Data-Driven Drug Coverage
Harnessing Information for a Better Medicare Prescription Drug Program

Jack Hoadley, Ph.D.  December 2008
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Introduction

The Centers for Medicare and Medicaid Services, the agency that administers Medicare, is a significant source of hospital and physician data on a variety of important health policy and health care matters. CMS collects and disseminates data that allow researchers both in and out of government to study such questions as the effectiveness of different treatments, the impact of different payment incentives on the behavior of health care providers, and the morbidity and health status of an aging population.

Under the new Medicare Part D prescription drug program, however, such data are not always available. About 57 percent of all Medicare beneficiaries—roughly 25 million seniors—now are enrolled in either stand-alone privately operated drug plans, paid for through Part D, or private Medicare Advantage plans, under which beneficiaries receive all their health services, including drugs. The exclusive use of private plans to deliver the benefit represents a departure from the traditional government-operated Medicare program. As such, these plans are not required to produce the same level of data on quality and effectiveness of care available when Medicare pays directly for services.

Broadly speaking, we know that the creation of Part D has dramatically increased the number of seniors with prescription drug coverage. According to a recent survey, only 8 percent of seniors lacked drug coverage in 2006, compared with about one-third before the program began. But many basic questions about the effectiveness of Part D, which carries a $50 billion annual price tag, cannot be answered.

Seniors are expected to voluntarily enroll in one of more than 1,800 stand-alone plans or more than 2,000 Medicare Advantage plans that make up the Part D program. This system is premised on market competition and the ability of beneficiaries to choose smartly one of these plans and, if necessary, switch to a different plan that better serves their needs. To what extent are beneficiaries switching from one plan to another? And which plans are proving most effective? There currently are no data to assess plan switching, and only limited data to judge plan performance—which, if collected and disseminated, could inform plan choices. The benefits of market competition are constrained by the absence of such information.

About half of all beneficiaries qualify for Part D’s Low-Income Subsidy program and face virtually no out-of-pocket costs. These LIS beneficiaries, however, may encounter coverage instability when plans make changes in premiums and become ineligible to be
assigned low-income beneficiaries; this happened to about 2 million beneficiaries in 2007. There also is concern whether plans available to low-income beneficiaries are inferior to other plans, both in coverage and performance. What should be done to mitigate the impact of coverage instability? And are LIS beneficiaries receiving sub-par care? The ability to answer these questions is limited because CMS does not disseminate data on plan-level LIS enrollment or plan-reported performance measures.

Beneficiaries who do not qualify for the low-income subsidy pay more of the cost of their drugs out of pocket than do beneficiaries under the typical employer-sponsored drug benefit or the Department of Veterans Affairs. Part D plans also more frequently exclude drugs from their formularies. To what extent do higher drug costs cause seniors to skip prescribed drugs? There already is evidence this is happening. And are beneficiaries able to find alternatives or receive exceptions for excluded drugs? It is not known how many beneficiaries face significant cost-sharing burdens or whether drugs are systematically more expensive under specific plans—information necessary to determine cost sharing but which plans consider proprietary. Nor are there data available on how often prescriptions are delayed at the point of sale because of a drug’s off-formulary status, or other restrictions, and how often exceptions are granted in these cases.

On top of regular cost sharing, beneficiaries may face a coverage gap—the so-called “doughnut hole”—where they must pay the full cost of their drugs after an initial coverage period. In 2007, nearly 30 percent of stand-alone drug plans offered enhanced coverage in this doughnut hole, but fewer than 10 percent of beneficiaries enrolled in these plans. It is assumed that seniors sometimes go without drugs when they hit the coverage gap, but how widespread is this problem? Claims data that could help answer this question have not yet been made available to researchers, and information on plan parameters that indicate when beneficiaries can expect to face out-of-pocket expenses is presented in a way that makes research extremely difficult.

The ultimate goal of Part D, of course, is to improve the health of seniors. Greater access to drugs should reduce morbidity, extend life expectancy, and improve quality of life. But to what extent is this actually happening? Are prescribed drugs producing desired results?

Steps have been taken only recently to make available a database that draws together the experiences of the program’s millions of beneficiaries. This new opportunity should provide a powerful tool to learn more about the effective use of drugs. Not only can we better assess the effectiveness of particular drugs and their comparative effectiveness against similar drugs, but we can more precisely track adverse side effects, monitor the effects of using multiple drugs simultaneously, identify overuse of medications, and assess outcomes for subpopulations, including seniors as a whole, that are not normally tested in drug trials. Decisions about which drugs to monitor would no longer be the chief domain of the manufacturers.
By giving seniors access to effective drugs, it was further anticipated that there would be fewer emergency room and physician visits, producing cost savings for the Medicare program. It stands to reason, for example, that seniors with diabetes or hypertension will suffer fewer complications if effectively medicated. Yet are these expected cost savings actually being realized? When drug claims data are made available to researchers, it is essential that they be merged with claims data for other Medicare services, such as hospital care, so that researchers can explore cause-and-effect relationships associated with expanded access to drugs. At the same time, inappropriate drug use can be harmful. Are plans monitoring the safety of the drugs as well as the cost?

The Part D benefit is unique in its total reliance on competing private plans, the onus it places on seniors to voluntarily enroll and make smart choices about plans, its extensive low-income subsidy, and its incorporation of a substantial gap in coverage. These program innovations must be closely scrutinized—especially as Congress considers reforms to Part D—and seniors must have adequate information to choose plans that best suit their needs.

At the same time, significant controversies have arisen recently over the safety and efficacy of various new drugs. Federal authorities have struggled to make informed decisions on whether certain drugs should be removed from the market or whether strong warnings should be added to drug labels. Patients and physicians have been under pressure to decide whether the benefit offered by these drugs is outweighed by their risks. Observation of drugs prescribed under the Part D program could bring greater clarity to such treatment decisions.

Unfortunately, the data now collected and disseminated under Part D are inadequate to assess competently both program and plan performance or to evaluate the effectiveness of drugs prescribed. Given the stakes involved—the health of millions of seniors and tens of billions of dollars in annual expenditures—closing these data gaps should be a top priority.

This report describes data now collected and used under the Medicare Part D program, dissemination of this information to the public or for research purposes, and data gaps that should be addressed. The primary types of data discussed are:

- Enrollment data maintained by the Centers for Medicare and Medicaid Services
- Data describing the private drug plans that participate in Part D, including benefit designs, formularies, and other plan features
- Data on plan performance submitted quarterly to the Center for Medicare and Medicaid Services
- Claims data representing transactions between beneficiaries and drug plans

Expanding collection and dissemination of data in these areas, as recommended in this report, would help ensure seniors are receiving quality care at an affordable price. Policymakers could better evaluate the effects of market competition and beneficiary cost.
sharing with complete data on plan-level enrollment and plan parameters. Seniors could make smarter choices about which plans to enroll in with greater access to information on plan performance. And doctors could more effectively treat patients if claims data were used to evaluate the effectiveness of drugs prescribed under Medicare Part D.

This information can be made available largely, if not completely, through administrative action, with no legislation necessary. Thus, the new Obama administration has an opportunity to achieve a quick and significant health-care victory. This opportunity should not be passed up.
Data on enrollment in the part D program and part D plans

The Centers for Medicare and Medicaid Services, or CMS, collects and disseminates significant data on Part D enrollment, including numbers enrolled in each state and in each plan by both region and county. Nonetheless, data gaps remain that make it difficult to assess cost-sharing, coverage instability, and plan switching.

Data collected and used by government

For administrative purposes, CMS tracks enrollment of Medicare beneficiaries in the Part D program and in stand-alone drug plans or Medicare Advantage drug plans. It also tracks whether the beneficiary is eligible and enrolled for the low-income subsidy—those who receive this subsidy face neither high cost sharing nor the “doughnut hole” coverage gap—and whether LIS beneficiaries selected a plan or were enrolled through the random assignment process. CMS uses these data to make reinsurance payments to plans for high-cost beneficiaries and to determine eligibility for future assignment of LIS beneficiaries to plans. Beyond these operational functions, the data could be used to understand the impact of policies such as the coverage gap or random assignment.

