CHAPTER 7

Issues in Medicare coverage of drugs

RECOMMENDATIONS

7A The Congress should direct CMS to identify selected overlap drugs and direct plans to always cover them under Part D. Identified drugs should be:

- low cost
- covered under Part D most of the time.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

7B The Congress should allow plans to cover a transitional supply of overlap drugs under Part D under the same conditions as the general transition policy applied by CMS.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

7C The Congress should permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

CHAPTER 7

Issues in Medicare coverage of drugs

Chapter summary

Medicare's Part D prescription drug benefit is built on the delivery system used by the commercial market. Pharmacy benefit managers process claims and design formulary systems. Most outpatient drugs are provided through retail or mail-order pharmacies. Claims are adjudicated in real time. When drugs are provided in settings or under conditions that do not fit this model, patients, physicians, plans, and pharmacies can experience difficulties navigating the system. In this chapter, we explore two such situations: overlapping coverage of drugs under Part B and Part D, and delivery of Part D benefits to Medicare beneficiaries who reside in long-term care facilities.

Overlapping coverage between Part B and Part D drugs

In most cases, stakeholders know whether Part B or Part D covers specific drugs. In some cases, however, they need additional information. For example, an immunosuppressive drug is covered under Part B only if it follows a Medicare-covered organ transplant; otherwise, it comes under Part D. Since a drug plan must determine whether a drug should be covered under Part B before it can approve a claim, plans

In this chapter

often require prior authorization before the pharmacist can dispense the drug. In other words, the plan will not approve the claim until it has collected additional information.

We offer recommendations to address three issues with overlap drugs. First, plans and pharmacists agree that drugs that can be prescribed for many indications pose a problem. To mitigate this problem, the Commission recommends that the Congress change the law to allow CMS to identify low-cost drugs that are sometimes covered under Part B but are covered under Part D more than 90 percent of the time and direct plans always to cover them under Part D.

Recommendation 7A

COMMISSIONER VOTES:
YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

The Congress should direct CMS to identify selected overlap drugs and direct plans to always cover them under Part D. Identified drugs should be:

- *low cost*
- *covered under Part D most of the time.*

A second issue we identified in our research is permitting plans to cover a transitional supply of drugs under Part D. Interviewees report that, until a plan determines whether a drug is covered under Part B or Part D, it is not allowed to provide emergency supplies to beneficiaries under Part D. Some pharmacists do provide emergency supplies but must absorb the cost if coverage is denied and the beneficiary cannot pay out of pocket. We recommend that the Congress authorize prescription drug plans (PDPs) to approve transition supplies while coverage is being determined.

Recommendation 7B

COMMISSIONER VOTES:
YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

The Congress should allow plans to cover a transitional supply of overlap drugs under Part D under the same conditions as the general transition policy applied by CMS.

A third issue concerns vaccines administered by physicians. Physicians and public health agencies are concerned that new preventive vaccines are covered under Part D instead of Part B. Since physicians have no direct billing relationship with drug plans, patients might have to pay directly for vaccines and seek repayment from their drug plan. Interviewees reported that the high out-of-pocket cost of new vaccines under an indemnity model might discourage beneficiaries from seeking recommended preventive care.

The Congress should permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D.

Recommendation 7C

COMMISSIONER VOTES:
YES 15 • NO 0 • NOT VOTING 0 • ABSENT 2

Delivering Part D benefits to residents of long-term care facilities

When policymakers created Part D, they gave most attention to how competing private plans would work for beneficiaries who fill prescriptions at retail pharmacies. However, about 5 percent of Medicare beneficiaries reside in long-term care facilities, and more than half of them are dually eligible for Medicare and Medicaid. Residents in nursing facilities (NFs) are typically sicker and frailer than Medicare beneficiaries in the community: They take, on average, 6 to 10 prescription drugs per day compared with 2 to 4 among the noninstitutionalized. They do not fill prescriptions at retail pharmacies.

A different system is used to dispense drugs to residents of NFs, and Part D has affected that system. Previously, long-term care pharmacies (LTCPs) interacted most frequently with one payer—a state Medicaid program. Under Part D, LTCPs must negotiate with numerous plan sponsors over payments for services delivered to NF residents. LTCPs consider some Part D plans "friendlier" than others—for example, covering drugs that NF residents currently use and requiring prior authorization less frequently. Yet tensions have grown between some Part D plans and LTCPs over pharmacies' desire for timely dispensing and plans' desire to determine whether prescriptions are covered and appropriate before paying for them. Also, CMS is concerned

that the separate rebates LTCPs receive directly from drug manufacturers could interfere with the formularies Part D plans use and could raise program costs.

No empirical analyses based on drug and medical claims evaluate the effects of Part D on NF residents. The Commission intends to monitor this issue and will look at data as they become available. Policymakers may want to evaluate various approaches for providing Part D benefits in long-term care settings. Although the Commission does not make recommendations on these issues, this chapter looks at three alternatives as an initial step in exploring potential options:

- continuing with multiple Part D plans, but adding requirements to report data on the quality and appropriateness of drugs dispensed to residents of NFs;
- holding periodic competitions to select a single PDP for all residents of NFs within the same geographic region; and
- reimbursing LTCPs directly for delivering Part D benefits to residents.

Under all three approaches, Medicare could require the entity delivering Part D benefits to bear insurance risk for the drug spending of its enrollees in the same way that it does today. ■

Since 2006, Medicare beneficiaries have had the option of receiving outpatient drug benefits through stand-alone prescription drug plans (PDPs) or Medicare Advantage–Prescription Drug (MA–PD) plans that offer drug benefits under Medicare Part D. Before the program started, policymakers were concerned that few private organizations would be willing to offer stand-alone drug coverage. Another uncertainty was whether Medicare beneficiaries would enroll in the voluntary program. However, many drug plans and beneficiaries now participate in the program. In 2007, plan sponsors offered 1,866 PDPs, about 30 percent more than the previous year. According to the most recent figures from CMS, about 24 million beneficiaries are enrolled in PDPs or MA–PDs, or about 56 percent of all Medicare beneficiaries. Our March 2007 report provides an update on enrollment, plan participation, and benefit design.

In this chapter, we explore two particular issues we identified in the Part D program. Medicare's Part D prescription drug benefit is built on the delivery system used by the commercial market. Pharmacy benefit managers process claims and design formulary systems. Most outpatient drugs are provided through retail or mail-order pharmacies. Claims are adjudicated in real time. When drugs are provided in settings or under conditions that do not fit this model, patients, physicians, plans, and pharmacies can experience difficulties navigating the system. Two such situations include:

- overlapping coverage of drugs under Part B and Part D, and
- delivery of Part D benefits to beneficiaries who reside in long-term care facilities.

Overlapping coverage between Part B and Part D drugs

Before 2006, Medicare covered few outpatient drugs. Those that were covered under Part B include drugs administered by physicians, drugs used with durable medical equipment (DME), and drugs specifically named in statute. Since 2006, Medicare beneficiaries have been able to obtain coverage for most other types of outpatient drugs through Part D stand-alone PDPs or MA–PDs. Some drugs are covered under both Part B and Part D. For example, immunosuppressive drugs are covered under Part B for beneficiaries who received Medicare-covered organ transplants, and they are covered under Part D if Medicare did not cover the transplant.

In the course of research for our mandated report to the Congress on the effect of Medicare payment changes for Part B drugs (MedPAC 2007a), interviewees reported instances when the overlap in drug coverage under Part B and Part D increased the administrative burden for physicians, pharmacists, and health plans and delayed beneficiary access to needed medications. To further examine the issue of overlap drugs, a research team from NORC and Georgetown University conducted structured interviews with drug plans, pharmacists, beneficiary advocates, and trade associations. Staff also met with representatives from CMS and other government agencies. We further discussed Part B/Part D overlap issues with physicians, beneficiary advocates, and other stakeholders.

In most cases, stakeholders know whether drugs are covered under Part B or Part D. In general, Medicare covers drugs that must be administered by physicians under Part B and drugs that are purchased at pharmacies through Part D. In some cases, however, pharmacists and PDPs are unable to determine which program covers a particular drug without additional information. Stakeholders estimate that about 6,000 products (unique national drug code (NDC) numbers) potentially could be covered under either Part B or Part D (PCMA/NACDS 2006). Interviewees told us that coverage overlaps can result in delays for patients and increased costs. Since PDPs must determine whether a drug should be covered under Part B before they can approve a claim, plans often require prior authorization, meaning that physicians must provide additional information before the pharmacist can dispense the drug. Interviewees report that this process takes time and can delay beneficiaries getting their drugs.

In addition, some interviewees are concerned about coordination of coverage when drugs are covered under Part D but necessary supplies or clinical support are covered under Part B, Medicaid, or not at all. For example, home infusion specialists note that Part D does not cover the pharmacy and nursing services, supplies, and equipment needed to administer home infusion therapies. Beneficiaries may be unable to receive their medication because of lack of coordination among coverage sources.

Interviewees described how they manage these situations. In some cases, they also discussed possible solutions. Many interviewees believed that particular products were best suited to one type of coverage.

Overlapping drug coverage

The Congress gradually has expanded the type of drugs eligible for Part B coverage. For example, as some older chemotherapy drugs became available in oral form, the Congress decided to cover oral chemotherapy and antiemetic drugs that are exact replacements for covered infusible drugs under Part B. When beneficiaries take these medicines orally, Medicare does not have to pay for drug administration services and beneficiaries spend less time undergoing infusion sessions. The Congress also extended coverage to some vaccines, immunosuppressive drugs used after a Medicare-covered organ transplant, blood products, and drugs used with DME. Retail and mail-order pharmacies dispense some of these drugs (e.g., immunosuppressive drugs), although physicians continue to provide most Part B drugs.

