The implementation of the Medicare prescription drug benefit plan (Part D) fills an important omission from the standard set of Medicare benefits. Despite this, the new benefit has been controversial because of its complexity, concerns about the adequacy of its coverage, and its reliance on the free market. However, many Medicare beneficiaries may realize meaningful savings in prescription medication costs when they sign up for Part D. This is important because reliable access to medications, and by extension adherence to medications, is a common and serious concern in the management of patients with acute and chronic illness.

Although many physicians may be confused by the complexities of Part D, they share some responsibility for helping patients manage potential obstacles to obtaining needed medications. Many beneficiaries expect this assistance, and physicians have both a vested interest in and a unique opportunity to help demystify the Medicare drug benefit for patients because of their roles as agents for their patients’ health and as medication prescribers. The importance of this role will not diminish any time soon. Although the initial open enrollment period extended only through May 15, 2006, many beneficiaries will change plans or enroll anew after this deadline. Moreover, in the coming decade, more than 2 million adults will become eligible for Part D annually, and with that eligibility will come a new round of questions and concerns about the drug benefit plan. Although the benefit plan is likely to evolve over time and perhaps even be simplified, the complicated federal regulations behind Part D and the presence of multiple Part D plans (PDPs) will persist in the foreseeable future.

Despite its complexity, physicians can share a few facts about Part D with their patients to help them understand key coverage and benefits issues.

CHALLENGING ELEMENTS OF PART D FOR PATIENTS AND HEALTH CARE PROFESSIONALS

Rather than provide a comprehensive review of the Medicare drug benefit plan, we focus on the main features of Part D that present challenges for patients and physicians: (1) coverage choices, (2) costs of the coverage choices, and (3) medication formularies.

Coverage Choices. Part D offers Medicare beneficiaries an unprecedented number of coverage choices. Most Medicare beneficiaries must first choose between enrolling in a PDP vs remaining with their current level of prescription coverage (beneficiaries with both Medicaid and Medicare, the “dual eligibles,” should have been enrolled automatically in plans if they did not select one by January 1, 2006). The main factors guiding this decision include the beneficiary’s current out-of-pocket prescription costs and whether their current coverage is “credible,” meaning that the Centers for Medicare & Medicaid Services (CMS) has deemed the coverage to be actuarially equivalent to or better than the standard Part D drug benefit. Medicare beneficiaries with supplemental drug coverage should receive a letter from the carrier indicating whether their current coverage meets this standard. Although most employer-sponsored plans, state pharmaceutical assistance programs, and Medicare health maintenance organization plans are as good as the Part D benefit, most Medigap plans that include prescription coverage are not.

Medicare beneficiaries must also weigh the costs of the late enrollment penalty in their decision to enroll in a PDP. The late enrollment penalty is a 1% increase in the monthly premium for each month that enrollment in Part D is delayed beyond the beneficiary’s initial 7-month enrollment period. For most beneficiaries, this premium penalty remains for the duration of their participation in Part D. Low-income Medicare beneficiaries who receive premium- and cost-sharing support (Extra Help for People With Limited Incomes and Resources [Extra Help]) after enrollment in Part D face a 0.5% penalty for late enrollment that is applied for 5 years.

Once a decision to enroll has been made, the beneficiary must choose a plan. Two types of drug plans are offered: stand-alone prescription drug plans and Medicare Advantage prescription drug plans (MAPDs). When beneficiaries select an MAPD, they are choosing an entire benefits package that supplements Medicare Parts A and B in addition to covering prescription drug purchases. Enrollment in an MAPD may require beneficiaries to change their network.
of physicians, pharmacies, or hospitals. Stand-alone PDPs cover only prescription medications. Dozens of stand-alone plans exist in each region, and they may vary widely in costs and medications covered. The 2 primary sources for information on specific Part D and Medicare Advantage plans are the Medicare Web site (www.medicare.gov), where one can search for plans by cost or by formulary, and the Medicare Hotline (1-800-MEDICARE), where beneficiaries can receive assistance with plan selection.

Costs of Coverage Choices. Many beneficiaries are confused by the costs of the Part D benefit. The standard benefit has an average premium of $32 per month, a $250 deductible, and a 25% copayment on drug expenses from $251 to $2250. From $2251 to $5100, the beneficiary is responsible for 100% of drug costs. This coverage gap is often referred to as the “donut hole.” After $5100, catastrophic coverage begins, and the beneficiary is responsible for only 5% of medication costs in a calendar year. However, PDPs are only required to be actuarially equivalent to, or more generous than, the standard benefit. For this reason, beneficiaries’ options include plans with premiums ranging from about $2 to $100, deductibles of $0 to $250, and widely varying copayments.