Data collected on enrollment

- **Enrollment numbers.** CMS tracks beneficiaries enrolled in the Part D program as a whole and whether they are in stand-alone drug plans or Medicare Advantage drug plans.

- **Enrollment in the low-income subsidy.** CMS keeps data on whether a beneficiary is eligible for and enrolled in the low-income subsidy.

- **Low-income enrollment process.** CMS tracks whether beneficiaries of the low-income subsidy selected a plan or were enrolled through random assignment.
Data dissemination

CMS releases aggregate national and state enrollment totals after the close of the annual open season in a press release with accompanying data spreadsheets. These totals include the numbers enrolled for the LIS as well as overall Part D enrollment. In April 2008, the agency started releasing monthly enrollment data (but, as in previous years, the plan-level data are not broken down by LIS status). Such data are valuable for basic tracking of overall enrollment in Part D and answering the important question of how many Medicare beneficiaries remain without drug coverage. Considerable policy discussion has focused on the number of beneficiaries enrolled for the low-income subsidy compared to the number estimated to be eligible for that subsidy.

CMS sometimes has provided more detailed enrollment data to congressional oversight agencies such as the Government Accountability Office, but withheld that data from the public and outside researchers, including data on LIS enrollment and random assignment by plan. Over one-third of all Part D enrollees—and about half of those in stand-alone plans—are LIS enrollees, and the proportions are far higher (potentially over 90 percent) in the smaller set of plans for which LIS beneficiaries may enroll without paying a premium.

In a program design based on competition among private plans, enrollment data are important for examining which plans have higher market shares. Furthermore, they allow researchers to incorporate enrollment weighting into various analyses. Case in point: It is important to understand that although nearly 30 percent of stand-alone Medicare Part D plans offered enhanced coverage in the coverage gap in 2007, fewer than 10 percent of beneficiaries enrolled in these plans. At the same time, about half of all beneficiaries enrolled in stand-alone plans face no coverage gap in their benefit because they receive the low-income subsidy.

Enrollment data are also important for tracking variations from place to place. In mid-year 2006 and 2007, CMS released plan-level enrollment by region on its website. More detailed information by geographic areas was released for the first time in April 2008 and will apparently be released on a monthly basis. These data allow more extensive analysis of enrollment trends, for example, to identify differences in choices made by beneficiaries living in urban and rural areas.
Data gaps

Despite the availability of significant enrollment data, gaps remain. As discussed above, CMS does not publicly release LIS enrollment data by plan, which places limitations on analysis. It is not possible, for example, to calculate accurately the percentage of beneficiaries who face a deductible, because there is no way to separate out beneficiaries who are fully subsidized and therefore have no deductible.

The story is the same when analyzing the coverage gap or cost sharing. LIS beneficiaries face no coverage gap, unlike other beneficiaries, and far less cost-sharing—in 2008, they had maximum cost sharing of $5.60 while other beneficiaries have average copayments of $71 for a drug with non-preferred status on a plan’s formulary (and more when paying percentage coinsurance for a high-priced drug). Researchers, however, lack the ability to adjust for the differences between these two types of beneficiaries.

More detailed data also are needed to address some critical policy questions. Both CMS and Congress are currently addressing coverage instability experienced by low-income beneficiaries when there are changes in plan premiums or the regional benchmarks that determine which plans are eligible to be assigned LIS beneficiaries.

In April 2008, CMS published a final rule to change how it calculates the regional benchmarks that determine which plans may be assigned LIS beneficiaries. This change is designed to reduce the number of low-income beneficiaries that must be reassigned to new plans each year. But even with temporary transition rules in place, over 2 million beneficiaries were reassigned to new plans during the fall 2007 open enrollment season.

Other proposals have been advanced for a more beneficiary-centered approach to plan assignments. Attempts by the public to analyze the impact of these policies are limited, however, by the absence of data on how many LIS beneficiaries have been previously assigned to a given plan and how many opted on their own to select an alternative plan.
More broadly, because the Part D benefit is structured around market competition among private plans, a key question for researchers and policymakers is the degree to which beneficiaries switch enrollment from one plan to another in open enrollment periods. This sort of analysis would require enrollment data on how many people changed from one plan to another.

**Data gaps on enrollment**

- **Plan-level data for low-income enrollment.** CMS has provided Congress but withheld from the public detailed plan-level data, including numbers of low-income beneficiaries.

- **Beneficiaries facing out-of-pocket costs.** Because CMS does not provide data on LIS enrollment by plan, it is impossible to calculate accurately the number of beneficiaries who face a deductible, cost sharing, and the coverage gap.

- **Plan switching and reassignment.** There are insufficient data available to assess the extent that beneficiaries switch from one plan to another or the reassignment of LIS beneficiaries who face coverage instability.
Information on drug plan benefits

CMS regularly collects and disseminates information about plan premiums, benefit design, cost-sharing requirements, and plan formularies listing drugs covered. Information on drug prices, however, is considered proprietary and is not publicly shared. Nor is there a single repository for complete data on each plan’s coverage parameters. These data limitations make it difficult to determine the level of cost sharing borne by plan beneficiaries.

Data collected and used by government

Organizations submit bids each year to participate in Medicare Part D. CMS requires submission of extensive information as part of these bids. Key elements include the premium (together with accompanying information, such as the breakdown of the premium for the basic benefit and any enhanced benefit), the benefit design, and the formulary.

A plan that deviates from the standard benefit design of 25 percent coinsurance for all drugs, a deductible, and a coverage gap must indicate whether it has a deductible; the cost sharing amounts assigned to different coverage tiers, such as those for generic, preferred, and non-preferred drugs; the nature of any coverage in the coverage gap; and other specific provisions. The formulary includes a detailed listing of covered drugs enumerated at the level of National Drug Codes—the codes that correspond to each unique version of a drug. Plans must submit information on whether the drug is listed on the formulary, the tier and cost sharing that apply to that drug, and any utilization management restrictions that apply.

CMS reviews submitted information to ensure that the plan has a valid bid. The premium and benefit design for a basic benefit, for example, are reviewed to ensure that they are actuarially equivalent to the basic benefit built into the statute for Part D. The benefit design and the formulary are reviewed together to ensure that the plan’s design meets the statutory prohibition against discriminating among beneficiaries based on their medical status or health conditions.

The formulary is further reviewed to ensure that it passes a variety of tests from the statute and accompanying CMS guidance. Thus, for example, the formulary must include at least two drugs in each drug class and must include most or all drugs in certain protected classes, such as drugs for HIV/AIDS or mental health conditions. Similarly, if a plan uses
a specialty tier for coverage of certain high-cost drugs, such as injectibles, then the tier is reviewed for compliance with CMS guidance, such as whether its cost-sharing level is appropriate and whether it includes only drugs with a monthly cost of over $600.

During the review process, drug plan sponsors have an opportunity to make adjustments to their benefit designs and formularies. New, updated information may be submitted prior to the time when CMS formally signs contracts with these sponsors and then announces which plans have been accepted for the program each year. The premiums and most benefit design features may not be changed midyear, and plans have only limited leeway to make formulary changes during the year—particularly changes that make their formularies more generous or changes that result from decisions by the Food and Drug Administration to approve new drugs and generic entries or to pull a drug from the market or add a clinical warning to a particular drug.

Data collected on plan benefits

- **Premiums.** Plans report to CMS the monthly premiums that beneficiaries must pay, which average about $30 in 2008 (weighted by enrollment).

- **Benefit design.** Benefit design information indicates whether a plan has a deductible, cost-sharing requirements, and any coverage in the doughnut hole.

- **Formularies.** A plan’s formulary lists the drugs it covers, the tier and cost sharing that apply to such drugs, and any utilization management restrictions that apply.