With the addition of Part D, Medicare beneficiaries now have access to coverage for most outpatient drugs pharmacies dispense. As in the private sector, plans adjudicate claims in real time. Pharmacists know instantly whether a drug is covered, requires prior authorization, or is off the plan's formulary.

Most drugs are clearly covered under one or the other program, but in some instances pharmacists need additional information to determine which program covers a particular drug. In this section, we explore how drug coverage depends on:

- patient diagnosis
- timing of treatment
- use of DME
- where the drug is dispensed

Coverage depends on patient diagnosis

The Food and Drug Administration (FDA) approves many drugs for multiple indications and patients may find that their drug coverage depends on the condition for which they are being treated. In 2005, CMS advised plans to use prior authorization processes to determine whether an overlap drug should be covered under Part B or Part D. Although prior authorization processes differ among plans, prescribing physicians generally have to contact the plan to explain why a drug is prescribed. With that information, plans determine whether the drug meets the criteria for coverage.[1] Examples include:

- Physicians use immunosuppressive drugs to treat many conditions. If physicians prescribe them after a Medicare-covered organ transplant, the drugs are covered under Part B. The same drugs are covered under Part D for all other indications.
- When physicians prescribe oral antiemetics in conjunction with chemotherapy, they are covered under Part B; for all other indications, they are covered under Part D.
- Parenteral nutrition is covered under Part B only for beneficiaries with permanent dysfunction of the digestive tract.
- Erythropoietin, if dispensed at a pharmacy, is covered under Part B only for patients undergoing dialysis.

Coverage depends on timing

Patients may also find that drug coverage depends on when they had a particular medical procedure or treatment that requires additional medication. This issue is similar to the one described above but applies to drugs covered for the same indication.

For example:

- Immunosuppressive drugs prescribed after a Medicare-covered transplant are covered under Part B; for individuals who had a transplant before they were covered by Medicare, the drugs are covered under Part D.
- Most oral antiemetics dispensed within 48 hours of chemotherapy are covered under Part B; after that time, they are covered under Part D even if they still are being used to treat nausea caused by chemotherapy.

To determine coverage in these cases, plans must know both the patient's diagnosis and the timing of treatment.

Coverage depends on use of durable medical equipment

Drugs may be covered under Part B if they are administered to beneficiaries in their homes through covered DME. PDPs cover the same drugs if beneficiaries take the medication using other devices that are not included in the DME benefit. For example, pharmacies would process an inhalation drug administered through a nebulizer or an intravenous drug administered with an

infusion pump under Part B. PDPs would cover the same drugs administered in an alternative fashion under Part D.

Coverage depends on setting

Interviewees report that drug coverage can depend on where beneficiaries live or where their drugs are dispensed. In written guidance, CMS noted that Part B coverage for drugs administered through DME is limited to beneficiaries living in their homes (CMS 2005). They explain that most long-term care facilities do not meet the statutory definition of "home," so these drugs must be covered through Part D.[2]

Medicare covers most physician-administered drugs such as those used for chemotherapy under Part B. Physicians purchase these drugs and bill the carriers.[3] However, long-term care pharmacies (LTCPs) (discussed in greater depth in the second part of this chapter) typically provide injectable and infusible drugs to patients in long-term care facilities. Facility personnel then administer these drugs under medical direction. CMS determined that by definition a pharmacy cannot provide a drug "incident to" a physician's service. Thus, Part D covers these drugs in long-term care settings.

In further guidance, CMS determined that any drug dispensed at a retail pharmacy cannot be considered incident to a physician service and should be eligible for coverage by PDPs (CMS 2006a). As a result, some physicians have begun requiring patients to purchase drugs at a pharmacy (in such cases their PDP pays for them under Part D) and bring them to the office for administration in a process called "brown-bagging." Some physicians say this allows them to provide drugs to their patients without assuming the financial risk of buying them or the administrative burden of acquiring them through the competitive acquisition program.

Interviewees did not describe the practice as widespread. A number of pharmacists reported that they knew about the practice and asked physicians to order the drugs in advance because they did not routinely stock these medications. They also tried to arrange for patients to pick up their medication on the way to their physician's office so that the drug would not be improperly stored. No plan representative reported brown-bagging as a problem, although plans may not have any way of knowing whether patients are going to self-administer a drug or take it to their doctor's office.

While some physicians were experimenting with the practice, others raised concerns about the use of brown-bagging. Doctors did not want to put patients in charge of maintaining the proper storage environment for drugs. In addition, many pharmacies do not regularly stock these drugs, and waiting for them to acquire the drug could create problems with a patient's treatment schedule.

With Part D claims data, analysts will be able to measure how widespread the practice of brown-bagging is. The Commission will monitor this issue to determine whether brown-bagging affects spending and quality of care.

Managing overlap drugs

Interviewees told us that sorting out who to bill for drugs that could be covered under either program took considerable time and resources at the beginning of 2006. Since plans are legally prohibited from covering drugs under Part D that are eligible for Part B coverage, many plans require prior authorization to determine coverage for all overlap drugs. Plan procedures vary but, in general, they require physicians to provide information on why the drug is being prescribed. Then the plan determines whether the drug meets the criteria for coverage. Interviewees reported that this practice resulted in significant delays and many patients had to make more than one trip to the pharmacy before they could receive their medications. In addition to the added burden placed on pharmacists, plans also had to devote considerable resources to staffing prior authorization requests. If plans pay for a drug under Part D that should be covered by Part B, they could be in legal jeopardy. For example, they would be counting their payments for drugs that should be covered under Part B as part of beneficiary out-of-pocket spending for purposes of calculating risk corridors and reinsurance. Auditors could interpret this as a false claim. Physicians also had to spend time and resources responding to requests for information.

Stakeholders told us that the process of determining whether a drug is covered under Part B or Part D has improved. CMS made some decisions early in 2006 that allowed plans to determine program coverage more quickly. The agency determined that plans could accept physician diagnosis codes on prescriptions as sufficient information to determine which program should cover a drug. As noted above, CMS also decided that no drug dispensed at a pharmacy could be classified as a physician-administered drug. Thus, plans could assume that such drugs were covered under Part D. In addition, plans have developed various strategies to streamline some decisions on overlap drugs, including the use of

information systems that track what patients are being treated for and whether they live in long-term care facilities.

These administrative changes and plan program edits eased many of the problems, but significant issues remain. Interviewees reported that the most common continuing problem is determining correct coverage for drugs prescribed for many medical conditions. When they are unsure which program covers a drug, pharmacists have difficulty coordinating with Part B and Part D. A PDP may produce an online denial of a claim, while some medical carriers require a paper denial from a plan to process the claim under Part B.

In addition, drug claims are processed quite differently under Part B and Part D. Pharmacists told us that claim adjudication under Part D is simpler for them. Determination is generally made instantly. Under Part B, they dispense a drug, submit a claim, and wait to see if it will be covered. Carriers may take several weeks to make a determination. If the claim is denied, the pharmacist must then submit the claim to the beneficiary's PDP. During this period, the beneficiary may not be receiving the drug.

Prior authorization

When a drug is placed on a prior authorization list, pharmacists cannot dispense it until the PDP receives information that shows the drug meets the criteria for Part D coverage. Many plans use information collected from an initial prescription for a drug on prior authorization to automate the process for refills. If a PDP learns that a patient is taking immunosuppressive drugs because of a Medicare-covered transplant, the plan knows that future immunosuppressive prescriptions are covered under Part B. Plans include codes in their information systems to track whether a beneficiary is living in a long-term care facility. If that is the case, plans know that physician-administered drugs for that patient are covered under Part D. However, stakeholders told us that the use and accuracy of codes denoting that a patient lives in a long-term care facility vary considerably among plans.

In general, pharmacists report that plans have different prior authorization requirements for Part B overlap drugs. Plans are most likely to ask physicians for diagnosis information. Some plans also request information on the indications for the drugs, a faxed statement from the physician, or proof of denial from Part B. Some plans allow pharmacists to ask physicians about their patient's diagnosis, while others require that physicians complete written authorization forms.

If a physician writes the needed information on the prescription, plans can provide immediate authorization.[4] However, few physicians do this. Physicians who prescribe a large volume of drugs covered by both Part B and Part D (e.g., rheumatologists) are most likely to include diagnosis on the prescription, but other doctors are less likely to do so. In addition, many physicians are reluctant to include diagnosis on prescriptions because of concern about patient privacy.

Some researchers believe that including diagnosis codes on all prescriptions would provide valuable information in examining treatment outcomes. In the future, plans might develop information systems that include medication, dosage, and diagnosis for each claim. Researchers could use the resulting database to inform studies of evidence-based medicine.

Trade groups representing pharmacy benefit managers and chain drugstores issued a white paper recommending that CMS eliminate the need for prior authorization of low-cost overlap drugs (PCMA/NACDS 2006). They suggest that CMS identify low-cost drugs that are covered under Part D more than 90 percent of the time but could be covered under Part B and allow plans always to cover them under Part D. Interviewees most often mentioned prednisone and methotrexate, two inexpensive generic drugs that are frequently prescribed for many indications. Part B covers these drugs when physicians prescribe them after a Medicare-covered transplant. PDPs cover them for all other indications. IMS Health estimates that PDPs cover the drugs 98 percent of the time.

Both pharmacists and plan representatives repeatedly told us that placing very inexpensive drugs on prior authorization delayed beneficiary access and increased costs for them. They noted that the cost of determining whether the drug should be covered by Part D may be higher than the cost of covering the drug. In interviews, some plan representatives said that they had already instructed pharmacists to cover these drugs without prior authorization but are concerned about future audits. If an audit determined that a plan had paid for a drug under Part D that should have been covered by Part B, Medicare could consider the payment a false claim and the plan could be in legal jeopardy. If the Congress gave CMS the authority, the agency could draft a regulation that lists drugs that should always be covered under Part D.

