; and (*3*) all SSI recipients.[7] The final regulations indicate that CMS will work with states and the Social Security Administration (SSA) on an outreach strategy to encourage low-income beneficiaries to apply and "prequalify" for the low-income subsidy before enrolling in a PDP.

If a low-income subsidy is reduced or terminated, the final regulations clarify that "decisions made by the State or SSA to reduce or terminate a subsidy would trigger a right to continued coverage at the pre-reduction levels pending the appeal." In other words, the subsidy would continue pending the outcome of the appeal. This is because unlike the Medicare drug benefit itself, the subsidy is a needs-based program, and the law requires that its administration be consistent with how states process appeals under Medicaid.[8]

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

Part D is an enormously important but complex benefit. Given the profound implications of prescription drug access for the life and health of elderly and disabled persons, public health agencies have a natural interest in ensuring that beneficiaries without employer-sponsored prescription drug coverage take full advantage of the program.

At the same time, the new program poses certain challenges: (*1*) assuring that Medicare beneficiaries understand the value of Part D and enroll when coverage becomes available (as with insurance generally, late penalties apply to most persons who fail to take advantage of the program as soon as it becomes available); (*2*) ensuring that Part D enrollees are educated about how to use their benefits (and that physicians and pharmacies—which may be the first point at which an enrollee learns that a prescription is being rejected—are positioned to provide information about how to make a formal coverage request and advocate for patients' treatment decisions); (*3*) ensuring that the approximately 8 million potentially eligible low-income Medicare benefi-

ciaries understand and receive help in applying for subsidies; and (*4*) ensuring complete transition into Part D of the poorest "dually enrolled" Medicare beneficiaries who are currently covered through Medicaid but whose prescription drug benefits will cease as of January 1, 2006. Although auto-enrollment of Medicaid beneficiaries into managed care plans has been a feature of the Medicaid managed care landscape since the early 1990s when managed care became compulsory for most Medicaid beneficiaries, states' auto-enrollment experience has been with women and children in good health with low health care utilization rates.

Public health agencies play a critical role in making Part D successful. Among other things, they must coordinate health education efforts in collaboration with senior citizen organizations, disability consumer groups, churches, civic organizations, and others; provide outreach to the pharmacies, health professionals, and health care agencies that regularly interact with Medicare beneficiaries; support home health agencies and long-term care institutions that will face the need to transition the sickest beneficiaries; monitor PDP enrollment to discern early signs of rejections or lapses in auto-enrollment; and establish hotlines for families. The cost of outreach and enrollment support for subsidy-eligible beneficiaries and dual enrollees is recognized as an allowable Medicaid administrative cost, and health agencies should therefore be able to enter into memoranda of understanding with state Medicaid agencies to support the cost of these activities.

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3. 42 CFR §§ 423.568 (a) and 423.570 (c).
4. 42 CFR § 423.590 (a) and (d).
5. 42 CFR § 423.578 (a) and (b).
6. Pub. L. 108-173 (Dec. 8, 2003).
7. 42 CFR § 773(c).
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