Data dissemination

Much of the information submitted to CMS about plans’ benefits and formularies is made public at the time of each year’s open season for enrollment into plans for the following year. CMS places an array of descriptive information on the Plan Finder website available through Medicare.gov. The agency also releases a landscape file that provides summary information on premiums and benefit designs for all plans. The primary purpose of these files is to provide a common information base for beneficiaries and those who advise them during the annual open enrollment season. These data releases also constitute a comparative database for researchers and others who wish to study the market offerings as a whole.

During or soon after the annual open season, CMS also releases a set of public use files that include plan formularies and basic plan benefit information. These files, which are
updated on a monthly basis, include the formulary status of all drugs (from a reference
drug list specified by CMS) and information on tier placement and utilization manage-
ment restrictions of each listed drug. These files do not include price information, because
this information is considered proprietary by the plans.

The data made available on drug plans’ benefit designs and formularies constitute an
important source for researchers. These data have supported the examination of trends in
benefit features such as the declining availability of coverage for brand-name drugs in the
coverage gap (the doughnut hole), the growing use of special tiers for high-cost injectible
drugs, and rising annual premiums.11

Similarly, data on plan formularies have provided researchers opportunities to show that
some drugs are less frequently covered on plan formularies or are more often subject to uti-
lization management restrictions, such as requiring that plans approve certain prescriptions
before paying for them. In 2008, stand-alone drug plans vary considerably in the extensiv-
eness of their formularies and their use of restrictions. Plans offered nationwide list an average
of 85 percent of a set of 169 sample drugs. But while some plans list all drugs in the sample,
others are far less generous—one listed fewer than 70 percent of these drugs. Similarly, plans
on average place restrictions on nearly one-third of the sample drugs. But the 10 stand-alone
Medicare Part D plans with the most enrollment had restrictions on anywhere between 3
percent and 63 percent of the drugs they listed on formulary.12

Combined with plan-level enrollment data, these data on plan offerings allow researchers the
opportunity to study questions such as whether beneficiaries are more likely to select plans
with deductibles or plans with more drugs listed on their formularies. But analysis of these
questions is limited by the inability to separate out the LIS beneficiaries who were assigned
into plans and who face no deductible in their coverage. As a result, policymakers lack
knowledge to gauge the adequacy of the Part D basic benefit and assess whether seniors are
benefiting from the flexibility granted to plans to design specific benefit packages.

### Data disseminated on plan benefits

- **Plan Finder.** CMS regularly updates information about plan benefits and formularies on
  its Plan Finder website, available through Medicare.gov.

- **Summary files on plan premiums and benefit designs.** CMS annually releases a landscape
  file that provides summary information on premiums and benefit designs for all plans.

- **Monthly files on plan formularies.** On a monthly basis, CMS makes available a public
  use file on all plans, including the formulary status of all drugs, tier placement of each
  drug, and utilization management restrictions that apply.
Data gaps

Gaps in the data on plan benefits and formularies create challenges for researchers. The landscape files on plan benefits, for example, currently exclude certain parameters such as plans’ initial coverage limits (the level at which the coverage gap begins) and detailed information on cost-sharing levels and tier structures. These parameters can be obtained one plan at a time through the Medicare Plan Finder Web site, as well as on individual plan Web sites, but collecting data in this way is not easy.13

Like the plan benefit design data, the formulary files have gaps as well, most significantly the absence of price data. As noted above, plans consider price information proprietary, and thus CMS omits these data from public-use formulary files. Drug prices are posted on the Medicare Plan Finder Web site for use by beneficiaries in selecting plans. Although prices are displayed for all drugs, including prices at different stages of the benefit, prices are imputed in situations where the plan chooses not to supply an actual price.

The absence of price data means complete cost-sharing data are also unavailable. Although many plans use flat copayments for most drugs, about one-third of stand-alone drug plans use percentage coinsurance for most or all drugs, and most other plans use coinsurance for drugs on their specialty tiers. In these cases, beneficiary cost-sharing amounts cannot be determined from information on tier placement together with benefit design information.

Researchers can collect price data as well from the Plan Finder. This data collection is simple for a small set of drugs, and the Web site allows lists of up to 25 drugs to be entered and saved for future use. Some researchers and consulting firms have developed “web-crawler” programs to collect prices (and other formulary information) for large sets of drugs or even for the universe of eligible drugs. This situation requires increased resources for data collection and effectively limits data availability.

The combination of these data gaps significantly limits the range of policy questions that researchers can address. Without complete information on drug prices or beneficiary cost sharing, researchers cannot look at typical out-of-pocket costs for beneficiaries across plans, variations in drug pricing across plans with different market shares, or whether there is significant regional variation in drug pricing. These limitations inhibit a full understanding of how the Part D program is meeting beneficiaries’ prescription drug needs.

For the most part, these data gaps do not adversely affect the ability of consumers to choose plans, since the Medicare Plan Finder provides access to drug prices for the purpose of selecting a plan. But the gaps identified here limit researchers’ ability to develop tools that might improve on the Plan Finder and increase the resources available to beneficiary counselors.
Data gaps on plan benefits

- **Drug prices.** Part D plans consider drug prices proprietary and CMS excludes this information from the monthly public use files.

- **Cost sharing.** Because information on drug prices is lacking, it is not possible to calculate the level of cost sharing borne by beneficiaries for specific drugs.

- **Coverage parameters.** There is no single repository for data on each plan’s parameters, such as coverage limits, cost-sharing requirements, and tier structures.
Plan performance data

CMS collects quarterly plan performance reports and surveys beneficiaries to measure consumer satisfaction with each plan. This information is used to rate plans from one to five stars. CMS does not, however, collect adequate information related to exceptions and appeal outcomes when drugs are not covered by a plan’s formulary. Nor are there adequate measures to assess whether beneficiaries are correctly medicated and have access to effective care. Furthermore, most of these performance data are not disclosed to the public.

Data collected and used by government

The Medicare Payment Advisory Commission, or MedPAC, in its June 2005 report to Congress, highlighted the importance of monitoring implementation of the new drug benefit and “to measure how well Part D meets cost, quality, and access objectives for pharmaceutical care.”14 In particular, it focused on the need for developing measures and data for purposes of program evaluation in four areas: cost control; access and quality assurance; benefit administration and management; and enrollee satisfaction. At least some measurement on most of these dimensions is being accomplished already, but the data are not being widely disseminated.

Starting in the program’s first year, CMS required that plans report certain data, mostly on a quarterly basis.15 These reporting requirements are based on the general statutory requirement that each Part D sponsor be able to provide statistics on the cost of its operations; the patterns of utilization of its services; the availability, accessibility, and acceptability of its services; information demonstrating it has a fiscally sound operation; and other matters as required by CMS. In developing these requirements, CMS applied several criteria. Specifically, the requirements should impose a minimal administrative burden on the Part D sponsors and be based on clear legislative and regulatory authority. The agency also considered the validity, reliability, and utility of the requested data elements, as well as whether they have wide acceptance and current utilization within the industry.

Since the program’s inception, CMS has published revised reporting requirements for each subsequent contract year.16 Some changes reflected a response to plan concerns that the existing measures did not correctly capture the underlying information, while others reflected the agency’s attempt to capture more refined information or collect informa-
tion on topics that had become important over time. These modifications and additions represent a significant expansion of the performance measures collected from the plans. Appendix I on page 32 shows the measures plans were required to submit in 2006, and the changes to requirements implemented for 2007 and 2008.

In addition to the measures that plans are required to report, CMS uses its internal data systems to measure certain elements of plan performance. In particular, CMS is required by law to conduct consumer satisfaction surveys with beneficiaries enrolled in stand-alone drug plans, building on the existing Consumer Assessment of Health Providers and Systems surveys already conducted with enrollees in MA plans. The CAHPS surveys were initially conducted for drug plan enrollees in 2007, with an emphasis on compiling information about issues that may vary across plans (features such as formularies or customer service) as opposed to satisfaction with the overall benefit.

In addition to the CAHPS surveys, CMS collects and compiles some other measures on plans, such as delays in appeals decisions, the number of times the independent review entity (the organization designated by CMS to review reconsiderations of a plan sponsor’s decision) agrees with plan decisions, or the number of complaints received in various categories.