RECOMMENDATION 7A

The Congress should direct CMS to identify selected overlap drugs and direct plans to always cover them under Part D. Identified drugs should be:

- **low cost**
- **covered under Part D most of the time.**

RATIONALE 7A

Prior authorizations placed on inexpensive drugs that are nearly always covered by Part D may delay beneficiary access, increase costs for plans and pharmacists, and increase the administrative burden on physicians.

IMPLICATIONS 7A

Spending

- None

Beneficiary and provider

- This recommendation would improve beneficiary access and reduce provider costs and administrative burden.

Transition supplies

According to law, plans may not provide emergency supplies to beneficiaries while the plan decides whether coverage should be under Part D or Part B. If a patient's drug requires prior authorization, beneficiaries may not receive their medication until coverage is resolved. Some pharmacists do provide emergency supplies but they sometimes must absorb the cost if coverage is denied and the beneficiary cannot pay out of pocket. The Commission recommends that the Congress authorize PDPs to approve transition supplies to beneficiaries under Part D while the plan determines coverage.

When a physician submits a request for a drug that requires prior authorization and supplies accompanying information, the plan must complete a coverage determination or an expedited coverage determination within a set time frame. For example, plans must decide on an expedited request for coverage within 24 hours. However, this time frame does not begin until a physician or the enrollee has attempted to fulfill the prior authorization requirement. When a beneficiary brings a prescription to a pharmacy and the claim is denied because the plan does not know whether the drug should be covered under Part B or Part D, the plan is not making a coverage determination because the plan has not received a request for coverage with accompanying information and no time frame applies (CMS 2007a). Since it is unlikely that a pharmacist can contact the beneficiary's physician and the physician can complete a prior authorization form while the beneficiary is waiting at the pharmacy, the beneficiary may have to pay for the drug out of pocket or leave without needed medication.

Part D plans currently must maintain a transition policy to provide temporary supplies of medications for new plan enrollees who are stabilized on drugs that are not on their plan's formulary or are subject to utilization management requirements. This policy requires plan sponsors to provide a temporary supply of the requested medicine and to send the enrollee written notice explaining when the supply will end and the procedures for requesting a coverage determination or exception. The transition supply is limited to a 30-day fill and is subject to the plan's general cost-sharing requirements.[5] However, the transition policy does not apply to overlap drugs that may be covered under Part B or Part D (CMS 2007a).

RECOMMENDATION 7B

The Congress should allow plans to cover a transitional supply of overlap drugs under Part D under the same conditions as the general transition policy applied by CMS.

RATIONALE 7B

If PDPs were able to apply the transition policy to overlap drugs while coverage is being determined, beneficiaries would not risk disruptions in their medical regimens. Physicians would have more time to meet prior authorization requirements to determine the coverage status of the prescribed drugs. Both pharmacy and pharmacy benefit management trade associations support this policy (PCMA/NACD 2006).

IMPLICATIONS 7B

Spending

- Negligible

Beneficiary and provider

- This recommendation would improve beneficiary access and reduce risk for pharmacists.

Vaccines and Part D

Physicians report that coverage of preventive vaccines under Part D is problematic for them. By statute, under Part B Medicare covers preventive vaccines for influenza, pneumonia, and hepatitis B for patients at high or intermediate risk. Medicare covers other vaccines under Part B if they are administered to treat an injury or direct exposure to a disease. For example, Part B covers rabies vaccine for beneficiaries bitten by animals. However, Medicare covers any other preventive vaccines under Part D. Currently, PDPs are paying for few preventive vaccines. Interviewees mentioned that the most likely new vaccine to be covered under Part D is a vaccine for shingles licensed by the FDA in 2006. However, if more vaccines become eligible for Part D, physicians are likely to have a problem billing plans. Like most Part B drugs, physicians purchase vaccines and provide them in their offices, but most have no direct way of billing PDPs.

Currently, CMS is seeking to clarify how plans intend to pay for vaccines under Part D. Plans would also have to develop a method to pay providers to administer the vaccines. To date, plans have suggested a variety of methods to pay for Part D-covered vaccines including:

- delivering vaccines directly to the physician's office,
- providing vaccines to network pharmacies,
- reimbursing patients after administration of the vaccine, and
- developing a web-based tool that allows physicians to submit claims electronically (Banner 2007).

These methods are largely untested. Recognizing this concern, the Academy of Managed Care Pharmacy notes that physicians do not have the appropriate information systems to bill under Part D (AMCP 2007). They endorse moving all vaccines to Part B.

If beneficiaries have to pay the full payment rate for vaccines and then seek reimbursement from their plans, physicians are concerned that the out-of-pocket cost will discourage beneficiaries from seeking preventive care when appropriate vaccines are available. Public health agencies—for example, the Centers for Disease Control and Prevention (CDC) and the National Vaccine Program Office in the Department of Health and Human Services (HHS)—share this concern. Beneficiaries without Part D coverage might also be unable to receive recommended vaccines unless they are able to pay the full payment rate.

Before implementation of Part D, Medicare covered preventive vaccines only if they were listed in statute. The Congress could simplify the process for coverage. For example, Medicare carriers could decide on coverage for preventive vaccines based on medical evidence as they do with other Part B services. Medicare payment for vaccines, like other Part B drugs, would be based on the average sales price methodology.

One source of information about Part B coverage for vaccines could be the recommendations of the Advisory Committee on Immunization Practices (ACIP), which consists of 15 experts in fields associated with immunization who have been selected by the Secretary of HHS to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the most effective means to prevent vaccine-preventable diseases. The Committee develops recommendations for the administration of preventive vaccines to the pediatric and adult populations, along with schedules regarding the appropriate time frame, dosage, and contraindications applicable to the vaccines. ACIP recommendations are currently used to determine vaccines covered under the Vaccines for Children program. ACIP could develop similar recommendations for the Medicare population. Medicare could use this source of information for help making coverage decisions.

Although this section relates only to preventive vaccines, beneficiaries might have better access to some other drug products under Part B than under Part D.[6] CMS is studying whether some drugs should be moved from one part of the program to the other. The Commission also will study potential cases in future work. Any significant shift of drugs from one part of the program to the other should consider the time needed for drug plans to take the changes into account before submitting their bids to CMS for the following year.

RECOMMENDATION 7C

The Congress should permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D.

RATIONALE 7C

Since physicians have no direct way to bill Part D plans, they face administrative barriers to providing appropriate preventive care to beneficiaries. Under Part B, physicians

would be able to administer new vaccines in their offices as they do current covered vaccines and beneficiaries would have more access to preventive care.

IMPLICATIONS 7C

Spending

- This recommendation would increase spending by less than $50 million for 1 year and by less than $1 billion over 5 years.

Beneficiary and provider

- This recommendation would improve beneficiary access to preventive care and reduce the administrative burden for physicians.

Delivering Part D benefits to residents of long-term care facilities

The overall fit between Part D and the nursing home pharmacy sector is a matter of debate. Some stakeholders characterize the Part D benefit as a better fit for community-based beneficiaries who fill prescriptions in retail pharmacies than for institutionalized beneficiaries because the latter often have cognitive as well as physical impairments. However, current law states that Medicare beneficiaries in nursing facilities (NFs) should have the same freedom as community-based beneficiaries to choose among Part D plans. Here we examine how the introduction of Part D is affecting pharmacy services for residents of NFs and other stakeholders. We also describe several approaches policymakers can consider for delivering Part D benefits in this care setting but do not offer recommendations.

Medicare beneficiaries in NFs

According to data from the Medicare Current Beneficiary Survey (MCBS), in 2003, about 5 percent of all beneficiaries lived in long-term care facilities.[7] This group is made up disproportionately of individuals age 85 or older (43 percent vs. 12 percent of the entire Medicare population), and they are much more likely to be widows or to have never married (only 14 percent remain married vs. 52 percent overall) (CMS 2006b). More than half of beneficiaries in long-term care facilities did not complete high school compared with 30 percent overall, and about half have incomes of $10,000 or less compared with 22 percent overall. Individuals who reside in NFs often are there because they are in a weak physical state with difficulty performing activities of daily living. About two-thirds of the institutionalized are also mentally or cognitively impaired (Table 7-1).

TABLE 7–1 **About two-thirds of institutionalized Medicare beneficiaries are mentally or cognitively impaired**

	Dual eligibles	Nondual eligibles	All
All institutionalized beneficiaries	56%	44%	100%
Percent who are mentally or cognitively impaired			
Aged	32	26	58
Disabled	8	1	10
Total	40	28	68

Note: Dual eligibles are individuals who receive both Medicare and Medicaid benefits. Mentally or cognitively impaired includes beneficiaries who have dementia, mental illness, or mental retardation. Sums may not add to totals due to rounding.

Source: MedPAC analysis of Cost and Use files, 1999–2001 Medicare Current Beneficiary Surveys.

The population of beneficiaries in long-term care facilities is made up disproportionately of individuals who are dually eligible for Medicare and Medicaid.[8] In 2003, 19 percent of duals lived in long-term care facilities compared with about 2 percent of nondual Medicare beneficiaries. More than half of all institutionalized Medicare beneficiaries are duals (Table 7-1). Definitions of institutionalization can vary, but this result corresponds roughly with other data. As of April 2007, data from CMS's On-line Survey, Certification, and Reporting system suggest that nearly 14 percent of residents at certified NFs were on a Medicare Part A stay, 65 percent were on a Medicaid stay, and the remaining 21 percent either had another source of coverage or paid out of pocket (CMS 2007b).