Although individuals who spend as little as $600 annually on prescription medications may save money through Part D, out-of-pocket expenses for medication will remain a challenge for many, with the consequent risk of medication rationing. In addition, individuals with both Medicare and Medicaid benefits may find themselves paying more out-of-pocket for prescription drugs with Part D because of required drug copayments, which range from $1 to $5. Currently, 80% of state Medicaid programs require drug copayments for elderly persons, ranging from $0.50 to $3. Copayments as small as these are associated with reductions in prescription medication use of up to 21% by elderly patients.

Medication Formularies. Drug formularies are another important feature of PDPs. Most provide incentives for generic medicines by using tiered formulary structures that require larger copayments for more costly or nonpreferred medications. Because individual plans may contract with different drug companies, the number of medications covered by a plan may vary greatly, and interplan variability is high. In most cases, plans are legally required to cover at least 2 drugs per therapeutic drug class, but otherwise, individual plans determine which medications will be covered. Therefore, patients may find that some of their medications are not covered by their plan, are covered only in a high-cost tier, or are available for a limited time or only after a trial of less expensive medication fails (ie, step therapy). Exceptions to the rule of providing 2 drugs per therapeutic class include coverage of all drugs from every class for the treatment of human immunodeficiency virus and psychiatric disorders, and no plans cover benzodiazepines, barbiturates, or over-the-counter drugs.

Research suggests that both patients and physicians are typically unaware of the medications covered under patients’ prescription plans, and physicians are frequently contacted by pharmacies to change prescriptions to preferred agents. This problem increases as Part D enrollment shifts a large proportion of Medicare beneficiaries to prescription coverage with restricted formularies, straining pharmacists’ ability to contact physicians when medications are not covered. By prescribing generic drugs or switching to preferred agents, physicians can enhance access to medications for patients with Part D coverage and, in turn, help promote adherence to essential long-term medications. However, achieving this goal will require frequent communication between physicians and patients about medication costs, about problems paying for medications, and about their Part D coverage. Unfortunately, research indicates that physicians and patients often neglect to discuss these issues.

Determining Patients’ Need for Assistance

Because patients infrequently discuss health care costs and insurance issues with physicians, physicians should establish a habit of inquiring about these issues. Such inquiries might reveal problems like confusion about Medicare Part D, difficulty paying for covered medications, or lack of coverage of a particular medication. As we describe in the following paragraphs, physicians may be able to address some problems directly or refer patients to available resources such as social workers, their State Health Insurance Assistance Program (SHIP), Medicare, or local advocacy groups.

Assisting Patients With Part D Decision Making

Most physicians do not have the time or expertise to conduct the lengthy searches and comparisons needed to identify appropriate PDPs or otherwise act as insurance counselors for their individual patients. However, a limited knowledge of the drug benefit plan may go a long way in enabling physicians to address patients’ concerns and questions and to ensure their awareness of the program’s benefits and pitfalls regarding affordable prescription drug coverage. Physicians should be prepared to help patients answer the following questions.

Should This Patient Enroll in Part D? The physician should first determine whether the patient’s current prescription coverage is creditable, that is, whether the patient’s coverage is actuarially equivalent to or better than the standard Medicare Part D benefit. If patients are satisfied with their current source of prescription coverage and the coverage is as good as or better than the standard Part D drug benefit, they can stay with their coverage and switch
to a PDP during any future annual enrollment period without incurring a late enrollment penalty. However, disenrolling from a creditable employer-sponsored prescription medication plan to sign up for Part D could result in the loss of other retiree benefits.32

If the patient’s plan is not creditable, protection against future risk should be considered. Patients without creditable coverage should be encouraged to consider enrolling in a PDP, even if their current medication expenditures are low, to guard against future medication costs while avoiding late enrollment penalties. Patients with little or no medication expenditures could select a low-premium, high-deductible plan to reduce monthly costs and then switch to a higher-premium plan during the annual open enrollment period if their medication expenditures increase.

**Which PDP Should the Patient Select?** Physicians should emphasize important details of Medicare Part D and direct their patients to appropriate resources that will help them select a plan covering their medications (Table 1). It is unreasonable to expect most physicians to have the time to help patients identify an appropriate plan. However, physicians should make their patients aware of some key points: (1) not all medications are covered by a single plan, (2) costs may differ among plans for the same medication, (3) not all pharmacies can accept their PDP, and (4) important rules may apply to medications that are covered; these rules include a failed trial of agents from a different drug class before a specific drug is approved for coverage (step therapy) and higher copayments for some drugs (eg, middle- and high-cost tier medications).