CMS reports that it uses performance measures internally for evaluating the performance of both individual plans and the program as a whole. In fact, the agency has indicated that plans with ratings of one or two stars (on a five-star scale, described in more detail in the “Dissemination” section beginning on page 16) can expect monitoring and compliance actions. After plans are given a reasonable opportunity to improve their performance, CMS may impose intermediate sanctions, such as suspension of marketing and enrollment activities, or even pursue contract termination.

For example, CMS has used the measure of how often the independent review entity agrees with plan decisions in appeals cases to identify plans that are outliers. The agency reviewed individual cases where these plans had their decisions overturned and identified the basis for the decisions. Using that information, CMS staff met with plans to discuss changes to their internal review processes. Overall, it remains too early to know whether the data being reported are adequate for these tasks. Outside of CMS, there has been little opportunity for evaluating these data because little public disclosure has occurred to date.

CMS further uses these data for reviewing the performance of individual plans when reviewing the plan applications for new contracts that are submitted each spring. CMS might look, for example, at whether a particular plan has experienced a significant number of disenrollments, grievances, or claims reversals as an indicator of problems with how the plan is operating. In some cases, the agency has particular benchmarks for plans to meet.
Some performance measures could also play a role in the review of whether a plan’s formulary and use of utilization management pass the statutory test of not discriminating against particular types of beneficiaries. If the plan’s rates of prior authorization or step edits or its rate of being reversed on appeal is significantly greater than other plans, then CMS might initiate a closer look at the plan’s formulary and other policies.

Similarly, measures of plans’ use of medication therapy management programs, which are supposed to better treat beneficiaries with multiple conditions, could be important in indicating whether these programs are attracting significant participation. If they are not, this information could be the basis for requiring changes.

CMS also views the aggregate plan performance data as one tool for evaluating the overall success of the Part D benefit—both for internal analysis and for evaluations that are made public. For instance, overall rates of performance on various call center measures were cited by the agency in 2006 as evidence that plans were meeting first-year expectations—and in particular, that performance had improved since problems surfaced during the first few months of operation, generating considerable attention by policymakers and the media.

Data collected on plan performance

- **Quarterly performance reports.** Each plan is required to submit a quarterly performance report that provides data on the quality of the plan’s services, the use of its services by beneficiaries, the costs of the plan’s operations, and its fiscal soundness.

- **Consumer satisfaction surveys.** The Centers for Medicare and Medicaid Services is required by law to conduct consumer satisfaction surveys with beneficiaries enrolled in stand-alone drug plans as well as Medicare Advantage plans.

Data dissemination

There are several potential roles for public release of the plan performance data. In addition to supplementing CMS oversight of plans and the program, external users of the data could undertake research projects aimed at increasing knowledge of the dynamics of prescription drug coverage.

It is unclear when or to what extent data will be made publicly available for these purposes. Although the agency has released some performances measures for plans, it has not released
the set of aggregate performance measures collected from plans on a quarterly basis. Nor
has CMS offered any clear policies on making these measures available publicly.17

There is considerable interest among beneficiaries and their advocates for more infor-
mation to aid the selection of plans during the annual open season. In particular, Consumers
Union has called for public release of the quarterly reporting data—with a specific empha-
sis on the plan-specific generic dispensing rates. This information could be used to create a
“report card” for each plan.18

Not all measures are suitable for this use, but some could be of considerable interest. In
particular, beneficiaries and their advisers could make more informed choices with infor-
mation on generic dispensing rates, rates of request and disposition for such measures as
exceptions or prior authorizations, and appeals outcomes.

CMS began to make performance measures available on the Plan Finder website during
the fall 2006 open enrollment season. None of the available measures in 2007 (or 2006),
however, are based on the plan-reported performance data (see the table below). All of

Medicare part D plan ratings
Plan ratings released on the Medicare.gov website November 2007

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<th>Plan rating</th>
<th>Data Source</th>
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<tr>
<td>Drug plan customer service</td>
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<tr>
<td>1. Time on hold when customer calls drug plan</td>
<td>CMS-sponsored survey</td>
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<tr>
<td>2. Calls disconnected when customer calls drug plan</td>
<td>CMS-sponsored survey</td>
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<tr>
<td>3. Time on hold when pharmacist calls drug plan</td>
<td>CMS-sponsored survey</td>
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<td>4. Calls disconnected when pharmacist calls drug plan</td>
<td>CMS-sponsored survey</td>
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<tr>
<td>5. Complaints about drug plan</td>
<td>CMS complaints tracking</td>
</tr>
<tr>
<td>6. How helpful is plan when you need information</td>
<td>CMS CAHPS survey</td>
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<tr>
<td>7. Overall rating of drug plan</td>
<td>CMS CAHPS survey</td>
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<th>Using your plan to get your prescriptions filled</th>
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<td>1. Getting prescriptions easily</td>
<td>CMS CAHPS survey</td>
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<tr>
<td>2. Pharmacists have up-to-date plan enrollment information</td>
<td>Internal CMS data</td>
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<tr>
<td>3. Pharmacists have up-to-date information on plan members who need extra help</td>
<td>Internal CMS data</td>
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<tr>
<td>4. Complaints about plan’s benefits and access to prescription drugs</td>
<td>CMS complaints tracking</td>
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<td>5. Complaints about enrollment and disenrollment</td>
<td>CMS complaints tracking</td>
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<td>6. Delays in appeals decisions</td>
<td>Internal CMS data</td>
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<td>7. Reviewing appeals decisions</td>
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<th>Drug pricing information</th>
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<td>1. Availability of drug coverage and cost information</td>
<td>Internal CMS data</td>
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<td>2. How often the plan’s drug prices change</td>
<td>Internal CMS data</td>
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<tr>
<td>3. Complaints about pricing and out-of-pocket costs</td>
<td>CMS complaints tracking</td>
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Note: CAHPS = Consumer Assessment of Health Providers and Systems survey.
Source: Medicare Plan Finder website.
These measures are based on data collected by CMS—perhaps to ensure that data are measured in a consistent way across all plans. The measures are based on either internal CMS tracking systems such as its Medicare Complaints Tracking Module, surveys conducted by CMS contractors of plan call centers, or the CAHPS survey.

Plans are assigned from one to five stars (one to three stars in 2006) on each rating factor, based on their performance. These stars are what consumers see first on the Plan Finder website. More complete numerical data are available by clicking to a separate screen, although it can be hard to notice this option. There are many potential issues surrounding this system of plan ratings, including whether stars are allocated in a way that effectively highlights the best and worst plans, whether the measures used capture elements of interest to the typical Medicare beneficiary or those who might help them make plan choices, or whether measures should be added to capture other important dimensions.

One challenge is the absence of obvious benchmarks for many of the measures. For example, a low number of appeals or exception requests might mean that drugs were available when beneficiaries needed them (a desirable outcome) or that beneficiaries were discouraged from filing appeals (an undesirable outcome). The absence of unambiguous benchmarks might be used as an argument to limit public release of the plan performance measures. But the full release of the data would allow the public to suggest approaches to establishing benchmarks.

Researchers, in particular, might use plan-level data to develop improved consumer report cards and look more deeply at numerous analytical questions. It would be possible, for example, to ask whether various formulary or benefit design features influence outcomes. This might answer whether different cost-sharing approaches increase the use of generic drugs, or how plan formularies and utilization management restrictions affect access to drugs, as measured by how many exceptions are requested and granted and how often prior authorization is used successfully. These analyses would be particularly useful to program managers and policymakers’ efforts to improve access to medications while controlling costs.

The Part D program would also benefit from research examining whether there is a relationship between premiums, enrollment, and performance measures—for example, whether the most expensive plans or the most popular plans stack up well in various performance dimensions. Many policy analysts and advocates have asked whether the plans available at no premium to low-income beneficiaries are less generous (for example, list fewer drugs on formulary or impose more restrictions) or perform more poorly than other plans. This critical question could be tested if performance measures were made available.