Providing prescription drugs to NF residents before and after Part D

The distribution system for drugs dispensed to residents of NFs is quite different from that for beneficiaries living in the community, and Part D has affected how providers operate. NFs and the LTCPs with which they contract have always had to interact with multiple insurers because residents with individual or employer-sponsored supplemental drug policies had coverage through different

companies. Nevertheless, overall LTCPs interacted more frequently with just one payer because so many NF residents had their drugs paid by a single state Medicaid agency. Previously, most state Medicaid programs paid NFs a daily rate to cover the room, board, and nursing care services of dually eligible residents and made separate fee-for-service payments to LTCPs for pharmacy services (Figure 7-1).[9] LTCPs were reimbursed directly by residents with third-party coverage and those who paid out of pocket.

Regulatory requirements and current market practices make it advantageous for many NFs to rely on a single LTCP for all pharmacy-related services (Lewin 2004). Nearly one-third of all states require NFs to let residents use a pharmacy of their own choosing, and some NF residents with retiree drug coverage or coverage through the Veterans Administration receive medications through mail-order pharmacies or other providers. Nevertheless, many NF providers cite efficiency, predictability, and standardization of dispensing practices as advantages of contracting with one vendor.

Federal and state laws and regulations have led to certain standards of practice for delivering pharmacy services in NFs. For example, the Omnibus Budget Reconciliation Act (OBRA) of 1987 and OBRA 1990 require each state's Survey and Certification Agency to verify that NFs accepting Medicaid funding meet conditions of participation, including reviewing drug regimens monthly, documenting and maintaining low medication error rates, and reducing unnecessary drug use (Leavitt 2005). States also regulate and license NFs and pharmacies (including institutional pharmacies such as LTCPs) and the professionals they employ.

NFs must obtain the services of a licensed pharmacist to provide mandated standards of pharmacy practice. While NFs do not necessarily need to use LTCPs for these services, most do. In addition to the services that retail pharmacies provide, LTCPs often:

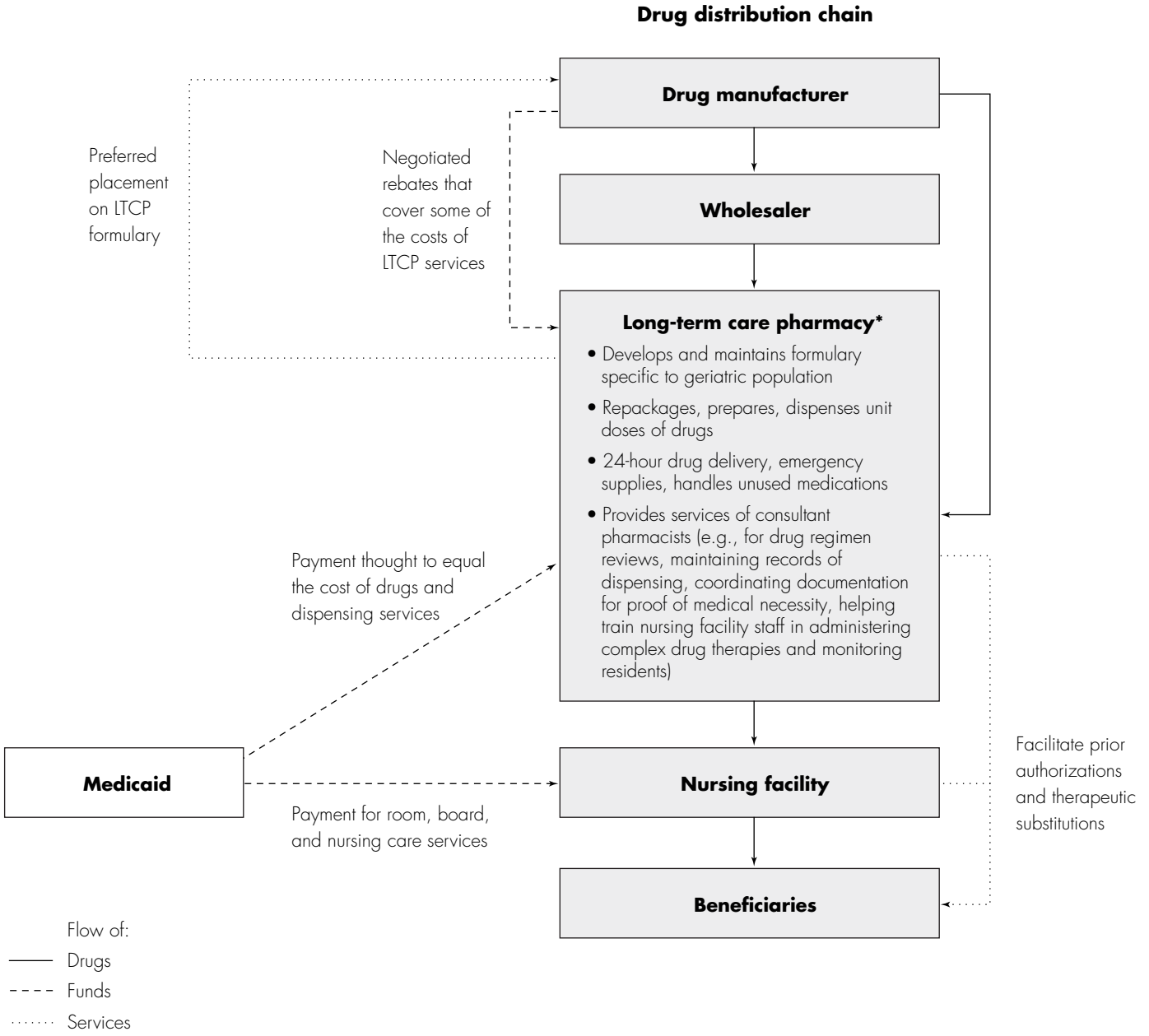
- develop and maintain an advisory formulary specific to the geriatric population;
- prepare and dispense unit doses of prescribed medicines, typically in blister packs, and provide medication carts with locked, nonremovable drawers for each resident's drugs;
- provide 24-hour drug delivery, provide emergency drug supplies, and handle unused medications;
- provide the services of consultant pharmacists who review residents' prescriptions prospectively, maintain records of drugs dispensed, coordinate documentation for prior authorization or proof of medical necessity, review drug regimens retrospectively, and help train facility nursing staff on how to administer certain complex therapies and monitor residents.

Prior to Part D, LTCPs provided many of these services for charges that were thought to approximate the cost of drug ingredients and dispensing. National chain LTCPs maintain their own formularies and are able to obtain rebates from pharmaceutical manufacturers in return for filling a certain volume of drug sales and for moving market share toward specific drugs. In turn, some analysts believe those rebates finance much of the cost of additional LTCP services such as drug regimen reviews. However, others believe that rebate revenues have led primarily to higher profits for some LTCPs than providers experience in other health sectors.

The nature of LTCP formularies differs somewhat from formularies that pharmacy benefit managers (PBMs) use. PBMs' formularies are continually updated lists of medications that a plan or payer will cover. A PBM covers all drugs listed on its formulary in some way; however, most formularies do not list all drugs and enrollees must pay out of pocket for drugs that are not listed. In addition, PBMs' formularies typically set different levels (tiers) of cost sharing or require that a particular condition is met before certain drugs or groups of drugs will be covered (MedPAC 2004). By comparison, LTCPs' formularies are more advisory in the sense that the pharmacy generally does not decline to cover prescriptions, except for limited circumstances. Under OBRA 1987, NFs must provide their residents with all needed care, including prescription drugs, whether or not the facility has identified a source of payment. Nursing home regulations also tend to focus on making sure that NFs provide the prescription to the correct resident in a timely manner. As a result, NFs pay close attention to the timeliness with which LTCPs deliver prescribed medicines rather than focusing on whether a drug should be covered. Nevertheless, LTCP formularies divide drugs into categories—for example, preferred, acceptable, or unacceptable. In the case of both LTCPs and PBMs, the designation of certain drugs as preferred or nonpreferred may reflect both clinical and economic factors.

One important issue to consider is whether the role of pharmacists in long-term care settings differs from that in community retail pharmacies. Some states require

FIGURE 7–1 **Before Part D: How prescription drugs were typically provided to dually eligible residents**



Note: LTCP (long-term care pharmacy). Dual eligibles are individuals who receive both Medicare and Medicaid benefits. Other nondual residents of long-term care facilities either paid out of pocket or used third-party drug coverage to reimburse the LTCP on a fee-for-service basis.
*Many of the services listed are required of nursing facilities under federal and state laws and regulations.

all types of pharmacies to substitute generic medicines automatically for brand-name drugs that have a generic available unless the physician explicitly asks for the brand-name drug. However, before making therapeutic substitutions—an alternative drug within the same therapeutic class but with a different molecular structure—pharmacists must first contact the prescribing physician for approval. Beneficiaries who live in the community and their pharmacists must get such approval from prescribing physicians to obtain coverage or pay lower copays under a PBM's formulary.

By contrast, in long-term care settings, consultant pharmacists review drug regimens monthly and can use that information to suggest therapeutic substitutions to the prescribing physician. Such suggestions may reflect clinical and safety concerns of the consultant pharmacist and may also reflect a drug's preferred status on the LTCP's formulary. In some states and under specific circumstances, consultant pharmacists can change a prescription without seeking the physician's approval.[10] Under current law, if a consultant pharmacist recommends changing a resident's prescription, the prescribing physician must consider that recommendation and respond to it (Lewin 2004). Some analysts believe that because most consultant pharmacists are employed directly by LTCPs, they may have the financial interests of the LTCP in mind when recommending therapeutic switches.[11] It is worth noting that a number of providers share responsibility for the quality and safety of drug use among NF residents, including prescribing physicians, LTCPs, and NFs.