With a list of current medications and dosages in hand, patients or their families can identify the optimal plan using the Medicare Personal Plan Finder (found at www.medicare.gov). The plan finder allows side-by-side comparisons of PDP formularies, including information on costs (premium, deductible, copayments), acceptance of the plan in local pharmacies, mail-order options, restrictions (eg, step therapy, tiered copayments, dispensing limits), and plan coverage outside the state of residence. Use of the Medicare Personal Plan Finder requires Internet skills and sufficient sophistication to make reasonable comparisons among complicated drug plans. If the patient or family lacks such skills or has no Internet access, personalized assistance in selecting a plan is available from the CMS via the Medicare Hotline or

### TABLE 1. Medicare Part D–Related Resources for Physicians and Patients*

<table>
<thead>
<tr>
<th>Areas of assistance</th>
<th>URL or hotline number</th>
<th>Service provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part D enrollment, plan selection assistance, and general Part D information Medicare</td>
<td><a href="http://www.medicare.gov">www.medicare.gov</a></td>
<td>Formulary Finder or Plan Finder can be used to search for plans by cost or by medications covered and learn details of specific plans</td>
</tr>
<tr>
<td>State Health Insurance Assistance Programs Pharmacies</td>
<td>1-800-MEDICARE</td>
<td>Personal assistance with plan selection 24 h per day, 7 days per wk</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.medicare.gov/contacts/static">www.medicare.gov/contacts/static</a> /allStateContacts.asp</td>
<td>Contact information for individual state programs</td>
</tr>
<tr>
<td></td>
<td>...</td>
<td>Some pharmacies, especially national chains, provide individual counseling</td>
</tr>
<tr>
<td>Medication selection and formulary information Medicare</td>
<td><a href="http://www.medicare.gov">www.medicare.gov</a></td>
<td>Formulary Finder or Plan Finder can be used to search for plans by cost or by medications covered and learn details of specific plans</td>
</tr>
<tr>
<td>Epocrates</td>
<td>1-800-MEDICARE</td>
<td>Personal assistance with plan selection 24 h per day, 7 days per wk</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>www2.epocrates.com/index.html</td>
<td>Free software download for personal digital assistance devices with up-to-date formulary information for PDPs</td>
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<td></td>
<td>...</td>
<td>Pharmacists can assist patients in finding a PDP that best covers their prescribed medications</td>
</tr>
<tr>
<td>Requesting exceptions Medicare</td>
<td><a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> /PrescriptionDrugCovGenIn/04 _Formulary.asp</td>
<td>Contact information for all PDPs</td>
</tr>
<tr>
<td>Medicare Rights Center</td>
<td><a href="http://www.medicarerights.org">www.medicarerights.org</a> /exceptionrequest_template.doc</td>
<td>Template for letters from physicians to request coverage from a PDP for a nonformulary drug</td>
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<tr>
<td>Additional assistance for low-income patients Extra Help</td>
<td><a href="http://www.ssa.org">www.ssa.org</a> (Social Security Administration)</td>
<td>Reduced Medicare Part D premiums and copayments for low-income Medicare beneficiaries</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.medicare.gov">www.medicare.gov</a> or 1-800-MEDICARE</td>
<td></td>
</tr>
<tr>
<td>Medicare Part D low-income subsidy State Health Insurance Assistance Programs (see above)</td>
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</table>

*Extra Help = Extra Help for People With Limited Incomes and Resources; PDP = Medicare Part D drug plan.
through its SHIP. Some national chain pharmacies have advertised a similar service. Contact information for individual SHIPs is available through the Medicare Hotline or at www.medicare.gov/contacts/static/allStateContacts.asp. Of note, patients should always call the PDP they have selected before enrolling to confirm coverage of their medications because inaccuracies in formulary information on the CMS Web site have been reported.

The physician should identify medications for which lower-cost alternatives—generic drugs or preferred agents—could be substituted. This approach may provide patients with greater flexibility in their search for an affordable plan. In a recent media report, an individual was able to find a lower-cost plan that covered her medications, saving an estimated $700 annually, by switching to a few cardiovascular drugs that were preferred agents. Time-saving approaches to identifying preferred drugs are discussed subsequently.

What Should Be Considered When Prescribing for Patients Enrolled in a PDP?
When possible, the physician should ensure that a medication is covered by the patient’s PDP before writing the prescription. Physicians can quickly access most plan formularies at the point of care by downloading them from Epocrates (www2.epocrates.com/index.html) onto personal digital assistant devices. This service is free. Alternatively, physicians and patients may speak with the patient’s pharmacist, who will have ready access to the plan formulary. Pharmacists can play an instrumental role in helping both physicians and patients navigate the complexities of prescribing under Medicare Part D.