Researchers could also use aggregate data on plan performance to help policymakers assess Part D’s overall successes and failures. Of particular importance in this respect are data on beneficiaries’ satisfaction with their access to drugs, the frequency of filing complaints, the
proportion of times beneficiaries received a drug after the initial rejection of a claim, and
the degree to which requests for exceptions or appeals are successful. Some of this informa-
tion is available through the ratings on the Plan Finder, but release of more detailed data,
now used by CMS only internally, could facilitate deeper understanding of the program.

Data disseminated on plan performance

- **CMS-generated performance data.** CMS provides plan-level performance data gener-
  ated by its internal tracking systems and beneficiary surveys.

- **Ratings of plan performance.** CMS uses its performance data to rate plans from one to
  five stars on the Plan Finder website.

- **No quarterly performance data from plans.** CMS does not release plan-reported
  performance measures such as beneficiary requests for exceptions to obtain drugs not
  covered and appeals outcomes.

Data gaps

Although current requirements provide a substantial array of data to the agency, there are
additional measures that would be useful for tracking plan and program performance.21 A
broad set of performance measures should be available to both policymakers and researchers.
At the same time, the measures made available to consumers on the Medicare Plan Finder
need refinement. It is not clear that beneficiaries currently make much use of the existing
ratings. Consumers need measures that are simple and easy to understand; a smaller set of
well-chosen measures is probably better than a long list of measures.

A major gap is in the domain of quality of care. A number of promising quality measures
are under development at the National Committee for Quality Assurance, the Pharmacy
Quality Alliance, and elsewhere. Such measures have the potential to assess the efforts of
plans to ensure beneficiaries are taking the right medication—so that adverse interactions
between drugs are avoided, for example, and seniors take only drugs that are appropriate
for their age and particular health conditions.

In developing quality measures, care must be taken to consider which ones are appropriate
to stand-alone drug plans. These plans have no direct relationship to prescribing physi-
cians, though it may be reasonable for plans to communicate with prescribing physicians
about appropriate drug use. As new measures are developed and validated, they should be
added to the set of measures that CMS routinely collects and disseminates.
Data are also incomplete to assess medication therapy management programs, which plans are required to provide under Part D to treat beneficiaries with multiple chronic diseases who take multiple Part D-covered drugs. Plans must report the amount of participation in their programs and the volume of drugs involved (measured both in dollars and number of prescriptions). But there is no outcome measure to determine whether participating beneficiaries took fewer drugs as a result of their participation, for example, or whether they were satisfied with the help they received. In other cases, impact measures have already been added. In 2006, there were no outcome measures for grievances filed, but new measures were added to help fill this gap for 2007.

Access to care represents a domain where many measures are available, but many important issues are not being measured. This domain is critical for informing consumers about variations among plans—in particular whether plans contain barriers that might block access to needed drugs—and helping policymakers identify significant access barriers. Toward this end, there should be better measures of how plans use prior authorizations, grievances, and appeals. CMS should know whether these procedures are serving the needs of beneficiaries who need access to particular off-formulary drugs.

In January 2008, CMS proposed a new performance measure to require plans to report the number of prescriptions delayed at the point of sale. This proposal, however, was ultimately dropped from the final call letter inviting potential plan sponsors to submit bids for 2009. Such a measure would identify those cases where beneficiaries are blocked from getting their prescription because of a drug’s off-formulary status, a prior authorization requirement, or a quantity limit.

Should this measure be implemented in the future, it will be important to distinguish between delays that are due to actual barriers and not simply a beneficiary’s failure to pick up a prescription. Other related measures could look at changes made at point of sale or eventual disposition at point of sale, incorporating the outcome of the original transaction, such as whether the prior authorization was obtained or whether a successful request for an exception was filed.

Leaving aside particular data gaps, there is also a global problem with plan performance measures currently available on the Plan Finder: They are reported by organization, not by plan. Most organizations offer a variety of plans at different premium and benefit levels. For some measures, such as the performance of their call centers, an organization-level measure is probably appropriate since all plans offered by an organization probably share the same call center. But when measuring the frequency of appeals or the granting of exceptions, the organization’s plans are likely to differ—especially if certain plans have more limited formularies or place more restrictions on their listed drugs.

Aggregate measures reported by plans on a frequent basis can substitute in part for items that can also be measured with claims. While some such measures are currently collected,
additional measures could provide more information about the distribution of utilization and spending. These might include the volume of drugs dispensed at each tier level, specialty drugs dispensed, and off-formulary drugs (both the number of prescriptions and the dollar volume for each item). Ideally these measures could be reported in total and for each of several designated drug categories or classes. The extent to which beneficiaries use mail-order pharmacies (number of prescriptions and dollar volume) and non-network pharmacies (both emergency and non-emergency situations) would also be of value to researchers and policymakers.

Data gaps on plan performance

• **Quality of care.** There are inadequate measures to assess efforts to ensure beneficiaries are taking the right medication.

• **Medication therapy management programs.** There are inadequate measures to assess the effectiveness of medication therapy management programs in treating beneficiaries with multiple chronic diseases.

• **Access to care.** CMS does not collect data on prescriptions delayed at the point of sale and has inadequate measures on how plans handle prior authorizations, grievances, and appeals.

• **Plan-level measures.** The Plan Finder reports performance data by organization only and not by the individual plans offered by an organization, which may differ in their formularies and restrictions.
Prescription drug claims

CMS collects significant data on drug claims, including information identifying the parties involved in a claim, drug prices and quantity dispensed, and cost-sharing information. CMS took an important step forward with a recent rule allowing the release of claims data to federal agencies and outside researchers. CMS, however, is not releasing information that might reveal the identities of specific plans. This decision limits the availability of information to research key questions. Moreover, there are still only limited data available on the effectiveness of drugs prescribed under the Part D program.

Data collected and used by government

Many questions of interest to policymakers and researchers will require prescription drug claims (in agency parlance, prescription drug events, or PDEs) data from the Medicare Part D plans. Claims data are collected as part of routine operations for every transaction conducted at a retail or mail order pharmacy. Claims data are submitted by plans to CMS and have 37 separate data elements, including:

- Information to identify the patient, the prescriber, the pharmacy, and the plan
- Information on the prescription drug, including the NDC number, quantity dispensed, and day’s supply
- Drug price information, including ingredient cost and dispensing fee
- Cost-sharing information, including the amount paid by the plan, the amount charged to the beneficiary, whether the beneficiary is above or below the catastrophic threshold, and the amount of any applicable low-income subsidy payment

Both operational and research offices within CMS use these data on a limited basis for various payment purposes. For instance, claims are the basis for the government’s reinsurance payments to a plan for catastrophic-level expenses—above $4,050 in beneficiary out-of-pocket costs, the government pays (reinsures) 80 percent of the cost of the claim. CMS also uses claims to audit its payments to plans and to determine the amount to pay for beneficiaries who qualify for the low-income subsidy. In addition, CMS researchers have used claims to study and refine the risk adjusters that are applied to plan payments.
According to the Part D statute, “In order to carry out this paragraph [the section of the law on risk-adjusted payments], the Secretary shall require … PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary.” The general counsel at the Department of Health and Human Services determined that this provision must be interpreted narrowly, thus allowing claims data to be used only for such purposes as refining risk adjusters, allocating reinsurance payments to the plans, tracking fraud and abuse, and other tasks with a direct link to payment.

Some researchers argue that “payment purposes” could be interpreted more broadly to allow claims to be used for analyzing patterns in the payment for drugs, or developing potential refinements to the benefit more generally. As described in the next section, HHS published a final rule on May 28, 2008, that will expand the ability of both the government and other researchers to use claims for these broader purposes.22

Congress and congressional support agencies such as GAO and MedPAC have a strong interest in gaining access to these data, both to exercise oversight authority on the Medicare Part D program and to understand the potential impact of proposed changes to the program. In March 2008, MedPAC strengthened an earlier call for claims data availability, with a formal recommendation that “Congress should direct the Secretary to make Part D claims available regularly and in a timely manner to congressional support agencies and selected executive branch agencies for purposes of program evaluation, public health, and safety.”23 HHS’s new rule should achieve this goal by the end of 2008.