LTCPs serve more than 80 percent of all nursing home beds nationwide (Stevenson et al. 2007). The LTCP market is highly concentrated, with the top three firms accounting for two-thirds of nursing home beds: Omnicare covers about 850,000 of the nation's 1.7 million beds (50 percent), PharMerica covers 220,000 (13 percent), and Kindred Pharmacy Services (KPS) covers 100,000 (6 percent). AmerisourceBergen and Kindred Healthcare, which own PharMerica and KPS, respectively, are in the process of spinning off those units to create a single firm. Smaller local or regional pharmacies (both retail and long-term care) serve the remaining one-third of nursing home beds. In the past, larger LTCPs had some important competitive advantages because they could negotiate large rebates from drug manufacturers. More recently, smaller LTCPs have turned to group purchasing organizations (GPOs), which give them greater bargaining power in negotiations. (GPOs bargain on behalf of member organizations that are smaller, thereby pooling their purchasing power.)

The introduction of Part D brought about a major shift in the financing of LTCP services. Previously, sources of nonrebate revenue for LTCPs mirrored the distribution of residents in NFs: 60 percent to 65 percent came from Medicaid, 10 percent to 15 percent came from Medicare Part A (for stays in skilled nursing facilities), and the remaining 20 percent to 24 percent was divided between private-pay residents and those with supplemental drug coverage (Lewin 2004). Most frequently, LTCPs were reimbursed on a fee-for-service basis. Now Medicare makes monthly payments to competing private plans that administer prescription drug benefits on behalf of the program, including for enrollees who reside in NFs (Figure 7-2). As of January 1, 2006, Medicare Part D replaced Medicaid as the primary source of drug coverage for full-benefit duals. Other residents may enroll in Part D plans if they choose. This means that LTCPs must now negotiate with numerous organizations that sponsor Part D plans to become part of each plan's pharmacy network. Part D plans are required to offer a contract to any pharmacy willing to participate in its LTCP network so long as the pharmacy is capable of meeting certain performance criteria, relevant state laws, and other contract terms. Many NFs continue to contract with a single LTCP, and the larger LTCPs have effectively negotiated contracts with all PDPs to join their pharmacy networks.

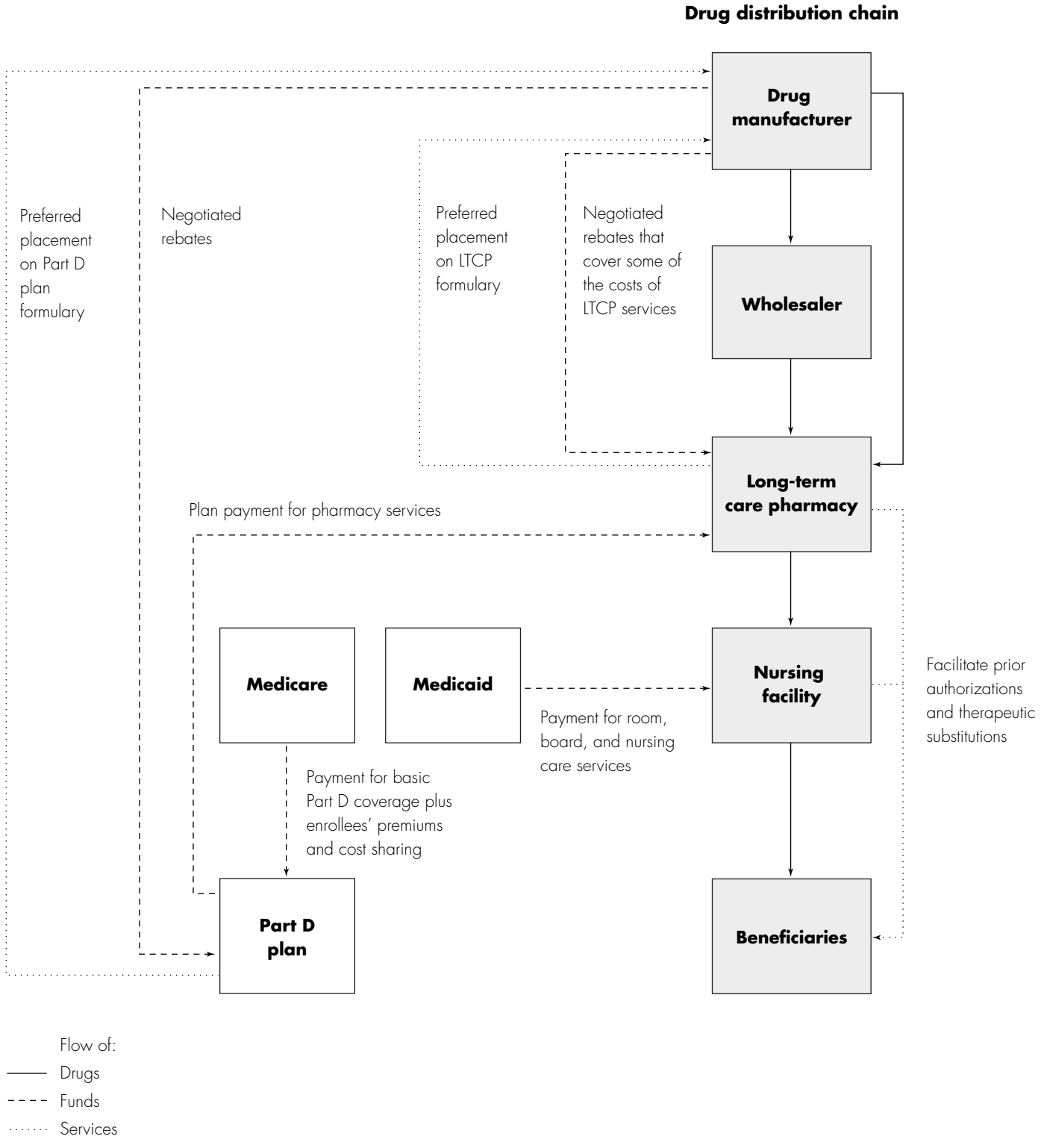
Now that Part D is in place, each facility's residents are enrolled among several different Part D plans with corresponding differences in formularies. Although the number will likely decline for 2008, during 2006, representatives of NFs and chains reported that residents were often enrolled in 6 to 10 or more plans (Stevenson et al. 2007).[12] CMS automatically assigned NF residents who are duals randomly among qualifying Part D plans prior to January 1, 2006 (the date their entitlement to drug coverage through Medicaid ended). Typically, duals are enrolled in a qualifying stand-alone PDP rather than an MA–PD because most duals are in fee-for-service Medicare.[13] NF residents who are not duals had until May 15, 2006, to select and enroll in a PDP. All Medicare beneficiaries who reside in NFs may switch to a different plan up to once per month. NF residents who are duals automatically qualify for Part D's low-income subsidy (LIS) program, which covers their monthly premiums if they are enrolled in a qualifying plan. Full-benefit dual eligibles who reside in NFs face no cost-sharing requirements. Otherwise, residents must pay premiums and cost sharing.

Throughout 2006, LTCPs maintained their own formularies, and stakeholder interviews suggest that LTCPs still receive rebates from drug manufacturers. These formularies and rebates are separate from those developed and negotiated by Part D plans with which LTCPs have contracts.

Findings from stakeholder interviews

MedPAC contracted with researchers at Harvard Medical School's Department of Health Care Policy to interview key stakeholders about how Part D is changing

FIGURE 7–2 **After Part D: How prescription drugs are typically provided to dually eligible residents**



Note: LTCP (long-term care pharmacy). Dual eligibles are individuals who receive both Medicare and Medicaid benefits. Other nondual residents of long-term care facilities may or may not choose to enroll in Part D plans.

the provision of drugs in NFs (Stevenson et al. 2007). They conducted 31 semistructured interviews between November 2006 and January 2007 with nursing homes and chain operators (6), LTCPs (6), GPOs/LTCP networks (2), Part D plans (4), financial analysts who cover the LTCP sector (3), physicians working in NFs (4), consultant pharmacists (2), state and federal policymakers (2), and advocates for nursing home residents (2). The researchers tried to select specific stakeholders to maximize representation of Medicare beneficiaries; for example, they tried to interview the larger nursing home chains, LTCPs, and PDPs.

The research team found that, by some accounts, the transition to Part D has been challenging in the long-term care sector. Part D brought about a substantial departure from how prescription drugs were previously financed and administered in NFs, and providers are struggling to adapt to some of these changes. At the same time, meeting the needs of NF residents and working with LTCPs are new challenges for most PDP sponsors as well. Interviewees identified a range of longer term issues that merit attention to ensure that Part D works well for residents of NFs. The Harvard team reported the following conclusions:

- The overall fit between Part D and the nursing home pharmacy sector is a matter of contention among the stakeholders interviewed. Many stakeholders characterized the Part D benefit as being a better fit for community-based beneficiaries who access medications in retail pharmacies than for institutionalized beneficiaries.
- Medicare beneficiaries in nursing homes have the same freedom to choose plans as community-based beneficiaries; however, stakeholder interviews highlighted sensitivities between ensuring this freedom of choice and allowing nursing home providers to encourage enrollment into plans they perceive to be a better fit with residents' medication needs and that minimize facility and pharmacy administrative burden.
- Part D increased the variation around formularies and drug management processes for residents at the facility level. In general, stakeholders described tension between cost-saving strategies PDPs used, such as prior authorization, and the burden these utilization management processes can place on clinical staff at NFs and pharmacy staff.
- Formulary coverage appears adequate for many medications used by NF residents, and the special protections required for six medication classes plus Part D transition coverage requirements helped to shield residents from coverage limitations. However, stakeholders noted what they consider to be important exceptions to overall formulary adequacy for the institutionalized population and instances when the application of utilization management policies was particularly problematic.
- Empirical analyses are needed to assess the impact of Part D on utilization patterns, outcomes, and quality of care. Noting this important caveat, stakeholders pointed to within-class drug utilization shifts but did not report a change in overall use of drugs. To date, stakeholders have not perceived any adverse impact on resident outcomes or quality of care attributable to Part D.
- Stakeholders indicated that Part D's financial impact on nursing homes is evolving. Part D altered the relationship between nursing homes and their LTCPs, introducing a tension between facilities' need to dispense medications quickly and LTCPs ensuring coverage for those drugs. Nursing homes and LTCPs have an incentive to minimize prescriptions for noncovered drugs, but how these entities will share the financial impacts of these costs depends on nursing home–LTCP contracting, which will likely continue to vary across providers.
- The impact of Part D on the future competitiveness of the LTCP sector is also evolving. Although the LTCP sector is concentrated, financial analysts with whom we spoke characterized the sector as very competitive overall, with few barriers to entry. The prominent role of GPOs and LTCP network organizations in particular has helped smaller LTCPs access more favorable pricing from manufacturers and PDPs so that most small LTCPs have joined these organizations.
- Consensus among stakeholders was that LTCP rebates—which currently continue—will likely decline in future years. CMS has not disallowed LTCP rebates under Part D, but it has expressed strong reservations about them, raising the possibility that they could constitute fraud and abuse.
- If LTCP rebates decline or disappear, these changes could lead to increased transparency of pricing

because LTCPs would need to unbundle their services and begin charging for services explicitly. Although reduced rebates would likely have a greater negative impact on larger LTCPs, these entities would still likely maintain certain economies of scale that might be advantageous in terms of service pricing, dispensing costs, and negotiating power.