Although physicians may lack the time to explore and use the Internet-based Medicare Part D formulary tools at www.medicare.gov, basic familiarity with the Part D Formulary Finder or Plan Finder allows for quick and easy identification of medications covered by a patient’s plan. These tools have a useful feature that shows alternative medications from within the same drug class that are covered by the patient’s PDP and may be substituted for currently used drugs. It shows the potential savings from switching medications and identifies any restrictions on use, such as step therapy requirements and limitations on the number of pills dispensed.

If the formulary details are unavailable at the time of prescribing, the physician should prescribe generic substitutes when available to ensure access to the lowest-cost agents. When generic drugs are not available, physicians can inform patients of the possibility that a medication will not be covered and establish a plan for such situations.

The physician should request an exception if a medically necessary drug is not covered by the patient’s PDP, requires step therapy, or is available only in a higher-cost tier. Requests for exceptions and appeals for denied exceptions are submitted to the individual plan, and a determination must be made within 72 hours. Physicians can also request an expedited exception whereby a determination is expected within 24 hours. Information on submitting exception requests can be obtained through individual plans (contact information for individual plans is available at www.cms.hhs.gov/PrescriptionDrugCoverGenIn/04_Formulary.asp). The Medicare Rights Center provides a template for exception letters that can be downloaded from their Web site (www.medicarerights.org/exceptionrequest_template.doc).

What Additional Information Should Patients Know?
Medicare beneficiaries with Medicaid or Medicare Savings Program coverage are automatically enrolled in Medicare Part D and assigned to a plan. The formulary of a plan to which dual eligibles are assigned may not cover some or all of their medications. Patients should be encouraged to review their plan formulary and consider a change to another plan if important medications are not covered. While all other Medicare beneficiaries are permitted to change plans only once each year (during the November 15th to December 31st annual open enrollment period), dual eligibles may change plans as often as once a month. However, dual eligibles must select from among a limited number of predesignated low-cost “benchmark” plans. If they choose a nonbenchmark plan, they will have to pay the difference in the premiums and cost sharing.

Many medications are excluded from coverage under Medicare Part D, including benzodiazepines and barbiturates and over-the-counter medications such as decongestants, vitamins, and minerals. In some states, these medications may be covered by Medicaid (for dual eligibles) or by the state pharmaceutical assistance program.

Individuals with incomes below 150% of the federal poverty level (about $17,000 per year) and limited financial assets may qualify for Extra Help, and if so, they have reduced-cost premiums, deductibles, and copayments. Medicare beneficiaries can get information on Extra Help or assistance with enrollment by calling 1-800-MEDICARE, by contacting their local Social Security Administration office (www.ssa.org), or by contacting their SHIP.

Most state pharmaceutical assistance programs for elderly persons provide creditable coverage. In addition, in some states, beneficiaries can be enrolled concurrently in their state’s pharmaceutical assistance program and a PDP. In approximately half of the states, these programs will supplement Part D coverage, for example, covering a portion of the premium or cost sharing, including medication costs incurred in the Part D coverage gap. State pharmaceutical assistance programs may also cover medications excluded from Part D coverage, such as benzodiazepines or medications not covered under a patient’s PDP formulary.
Patients may receive additional assistance from Medication Therapy Management Services (MTMS). Medicare will reimburse PDPs that implement MTMS programs, including services aimed at optimizing therapeutic outcomes for patients taking large numbers of medications or high-risk (e.g., warfarin) or high-cost medications (e.g., biologic agents) or patients known to have problems with medication adherence. The scope of services that will be offered remains unclear, and evaluation of the quality of services has not yet been conducted. Nevertheless, these services are likely to be of benefit to some patients. Physicians or patients must contact the individual drug plan or Medicare Advantage plan to learn about any MTMS provided.

**Summary**

Recent commentaries on Medicare Part D highlight both the early failings and the successes of the program. However, regardless of one’s opinions about the program, Part D is a reality that millions of Medicare beneficiaries must address now and in the future. The ultimate economic, policy, and clinical success of the Medicare drug benefit plan depends on its transparency and ability to be navigated together by patients, physicians, and other parties. Although Medicare Part D is likely to evolve considerably in the future, it will continue to present elderly adults with numerous plan options and rules and therefore present persistent challenges for patients and physicians. By focusing on a few crucial aspects of Part D and taking advantage of available resources, physicians can simplify Part D for their patients, help them make informed decisions about enrollment and plan selection, and possibly help them save money with their current PDP. This may, in turn, reduce beneficiaries’ out-of-pocket prescription costs, thereby improving patients’ access to medications and possibly their medication adherence and health outcomes as well.

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**References**