Furthermore, the Congress included language in the Medicare Improvements for Patients and Providers Act of 2008 to ensure that claims are available for “improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health services (as the Secretary deems appropriate).”

Data collected on claims

- **Claim participants.** CMS collects information to identify all those involved in a claim, including the beneficiary, the prescribing physician, the pharmacy, and the plan.

- **Drug information.** Plans provide CMS information on drugs involved in a claim, including the drug’s price and quantity dispensed.

- **Cost-sharing.** CMS collects cost-sharing information from plans to determine, among other things, the government’s payments for catastrophic expenses above $4,050 in beneficiary out-of-pocket costs.
Data dissemination

In October 2006, CMS requested comments on a proposed rule that marked a first step toward making the claims data more broadly available. In the proposal, CMS argued that the secretary of HHS retains the authority to collect data for such purposes as determining whether “access to Part D drug benefits affects beneficiary utilization of services under Parts A and B of the Medicare program.”

Under this authority, CMS proposed making claims data available to CMS staff for broader purposes than just payment. It also proposed to release the data to executive branch and congressional support agencies and to private researchers who sign appropriate data use agreements.

On May 28, 2008, CMS published a final rule in the Federal Register. It finalized most of the policies in the proposed rule, but with some significant modifications in response to stakeholder comments on the proposed rule.

Commenters broadly supported the basic goal of increasing data availability and recognized that expanded analytical opportunities could produce both improvements in health care and more informed policy debate over the future of the Part D program. There was, however, significant concern that release of certain data elements could have adverse effects on privacy. These elements include individual-level data that reveal a beneficiary’s plan, the name of the physician prescribing drugs to the beneficiary, the specific pharmacy filling a prescription, and the total charge for a claim and the amount paid by the beneficiary out of pocket. Commenters argued that release of such information would conflict with privacy protections in current law, and might be challenged in court. At the very least, they argued, plans might be required to distribute revised notices of privacy practices.

These are serious concerns, but CMS indicates that existing notices probably cover these circumstances, and will update its own notices to beneficiaries as necessary. CMS already maintains an extensive set of procedures when researchers receive claims data from other parts of the Medicare program. These procedures include signed data use agreements and substantial penalties for violations. Case in point: Personally identifiable data may only be released to researchers who comply with a variety of requirements and go through a review process before data are released. Furthermore, most data are released without individual identifying information; such information can be hidden using an encrypted identifier. When researchers do have identifiable information, they face significant restrictions on what can be published.

In the final rule, CMS stated that Part D claims data will be made available through the Chronic Condition Data Warehouse, created in response to the Medicare Modernization Act. The CCW, which is maintained under CMS contract by Buccaneer Computer Systems & Services, Inc., contains Medicare Parts A and B fee-for-service claims and assessment data from 1999 forward. The claims and other data—organized through 21 predefined chronic condition cohorts—are linked by beneficiary across the continuum of care.
care and include a unique, nonidentifiable key that is designed to reduce or eliminate the need for providing researchers with information that identifies individual beneficiaries.

Physician groups also raised concerns about releasing identifying information about physicians on the claims. Physicians are concerned that availability of these claims data would allow questioning of their prescribing behavior—in particular, that pharmaceutical manufacturers could obtain these data to help market their drugs to individual physicians. Current Medicare policy (unchanged by the claims data rule), however, does not allow publication of information that identifies individual physicians, although that policy could be changed either through a pending court decision or a legislative proposal by CMS. Even if that policy is changed, however, a separate requirement that claims data be used only for non-commercial purposes should prevent pharmaceutical companies from obtaining the data to target marketing activities.\(^\text{27}\)

A larger issue is the objection of participating drug plans that claims data could be used to profile activities of individual plans or publish information the plans consider to be proprietary. Insurers and pharmacy benefit managers argued in their comments that release of data identifying individual plans would risk undermining the competition inherent in the design of Medicare Part D. Their greatest concern is that any release of price information on the claims might reveal the nature and magnitude of plan discounts and rebates. In their view, revealing information on discounts and rebates would result in higher drug prices and thus higher costs to both the individual beneficiary and the federal government. For example, the Pharmaceutical Care Management Association—the trade association for U.S. pharmacy benefit managers—stated in its comments, “If such information becomes publicly available the concern is that brand manufacturers will scale back rebates and discounts in fear of such pricing becoming more broadly used in the commercial sector.”\(^\text{28}\)

In the final rule, CMS emphasized that it will not be releasing information on the rebates paid by manufacturers, which are actually not part of the transaction price reported on claims.\(^\text{29}\) Although some policymakers seek rebate data to learn whether private drug plans are negotiating post-rebate prices that are lower than prices that might be obtained by the government, there is substantial precedent for protecting rebate information. The Medicaid program uses rebate information to obtain prices that match the best prices achieved in the private sector, but it carefully protects this information at the individual drug level. Similarly, a House committee reported on average rebates based on information received from plans without revealing individual drug rebates.\(^\text{30}\)

Beyond price information, Part D plan sponsors expressed strong concerns that the release of claims with plan identifiers would inappropriately disclose what they consider proprietary information about the ways they manage drug utilization. Under the design of Part D, plans have discretion over a wide variety of benefit design parameters, unlike the way benefits are structured in other parts of Medicare. In addition to prices, drug plans are permitted to modify such things as cost sharing, strategies for managing utilization, and approaches to
medication therapy management. As articulated in the comments of the Blue Cross Blue
Shield Association, “The identity of plan sponsors, as well as beneficiaries, must also be
protected in any data analysis. While aggregate data analysis might be helpful to oversight
and other purposes, analysis of specific component[s] of a sponsor’s PDE [prescription drug
event or claim] used to compare one sponsor to another raises critical concerns.”31

In the final rule, CMS decided not to make plan identifiers available to researchers outside
the government. While the government will merge plan characteristics (such as plan-level
benefits or formulary information) with claims data upon request, this matching pro-
cess will not be done if it allows de facto identification of plans. Furthermore, CMS will
provide researchers only the minimum data necessary for a particular project. Government
researchers can receive the full data identified by plan, but CMS anticipates that plan names
will be reported only in connection with performance measures developed for the public.

Many researchers strongly supported CMS’s proposed rule and pointed to the many ques-
tions that could be answered with these data. But they expressed concern that a decision
to protect what plans consider proprietary information could be interpreted too broadly
and thus hinder the availability of information needed to research key questions.

The blanket protection to mask the identity of drug plans is in fact unique for institutional
providers in the Medicare program. Medicare publishes detailed comparative informa-
tion about hospitals, nursing homes, and other institutional providers, and it also allows
outside researchers to do the same. In contrast, the rule for drug claims will allow only
CMS to publish information about drug plans by name and then only specifically for
performance measures. Following past policies, Medicare will not allow publication of
information identifying prescribing physicians, although it does allow researchers to work
with data that identifies physicians.

Any allowable access to identifying information is protected by data use agreements to
ensure that only legitimate researchers seeking to publish studies with a broad public
interest use the data and that privacy of individuals and providers can be protected when
appropriate. These agreements, which also ensure that proprietary information is not
made available to competing plans or to drug manufacturers, work well and have not led
to inappropriate disclosures or other abuses. A similar approach could be used to grant
access to plan-identified data to qualifying researchers.32

CMS has indicated that it may make available some proxy measures of plan characteris-
tics or summarized information to substitute for plan identifiers. Creative use of proxy
measures may serve the needs of many researchers, but they have significant limitations.33
For example, in 2007, only a single plan offered any coverage for brand-name drugs in the
coverage gap. Thus, to avoid identifying such a plan, a proxy measure would likely have to
group it with other plans that covered only generic drugs in the gap.
CMS also plans to link drug claims data (as it does other claims) to data from the Medicare Current Beneficiary Survey, a detailed annual survey of over 10,000 seniors on the entire Medicare program. There is a lag of a couple years between collection of survey data and dissemination for analysis, so 2006 data, covering Part D’s first year, are not yet fully available. But once released, the merged data will provide an important analytical resource for studying the drug benefit. The survey data, for example, could allow researchers to study the reasons beneficiaries choose to enroll in Part D or select a particular plan. Researchers could also incorporate information on drugs obtained through sources outside Part D plans.