- A reduction or elimination of rebates also could result in LTCPs passing increased administrative costs or a greater share of costs for items like consultant pharmacist services on to the nursing homes with which they contract.
- PDPs generally did not express reluctance to have institutionalized enrollees in their plans; however, there seemed to be a level of uncertainty among PDPs about the adequacy of payment and risk adjustment for this population as risk corridors widen. Reassessing the methodology of risk adjustment going forward and possibly making future refinements could be important to ensuring adequate availability of plans for dual-eligible beneficiaries.

Policy concerns related to pharmacy benefits for NF residents

The use of Part D's system of competing private plans in the long-term care sector has led to a number of concerns among stakeholders. Some predate Part D and relate to the appropriateness of drug use among residents. Others arose because Part D uses multiple competing plans.

Concerns about quality and appropriateness of drug use in NFs

Historically, NFs have struggled with appropriate prescribing and dispensing for residents (Stevenson et al. 2007). Individuals who reside in NFs take 6 to 10 drugs per day, which raises their risk for adverse drug events (ADEs)—a term that describes harm caused by the use of a drug or the inappropriate use of a drug (Nebeker et al. 2004). Recent research suggests that preventable ADEs remain a significant problem (Gurwitz et al. 2005). Reducing medication errors and ADEs has been a focus of past federal reforms, such as those in OBRA 1987 and OBRA 1990.

While NFs operate within a highly regulated environment, processes for referring noncompliant facilities and enforcing standards do not always work well (OIG 2005). With respect to residents' drug regimens, CMS officials recently raised strong concerns about the overuse of drugs and safety. For example, in a meeting with investment analysts, CMS officials noted that about half of all ADEs occur in long-term care settings, despite the presence of consultant pharmacists and procedures intended to limit medication errors (Stifel Nicolaus 2007). Underlying this comment is the view that past standards of practice among LTCPs may not have served NF residents well. At a separate investors' conference, officials argued that LTCPs "have a very strong incentive to promote the use of drugs for which they receive rebates" (Lueck 2006).

An important goal for policymakers should be that, in the midst of changes brought about by Part D, beneficiaries in NFs receive safe and appropriate drug therapies. Data on drug claims are not yet available to examine the degree to which Part D has affected residents' drug utilization, health outcomes, and quality of care. Stakeholder interviews suggest that they have seen shifts among drugs within specific classes—for example, therapeutic substitution of one cholesterol-lowering statin for another. To date, however, stakeholders do not report broad changes—increases or decreases—in gross utilization of drugs. Nor have stakeholders reported changes in quality of care as Part D has gotten under way. Researchers need to conduct empirical analyses to examine the issue more systematically.

The apparent lack of change thus far is likely due to protections for residents within current law, such as OBRA 1987, which obligates NFs to provide residents' prescribed medicines even when financing for such services has not been identified. Other protections are through CMS guidance that requires Part D plans to supply all or nearly all drugs in certain therapeutic classes and to provide transition supplies during the first 90 days of enrollment.

Although stakeholders dealt with requirements for prior authorization under state Medicaid before, physicians and some NFs characterized these as more challenging under Part D.[14] NF and LTCP interviewees highlighted access challenges under Part D for drugs to treat Alzheimer's disease, selected antibiotics, erythropoietin, and some alternative formulations of medicines such as injectables and inhalation therapies. Importantly, the clinical impact of plans' coverage limitations or prior authorization requirements depends on a number of factors, including the prevalence of a drug's use, available alternatives, and the efficacy and safety of specific medications. For instance, limited access to therapies widely used among NF residents could affect the clinical quality of care. Alternatively, if a drug is seldom used because clinically

superior alternatives are available, a plan's coverage limitations may be appropriate.

Policymakers need to monitor closely the quality and appropriateness of prescription drug use among NF residents as the relationship among NFs, LTCPs, and Part D plans evolves. A few independent organizations such as the Pharmacy Quality Alliance are working to develop quality measures specific to long-term care settings. CMS has begun measuring certain aspects of quality for Part D plans, but initially the agency's efforts focused on measures such as call center performance, complaint rates, and generic dispensing rates rather than on measures of drug safety, polypharmacy, and the appropriateness of prescribing.

Concerns about directing residents into specific Part D plans

CMS guidance restricts providers who serve NF residents (the NFs themselves, physicians, and pharmacies) in the information they give residents about particular plans. Providers may give objective information to residents, including how well drug plans cover medications of interest, but they are restricted from directing residents to a smaller number of plans and from distributing information that could be construed as having that aim (CMS 2006c). This guidance was designed to limit conflicts of interest—for example, by keeping NFs from steering residents into plans solely out of concern for the facility's administrative ease or to retain a past working relationship.

At the same time, cognitive impairment among so many NF residents complicates the issue of plan selection. Some stakeholders believe that the marketing guidelines undercut an advisory role that many residents and families want providers to play. Along those lines, the Washington Legal Foundation filed suit against CMS, arguing that the guidelines violate the first amendment rights of NF providers (WLF 2006). Formularies of Part D plans vary a great deal, and CMS's random assignment process may have placed some NF residents in plans that typically do not cover the drugs that residents used (Long Term Care Pharmacy Alliance 2007, OIG 2006).

On the other hand, some NFs strongly support CMS's marketing guidelines because of concerns about undue pressure from large LTCPs to take actions that may not be in either the resident's or a facility's best interest. Not all NFs want such a responsibility—some are reluctant to assume liability for recommending a particular plan. Some NFs turned to outside assistance: Workers from State Health Insurance Assistance Programs (SHIPs) helped residents use CMS's Part D Plan Finder tool at www.medicare.gov to select among plans based on their current mix of prescribed drugs. Although SHIP resources are often limited, this approach is one way to provide residents with unbiased help in choosing a plan.

Stakeholders report that the existence of multiple Part D plans has increased the workload for NFs. One reason is that NFs must now educate residents and family members about their choices of Part D plans. This task was especially burdensome during 2006, the year Part D began, and the challenge associated with such education may diminish. An ongoing challenge is that NFs often have residents enrolled in several different Part D plans, and staff (with the help of their LTCPs) must navigate each plan's utilization management techniques. For example, to meet prior authorization requirements or initiate grievances and appeals procedures, NF staff may need to provide supporting documentation from residents' medical records on the clinical reasons why the prescribing physician prefers a specific drug. This task can be a logistical challenge when the prescribing physician is not on site—in other words, the drug order is written by a physician in a community practice rather than by the facility's staff or medical director. Under these circumstances, NF staff or the LTCP must contact the prescribing physician's office to initiate the process. Although CMS requires plans to accept standardized forms for prior authorization, providers report that some Part D plans continue to require their own forms.

Stakeholders describe this increased burden as sizable, but its costs are difficult to quantify. Interviewees from NFs report that so far they have largely handled higher administrative burden with current staff. However, at least for some NFs, financial constraints kept them from increasing staff levels to address the workload, and staff were reportedly stretched thin.

Concerns about how to manage relations between PDPs and LTCPs

In guidance to plans for 2007, CMS requires LTCPs to begin reporting rebate information to the Part D plans with which they contract and, in turn, to CMS (CMS 2006d). Under current law, Part D plans rather than LTCPs are expected to create and maintain formularies. Yet, in practice, LTCP formularies and consultant pharmacists

still influence NF prescribing practices. Agency officials have voiced concern about continuing rebates directly to LTCPs because, from their point of view, it could lead to higher Medicare program spending. This could occur if an LTCP is steering residents toward higher cost drugs for which they receive higher rebates, particularly if the LTCP's formulary placement is at odds with that of the Part D plan's formulary.

Disclosing rebates could change the way LTCPs do business. Rebate information is highly proprietary, and we do not know the magnitude of those revenues. However, given that LTCPs have the capacity to achieve significant formulary compliance, it is reasonable to assume that rebates have been sizable (Lueck 2006). If manufacturers begin to reduce or eliminate rebates, LTCPs may need to begin charging explicit fees for services such as drug regimen reviews.[15] In turn, this could have implications for other payers such as Medicaid.

CMS's guidance to plan sponsors and LTCPs regarding rebates raises the broader issue of the overall fit between Part D and the nursing home pharmacy sector. A specific question is whether the program's consumer choice approach will lead Part D plans to manage quality and costs well for the long-term care sector, including the potentially higher costs associated with separate rebates to LTCPs.

Ideally, Part D's competitive system should provide the incentive for plans to strike a balance between providing enrollees with access to appropriate and high-quality drug therapies while controlling drug spending. Under the program's approach, competing plans attract enrollees by offering formularies that cover many of the drugs they want at reasonable copayments and an attractive premium. Informed consumers should also look at the quality of plan services and the convenience of their pharmacy networks when selecting a plan. Medicare's payments to plans are based on plan bids and their relative popularity as measured by past enrollment. For dual eligibles who pay no premiums and minimal or no cost sharing, the program maintains competitive pressure by limiting the number of Part D plans that qualify to receive autoassigned enrollees to those with premiums at or below regional premium thresholds.

In the opinion of some stakeholders, several characteristics of NF residents make Part D's approach a questionable fit. About two-thirds of NF residents have cognitive or mental impairments, and some do not have family members or legal representatives to help them choose among plan options or consider alternatives to assigned plans. NF residents who are eligible for full Medicaid benefits pay no cost sharing and thus are not concerned whether they are enrolled in a plan that covers the drugs they currently use on tiers with lower cost sharing. It is also unclear how much attention, on average, Part D plans pay to managing this population. Stakeholder interviews suggest that, while this share varies among plans, NF residents typically make up just 3 percent to 5 percent of total plan enrollment—roughly the same percentage as in the overall Medicare population.

On the other hand, plans may pay more attention to managing this population than enrollment levels might suggest. NF residents have higher average drug spending, and thus Part D plans have more incentive to manage their care. Since the advent of Part D, some plans have made strides in becoming more knowledgeable and attuned to the long-term care setting, both to manage their own risk and to work effectively in meeting the needs of their nursing home enrollees. In addition, CMS adjusts monthly payments to plans for the higher average spending of institutionalized enrollees to provide an incentive for plans to enroll these individuals. Plan representatives generally did not express reluctance to enroll NF residents. For the future, however, there is some uncertainty about the adequacy of payment and risk adjustment as Part D's risk corridors widen and plans bear a greater degree of insurance risk.

Alternative approaches for providing drug benefits to residents

For the future, policymakers may want to consider whether Part D's consumer choice approach is most appropriate for Medicare beneficiaries who reside in nursing homes. Would other approaches better serve this population? When evaluating options, decision makers should consider whether policy alternatives address the following goals:

- less complexity of plan choice for long-term care residents and their legal representatives;
- close attention to the appropriateness of drug therapies provided to each resident to improve patient safety and reduce ADEs;
- timely access to appropriate drug therapies;

- reasonable administrative burden for carrying out requirements for prior authorization, exceptions, grievances, and appeals; and
- incentives for controlling drug spending.

What follows is a discussion of alternative delivery approaches. The Commission does not have recommendations on these issues. How the program evolves for beneficiaries and providers may influence whether these options make sense as alternatives to the existing structure.

Continue with multiple Part D plans

One alternative is to keep today's approach of using multiple PDPs to deliver pharmacy benefits in NFs. Since general enrollment in Part D is concentrated among relatively few plans, the number of plans available could decline. If plans with relatively few enrollees decide to exit the market, enrollment could become even more concentrated and there would likely be fewer plans with premiums at or below regional benchmarks for LISs. CMS has also announced certain policies for 2008 that will reduce the number of plans that qualify for autoassigned enrollees. In its notification of changes in Part D payments for 2008, the agency stated that Medicare will transition to enrollment-weighted averages for calculating monthly plan payments and regional low-income premium subsidy thresholds (CMS 2007c).[16] CMS will also lower its de minimus policy from $2 to $1—the monthly dollar amount by which a plan's premiums may surpass its regional low-income premium threshold before the plan is no longer premium-free to beneficiaries who receive Part D's LIS. Moreover, Part D's risk corridors are scheduled to widen in 2008 and beyond. Widened risk corridors mean that plan sponsors will bear relatively more insurance risk for the drug spending of their enrollees than they do today.

Fewer Part D plans would make choosing a plan less complex for residents and their representatives and would also reduce administrative burden for NFs and LTCPs. PDPs would gain experience at managing pharmacy benefits within long-term care settings and might become more attuned to the needs of this population. (The Commission is also exploring the pros and cons of autoassigning LIS beneficiaries into Part D plans based on the current mix of drugs they use—an approach that could be applied to the long-term care population.)

On the other hand, it is unclear how the relationship between PDPs and LTCPs will evolve and to what extent the incentives of those providers for controlling drug spending will align. Most PDPs are relatively inexperienced at providing benefits in long-term care settings, and plans use LTCPs to deliver benefits to comparatively few enrollees. Given the degree of concentration in the LTCP market, the largest providers retain considerable market power in their negotiations with PDPs.

Given the agency's concerns about ADEs and the overuse of drugs, CMS might want to consider requiring Part D plans to report specific quality data based on drug claims for their institutionalized enrollees. However, when discussing the quality of pharmacy services to NF enrollees, one central issue is the extent to which stand-alone PDPs, which manage only pharmacy benefits, should be held accountable for prescribing behavior. Policymakers may want to share responsibilities for quality reporting between Part D plans, which have more detailed information about individual drug claims, and NFs, which have access to the residents' medical history and may have more influence with providers about their prescribing behavior. Ideally, one would include physicians among the group responsible for such quality reporting as well. Policymakers may want to also ensure that CMS monitors Part D plans for compliance with provisions for patient protection.

Another approach toward improving and monitoring quality for NF residents could involve the medication therapy management programs (MTMPs) of Part D plans. The law requires each plan to administer an MTMP in cooperation with pharmacists and other providers, with the goals of improving therapeutic outcomes for targeted beneficiaries and reducing the risk of ADEs. Part D plans submit proposals to CMS for how their individual MTMP will operate. Current CMS guidance defines targeted beneficiaries as a Part D plan's enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and (for 2007) are likely to incur annual covered drug costs of $4,000 or more. Although many NF residents probably fit these criteria already, policymakers might want to consider requiring Part D plans to enroll all residents in plans' MTMPs. CMS may also need to make MTMPs somewhat more uniform than they are today; for example, not all currently review drug regimens (Touchette et al. 2007). However, a key legal question to investigate before using MTMPs in this manner is whether Part D payments to LTCPs for drug regimen reviews

would duplicate services required under NFs' conditions of participation for Medicaid and whether that would constitute an impermissible double payment.

Hold periodic competitions to select regional PDPs for NFs

Under a different approach, CMS would hold competitions periodically to select a PDP that would become the sole plan for all NF residents within a given PDP region (Frank and Newhouse 2007). This option would reduce complexity for residents, NFs, and LTCPs by virtue of using a single plan rather than multiple plans.

An open question is how well this approach would address CMS's concerns about patient safety, quality, and appropriateness of drug therapies. Arguably, if a PDP's sole focus is to deliver benefits to NF residents, that plan can devote greater attention to concerns about quality and safety. However, to promote quality improvement, policymakers may want to make a portion of payment and future contract awards conditional on attainment of certain performance goals.

Medicare could continue to pay the regional PDP the same way it pays other Part D plans; alternatively, the program could pay on a fee-for-service basis. Under the current approach, Medicare pays plans a monthly amount based on the nationwide average bid to provide basic Part D benefits.[17] This approach means that Part D plans bear some insurance risk for the drug spending of their enrollees, which, in turn, gives plans an incentive to control drug spending. One risk of using a single regional PDP is that only smaller or more specialized organizations may choose to bid for such contracts. Since NF residents tend to use many prescription drugs, smaller sponsoring organizations would probably have a combined pool of Part D enrollees with relatively high drug spending. This could lead to higher premiums for long-term care plans and, since Medicare pays the Part D premiums for many NF residents, potentially higher Medicare program spending. Using a single regional PDP for NFs would avoid any problems stemming from incentives among multiple plans to enroll relatively less costly NF residents or to avoid this population altogether. Paying a regional PDP on a fee-for-service basis would probably address concerns about timely access to residents' medications, but it would not create incentives to control drug spending or to examine patterns of drug use more closely.

If CMS pursued this approach, the agency may want to consider limiting the number of regions in which any one sponsoring organization could operate a long-term care PDP. By limiting sponsors to a few geographic regions, CMS could keep several organizations providing services in this market. A credible threat of losing the next period's regional contract to another sponsor would provide plans with a greater incentive to keep an eye on the cost and quality of their services.

To keep all sponsors of long-term care PDPs interested in this specific market, CMS would need to verify periodically that risk adjusters the agency uses to pay for the higher cost of institutionalized enrollees are accurate. This point may be especially relevant for 2008 and beyond as Part D's risk corridors widen. CMS would also want to consider explicitly requiring MTMPs for these long-term care PDPs as well as public reporting of quality measures.

Reimburse LTCPs directly for delivering Part D benefits

Under a third approach, Medicare could reimburse LTCPs directly for drugs delivered to residents who are Part D enrollees. This option would eliminate complexity for residents because they would no longer need to select a plan. It would also reduce the administrative burden for LTCPs, NFs, and prescribing providers. The incentives for how closely LTCPs monitor drug spending and the safety and appropriateness of drugs dispensed would depend on how policymakers structure reimbursements—on a fee-for-service basis or with risk-based payments.

Paying LTCPs on a fee-for-service basis would establish a system similar to what those providers experienced when Medicaid was the primary payer for the pharmacy benefits of dually eligible NF residents. This approach is also similar to the idea of a "fallback" plan—a provision in current law for situations in which no plan sponsor is willing to bear insurance risk. (To date, CMS has not needed to operationalize the law's fallback provision.) Unless coupled with strong pay-for-performance provisions, fee-for-service payments would provide no incentive to manage residents' drug spending; indeed, the incentive would be to increase utilization.