Normally, after the end of a given year, plans have several months to submit claims data for that year’s drug events. CMS intends to start releasing 2006 claims by December 2008, and the 2007 claims should be available soon thereafter. On an ongoing basis, the agency will release claims six to eight months after the relevant calendar year ends. The agency has begun work to ensure that the full claims are cleaned and linked to claims for other health services paid under Parts A and B of Medicare. Guidelines and procedures under which they will be released are now being developed.

### Data disseminated on claims

- **Claims data.** CMS will start releasing claims data to federal agencies and outside researchers late in 2008, based on the restrictions in a final rule published in May 2008.

- **Data linked with claims for other health care services.** The May 2008 rule also provides for release of drug claims linked to claims for hospital, physician, and other services, as well as to data collected from the Medicare Current Beneficiary Survey.

### Data gaps

Many research projects will be unaffected by CMS’s decision, in its recent final rule, to continue to withhold data identified by plan. For instance, a study of whether a particular drug is associated with adverse health consequences might not require knowing the name of the plan in which a beneficiary is enrolled. Research on whether beneficiaries change their use of drugs after reaching the coverage gap might require information on whether a particular plan offers any gap coverage, but not the plan’s identity.

In other cases, however, the decision to withhold plan identities could impede evaluation of prescription drugs, the Part D program, and individual plans. Researchers seeking to...
study drug safety and effectiveness need plan information to be able to control for the
effects of plan formularies and benefit rules. Program and plan evaluation may also depend
on detailed information on plan benefit designs and other policies to understand implica-
tions for access, costs, and quality.

A study of different cost-sharing designs and their impact on the use of generic drugs, for
example, may require information on each plan’s cost-sharing policies—quite likely at a
level that would risk identification of individual plans. Likewise, cost-sharing information
by person and by drug would be required to examine beneficiaries’ likelihood of obtaining
a particular drug when faced with out-of-pocket costs. It remains unclear whether such
information would run afoul of the restriction on revealing plan identities.

As described above, CMS is preparing proxy measures of plan characteristics to be added
to the claims data in lieu of plan identifiers. The full implications of the rule’s restrictions
cannot be evaluated until CMS decides exactly what proxies researchers will receive. But the
absence of plan identifiers may impose a significant limitation. It seems that there remains a
compelling public interest in knowing whether taxpayer dollars are being well spent and in
providing more information to beneficiaries seeking to choose among competing plans.

Despite its weaknesses, the final rule will enable some crucial data gaps to be addressed. In
particular, CMS’s promise to link claims data to data for other Medicare services will permit
some crucial questions on the effects of Part D to be answered. Has expanded access to
drugs for those previously lacking coverage reduced expenditures on health services, such as
emergency room and doctor visits, needed to treat complications from medical conditions
such as diabetes or hypertension? And at the same time, do restrictions on access to drugs
that were not present in prior sources of coverage ever lead to adverse health events?

In addition to facilitating program evaluation, the Medicare drug claims can serve far
broader purposes in answering questions about drug safety and effectiveness. Today the
primary evidence about drug safety and effectiveness comes from randomized controlled
trials, especially those required by the FDA for new drug approvals and post-market
surveillance studies. While randomized controlled trials remain the gold standard for such
research, important findings can result from observational studies that compare users of
particular drugs with similarly situated non-users. Such observational studies have uncovered
potential safety problems with newly approved drugs. Medicare beneficiaries tend to
be high users of drugs, and studies that exploit the 24 million drug plan enrollees should
offer many opportunities to identify early warning signs for problem drugs.

At the same time, such studies also provide opportunities to examine the effectiveness
of various drugs and especially the comparative effectiveness of similar drug treatments.
Pharmaceutical manufacturers, which finance the majority of drug effectiveness studies,
have mixed incentives in terms of performing comparative studies. For obvious reasons,
a manufacturer will be reluctant to initiate studies unless it is reasonably certain that
its product will prevail over its competitors. Should a manufacturer fund a study that does not support the superiority of its product, it is unlikely to release the results of that study. There is increasing interest among some leading policy experts to use government funds to support comparative effectiveness research, and several legislative initiatives have pointed in that direction.34

Medicare drug data also could be helpful in assessing the safety and effectiveness of medications for elderly patients, women, or individuals with multiple health conditions. Because advanced age or comorbidities make it more difficult to assess whether a particular drug works, the initial studies of a drug’s safety and effectiveness tend to focus on uncomplicated individuals with a particular health condition. Sometimes after the drug is approved for market, researchers will look at its safety and effectiveness for other populations. But too often this research is not done. Medicare drug data provide a potential opportunity to conduct observational studies in different subpopulations.

**Data gaps on claims**

- **Effects of expanded drug coverage on the Medicare system.** Drug claims data linked to claims data for other Medicare services will be released in late 2008, allowing for the first time assessment of how expanded drug coverage is affecting the overall use of health services, including rates of doctor and emergency room visits.

- **Plan identifiers on claims.** CMS will not release plan identifiers or other information that might identify the plan to outside researchers, which could impede evaluation of prescription drugs, the Part D program, and individual plans.

- **Drug safety and effectiveness.** There are limited data available on potential side effects and the effectiveness of drugs prescribed under the Part D program.

- **Comparative effectiveness of drugs.** Different drugs intended for the same or similar purpose are not regularly compared against one another to help determine the best treatment options.

- **Drug effects on vulnerable subpopulations.** There are currently inadequate assessments of drug safety and effectiveness for seniors, women, and those with comorbidities.
Policy recommendations

Medicare Part D was created through a contentious political process where competing program designs were debated. As policymakers consider revisions to the program’s design, there is a great need to answer questions that might inform this debate. At the same time, clinicians and patients need better information on the safety and efficacy of prescription drugs, and beneficiaries must be able to understand what drug plans are best for them. Many of these critical questions cannot be answered, by those in or outside of government, with the data that are available today.

Constraints on the dissemination or sharing of data present one significant barrier. CMS is only just beginning the process of sharing claims data, for example, with outside researchers or even other government agencies. This information will be particularly valuable in assessing the cost-effectiveness of the Part D program, patient health outcomes, and the safety and efficacy of individual drugs. CMS has indicated no plans to release plan-level data on low-income enrollment or plan-reported performance data, which would help judge beneficiary access to drugs.

Other crucial data, meanwhile, are not even collected. Information on the extent of plan switching by beneficiaries or on plan drug prices, while available for internal administrative purposes, does not appear to be maintained in a database even for internal agency use. There also are limited or no data available on prescription delays.

This sort of information again would contribute to a deeper understanding of whether the unique Part D program, premised on market competition, is delivering quality care at an affordable cost. To address these problems of data availability and collection, the Medicare program should take the following steps:

**Expand the planned release of prescription drug events (claims) data to researchers.** CMS should modify its planned release of claims data to include plan identifiers. Researchers should be permitted to study the impact of plan decisions on how to deliver the drug benefit and to publish results comparing the performance of competing drug plans.
• **Provide aggregate plan performance measures to researchers on a timely basis.** There may be exceptions to releasing such data to protect information where plans have an appropriate proprietary interest, but they should be limited. Rebate data have traditionally been protected, for example, and their use might be appropriately restricted to government researchers.

• **Expand the collection of plan performance measures.** The set of plan performance measures being collected should be expanded, especially in the areas of access to drugs and quality. Access measures should include data on how often beneficiaries fail to get a drug after providing a prescription to a pharmacy and whether they get an alternative drug. More complete measures of the use and outcomes of exceptions and appeals also should be collected. At the same time, quality measures need to be developed, tested, and then collected. Key measures should consider whether beneficiaries are receiving appropriate drug treatments and whether inappropriate treatments are avoided.

• **Expand the availability of plan-level enrollment data.** The data released on plan-level enrollments should include information on the enrollment of beneficiaries qualifying for the low-income subsidy (including how many were auto-assigned and how many switched from their original assignment). The data released should also allow tracking of enrollment changes over time.