By comparison, requiring LTCPs to bear some insurance risk would provide strong incentives for cost control and, particularly if coupled with performance measures and formulary reviews, for examining concerns about safety and overuse. Policymakers may want to give LTCPs the

Evaluating Part D

Before the start of Part D, the Commission discussed how policymakers would need to monitor implementation of the new drug benefit to evaluate plan performance and to measure how well the program meets cost, quality, and access objectives (MedPAC 2005). In 2005, MedPAC staff convened a panel of experts to discuss performance measures and to identify ways policymakers could use measures to monitor the Part D program over time. The panelists represented health plans, pharmacy benefit management companies, employers, pharmacies, consumers, quality assurance organizations, and researchers. Panelists discussed several areas of performance that purchasers often use when selecting and monitoring health plans or pharmacy benefit management companies. Table 7-2 lists these areas of performance as well as examples of more specific measures in each area. ■

(continued next page)

same incentives to manage residents' drug use as Part D plans face today: risk-based payments to ensure attention to cost control, coupled with individual reinsurance and risk corridors to mitigate incentives to stint on benefits. This approach would also likely change the relationship between NFs and LTCPs more than it has already changed under Part D. Specifically, NFs would continue to be most concerned with timely access to drug therapies for their residents, while LTCPs would face stronger incentives to consider prescription costs before dispensing.

Requiring LTCPs to bear insurance risk raises practical problems. For example, LTCPs would likely need to partner with insurers to meet state licensing requirements for risk-bearing entities. Pharmacies would need to develop information systems for verifying eligibility, enrolling and disenrolling residents in their plan, bidding, collecting premiums and cost sharing, and adhering to CMS's reporting requirements. Given stronger incentives for controlling drug spending, LTCPs might also apply utilization management tools such as prior authorization to a much greater degree than they do currently as well as administer processes for formulary exceptions, grievances, and appeals. Each of these new functions could raise costs, and it is not clear how well smaller LTCPs could take on these roles and compete with the larger ones.

Directions for future research

The Commission intends to continue monitoring the two topics discussed in this chapter—overlapping coverage of drugs under Part B and Part D and delivery of Part D benefits for residents of long-term care facilities. A unifying theme between the two topics is the need for performance measures to help watch for any problems that arise. For example, if overlapping Medicare drug coverage is leading to problems with beneficiaries' access to needed medications because of prior authorization requirements in certain plans, performance measures that capture wait time until dispensing or timeliness of handling requests for prior authorization presumably would reflect these difficulties. Likewise, monitoring performance measures such as ADEs for enrollees who reside in long-term care facilities might shed light on whether Part D's approach is addressing long-standing concerns about the safety and appropriateness of drug therapies for this population.

CMS has taken initial steps to measure the performance of Part D plans using metrics such as call-center wait times, complaint rates, and generic dispensing rates. However, the agency has considerably more work to do before measuring other important facets of pharmacy benefits (see text box).

The Commission urges CMS to capture more dimensions of Part D plan operations in its performance measures and make those measures available publicly in a timely manner. Part D's approach to delivering drug benefits provides consumers with a broad choice among private plans. However, for that approach to work well, beneficiaries need to be able to distinguish among plans by the characteristics they think are most important. Today, the Medicare Prescription Drug Plan Finder tool available at www.medicare.gov provides considerably more information about plans' premiums, cost-sharing requirements, and formularies than it does about important factors related to plan quality.

TABLE 7–2 Examples of performance measures for evaluating drug benefit management

Measurement area	Example
Cost control	
Plans' drug spending	Average drug spending per member per month (risk-adjusted)
Out-of-pocket drug spending	Average annual out-of-pocket spending on covered drugs (risk-adjusted)
Pharmacy discounts on drugs	Average rate of discount on brand and generic drugs
Pharmacy dispensing fees	Dispensing fees for brand and generic drugs
Manufacturer rebates	Total aggregated rebates as a percent of total drug spending, annually
Drug utilization	Average number of prescriptions per member per year, by therapeutic category
Generic use	Ratio of generic drugs to total drugs that have an available generic
Formulary adherence	Ratio of preferred to nonpreferred brand-name drugs covered
Access and quality assurance	
Pharmacy network	Ratio of preferred network pharmacies to all pharmacies in service area
Enrollee refill adherence	Percentage of members who refill chronic medications
Formulary review process	Average time P&T committee takes for initial review of new drug
Prior authorization and nonformulary exceptions	Average time for plan decision on prior authorization request
Appeals process and rates	Percentage of appeals that are overturned
Point-of-sale electronic messaging to pharmacists	Frequency of updates to clinical safety messaging software
Utilization of drugs contraindicated for the elderly	Percentage of drugs contraindicated for the elderly on prior authorization
Adverse drug interactions, events	Number of adverse drug interactions and/or adverse drug events per 1,000 members
Drug utilization review	Presence of screening to identify drugs filled beyond maximum therapeutic duration
Electronic prescribing use	Percentage of prescriptions submitted through e-prescribing per year
Benefit administration and management	
Claims processing	Percentage of claims processed accurately per year
Eligibility determination	Percentage of claims processed for ineligible individuals per year
Data management for coordination of benefits	Accuracy of benefit-spending calculations
Enrollee satisfaction	
Enrollee survey results	Member satisfaction rates
Call-center availability	Hours per day the call center is open
Call-center response times	Abandonment rates (percentage of time caller hangs up while on hold)
Grievance reporting	Average number of complaints reported per 100 members per year
Plan retention and disenrollment	Percentage of enrollees who voluntarily disenrolled

Note: P&T (pharmacy and therapeutics). The measures included in the second column are examples meant for illustrative purposes. Drug benefit purchasers (e.g., employers) may use many other more detailed measures to assess health plan or pharmacy benefit manager performance. In some cases, results from these measures can be interpreted differently, depending on other plan variables.

The Commission and other stakeholders also need more performance measures to evaluate how well Part D plans are complying with CMS's procedures and guidelines. The agency carried out the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implemented the Part D program admirably within very tight time constraints. Understandably, much of CMS's attention focused on attracting private plans to this new market, creating bidding processes and payment systems for those plans, and enrolling beneficiaries into the program. However, now that Part D plans are more established, policymakers may want to turn their attention to ensuring that CMS enforces the rules it created for the program, such as making sure that plans keep to the agency's timelines for reviewing requests for prior authorization, exceptions, and appeals. ■

Endnotes

1 Plans use prior authorization for many purposes, such as to prevent the overuse of certain high-cost medications. For additional information see MedPAC's June 2005 report to the Congress (MedPAC 2005).

2 Pharmacists do not bill separately for medication provided to patients in Medicare-covered stays in skilled nursing facilities.

3 Carriers are private organizations that contract with CMS to make coverage and payment decisions for items provided by physicians and suppliers.

4 Ultimately, plans have the final decision over what information to accept for coverage determinations.

5 In long-term care settings, plans must provide a 90-day supply of medication. They also must provide an emergency supply of a new prescription outside the transition policy.

6 Interviewees representing home infusion therapy companies and some specialty pharmacies also said they found it easier to obtain coverage for their patients under Part B. PDPs cannot cover the supplies, equipment, and nursing services necessary to administer some therapies. Under Part B, physicians are not limited by a formulary when they choose a drug for their patient.

7 Definitions of long-term care facilities vary. The MCBS (from which the 5 percent estimate was taken) includes facilities that have three or more long-term care beds and provide either personal care services to residents, continuous supervision of residents, or long-term care services throughout the facility or in a separately identifiable unit. Types of facilities include licensed nursing homes, skilled nursing homes, intermediate care facilities, retirement homes, domiciliary or personal care facilities, distinct long-term care units in a hospital complex, mental health facilities and centers, assisted and foster care homes, and institutions for the developmentally retarded and developmentally disabled.

8 See Chapter 3 of MedPAC's June 2004 report to the Congress for an analysis of the characteristics of all dual eligibles (MedPAC 2004).

9 By contrast, a few states such as New York bundle payment for most drugs with that for daily care. NFs must then reimburse LTCPs for their services. Likewise, Medicare bundles reimbursement for drugs provided during a covered stay in a skilled nursing facility within a broader prospective per diem rate.

10 Some states have collaborative practice agreements that permit the pharmacist to change prescriptions for a predetermined list of drugs. These agreements are between the pharmacist and the physician (Lewin 2004).

11 In 2006, one large LTCP reached a settlement agreement with 42 states and the federal government in a dispute over dosage switches for three drugs. In a separate settlement agreement, the same LTCP agreed to pay the state of Michigan over accusations of Medicaid overbilling. The company admitted no wrongdoing in either settlement (Lueck 2006).

12 The number will likely decline for 2008 because CMS announced changes to payment policy that will reduce the number of plans with premiums at or below regional low-income premium thresholds. See a further discussion of this point on p. 176.

13 To qualify for autoassigned enrollees, Part D plans must have monthly premiums at or below regional threshold amounts. In 2006 and 2007, PDP regions had a median of 13 and 15 plans, respectively, that qualified for autoassigned enrollees.

14 See, for example, a recent survey of long-term care physicians by the American Medical Directors Association (AMDA 2006).

15 One alternative is for LTCPs to negotiate with Part D plans to be paid for drug regimen reviews through each plan's medication therapy management program (MTMP). To date, however, the services provided in MTMPs vary widely and not all provide regimen reviews (Touchette et al. 2007). NFs have a clearer regulatory requirement to review drug regimens of their residents under their conditions of participation for Medicaid than do the MTMPs of Part D plans. One important question is whether drug regimen review services provided under MTMPs would duplicate those reviews required for participation in Medicaid. In turn, this would have implications for whether such arrangements constitute a double payment to the LTCP.

16 See Chapter 4 of MedPAC's March 2007 report to the Congress for a discussion of how enrollment weighting influences Medicare's payments to plans and enrollee premiums in Part D (MedPAC 2007b).

17 Plans also receive federal individual reinsurance subsidies that cover much of the cost of benefits for enrollees above a high threshold of drug spending as well as risk corridor payments that limit each plan's aggregate losses or profits.

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