• **Expand the availability of plan-level benefit design and formulary data.** Although most plan data are now available, benefit design files should include all plan parameters, including initial coverage limits. Formulary files should also include drug prices (which are already available on the Plan Finder), including designations of which prices are imputed. More detailed information on drug-level utilization management restrictions should also be included in formulary files.

Ideally, critical changes in data collection and dissemination can be accomplished through administrative actions by CMS. If CMS reports that statutory limitations restrict data collection or release, or if it does not take the appropriate actions, then the Congress should act to authorize or require the needed data collection or release.

The Medicare Part D prescription drug benefit represents a $50 billion annual investment in the health of 24 million seniors. Policymakers, beneficiaries, and the broader public need to know how and whether the program is working. Careful oversight and study are necessary to build this understanding, and this can only happen with robust and accessible data.
## Appendix I: plan reporting requirements, 2006–2008

<table>
<thead>
<tr>
<th>Data Category</th>
<th>Data Required in 2006</th>
<th>Changes in 2007</th>
<th>Changes in 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and Disenrollment</td>
<td>How many plan enrollees disenrolled for various reasons</td>
<td>Section deleted, because data are available in other ways</td>
<td>No section</td>
</tr>
<tr>
<td>Reversals</td>
<td>Claim reversals</td>
<td>No changes</td>
<td>No changes</td>
</tr>
<tr>
<td>Medication Therapy Management Programs</td>
<td>Amount of participation, cost of medications for participants</td>
<td>Added measures to report method used to enroll beneficiaries, reasons for disenrollment, average number of prescriptions</td>
<td>Technical refinements; added requirement for a person-level data file</td>
</tr>
<tr>
<td>Generic Dispensing Rate</td>
<td>Number of claims filled with generic drugs</td>
<td>No changes</td>
<td>Added measure of generic claims for drugs where both a generic and brand drug are available</td>
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<tr>
<td>Grievances</td>
<td>Number received</td>
<td>Additional types of grievances (quality of care, transition, exceptions, appeals)</td>
<td>Added count of grievance for LIS enrollees</td>
</tr>
<tr>
<td>Exceptions and Other Utilization Management</td>
<td>Number and disposition of prior authorization, step therapy edits, non-formulary and tier exceptions</td>
<td>Added measures on use of quantity limits</td>
<td>No changes</td>
</tr>
<tr>
<td>Appeals, Reconsiderations</td>
<td>Number and outcome</td>
<td>Additional types of resolution, such as partial reversals or adverse redeterminations due to insufficient evidence of medical necessity from the prescribing physician</td>
<td>No changes</td>
</tr>
<tr>
<td>Call Center Measures</td>
<td>Volume of calls, speed of response, hold time</td>
<td>Break out beneficiary service lines and pharmacy support lines; added measures. Reporting suspended because CMS is collecting data directly</td>
<td>Section deleted, because CMS is collecting data directly.</td>
</tr>
<tr>
<td>Overpayment</td>
<td>Dollars identified and recouped</td>
<td>No changes</td>
<td>No changes</td>
</tr>
<tr>
<td>Rebates, Discounts, and Other Price Concessions</td>
<td>By manufacturer and drug, amounts received (confidential)</td>
<td>No changes</td>
<td>No changes</td>
</tr>
<tr>
<td>Rebates Received by Long-Term Care Pharmacies</td>
<td>No requirement</td>
<td>Rebates paid by manufacturers, supplementing data already required on rebates to the plans</td>
<td>Added information on non-rebate discounts and price concessions</td>
</tr>
<tr>
<td>Business</td>
<td>Licensure and solvency, business transactions and financial requirements</td>
<td>Measures added for employer group plans</td>
<td>No changes</td>
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<tr>
<td>Pharmacy and Therapeutics (P&amp;T) Committees</td>
<td>No requirement</td>
<td>Midyear changes in committee membership</td>
<td>No changes</td>
</tr>
<tr>
<td>Transition</td>
<td>No requirement</td>
<td>Number of prescriptions authorized via transition policy and the number of enrollees affected</td>
<td>Some data elements deleted on number of enrollees in transition; others added on number of days supply of transition medications.</td>
</tr>
<tr>
<td>Drug Benefit Analyses</td>
<td>No requirement</td>
<td>Number of non-LIS plan enrollees at various benefit thresholds, i.e., before, during and after the coverage gap</td>
<td>Added separate count of enrollees in the deductible phase of the benefit; added separate counts for LIS enrollees. Reporting made on a monthly basis.</td>
</tr>
<tr>
<td>LTC &amp; Home Infusion Pharmacy Access</td>
<td>No requirement</td>
<td>No requirement</td>
<td>List of LTC and HI contracted network pharmacies; compliance with access standards</td>
</tr>
<tr>
<td>Retail Pharmacy Access</td>
<td>No requirement</td>
<td>No requirement</td>
<td>Percentage of beneficiaries with access to urban, suburban, and rural retail pharmacies</td>
</tr>
<tr>
<td>Pharmacy Network Changes</td>
<td>No requirement</td>
<td>No requirement</td>
<td>Number of contracted pharmacies (retail, LTC, and HI), number added, and number contracted</td>
</tr>
<tr>
<td>Coordination of Benefits</td>
<td>No requirement</td>
<td>No requirement</td>
<td>Number of supplemental payer transactions posted in real time and after the point of sale</td>
</tr>
<tr>
<td>Vaccine Administration</td>
<td>No requirement</td>
<td>No requirement</td>
<td>Number of vaccine charges through various means (network, out-of-network, paper claims, etc.)</td>
</tr>
<tr>
<td>Home Infusion</td>
<td>No requirement</td>
<td>No requirement</td>
<td>Number of beneficiaries receiving home infusion and total doses</td>
</tr>
</tbody>
</table>
Endnotes


4 Ibid.


10 NDCs (or National Drug Codes) describe drugs uniquely at the level of different forms, strengths, and package sizes of a particular chemical entity (package sizes refer to the different containers used at the pharmacy, not the pill bottles typically received by the consumer). Furthermore, different NDCs are assigned by the various manufacturers that make a particular drug. CMS requires plans to submit formulary information only for a subset of so-called reference NDCs defined at the form and strength level. For example, one reference NDC may represent the 20 milligram tablet of a particular chemical entity, regardless of the manufacturer or package size for which it is shipped.


13 The lack of standardization in the labeling of many plan features such as formulary tiers or gap coverage also makes research more difficult. Jack Hoadley, “Medicare Part D: Simplifying the Program and Improving the Value of Information for Beneficiaries” (May 2008), The Commonwealth Fund, available at http://www.commonwealthfund.org/usr_doc/Hoadley_MedicarePartD_1118_ib.pdf.

14 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005. MediPAC staff have continued to look at these issues and reported further to commissioners in March 2008.

15 Requirements for 2006 are available at http://www.cms.hhs.gov/PrescriptionDrugCOvContra/Downloads/PartDReportingReq_04.18.05.pdf.

16 Reporting requirements for 2007 and 2008 are available at www.cms.hhs.gov/PrescriptionDrugContra/08_8RxContracting_ReportingOverSight.asp.


19 Initially, consumers see a set of summary measures. But the individual measures can be viewed on the Plan Finder as well.


21 Other categories lack the level of detail that might allow a richer analysis of plan performance. For example, measures of generic dispensing rates could benefit by breakdowns for major categories of drugs or could also be calculated as a percentage of those drugs with generic alternatives or with generic alternatives within the drug class. Similarly, it might be useful to have data for prior authorizations and exceptions broken down by categories of drugs or by types of beneficiaries.


24 Centers for Medicare and Medicaid Services, DHHS, “Medicare Program; Medicare Part D Data.”


26 See www.ccwdata.org for more information on this data warehouse.


28 Letter from Mark Merritt (Pharmaceutical Care Management Association) to Leslie Norwalk (CMS), December 18, 2006.

29 Starting in 2008, the claim does include the estimated rebate amount applied to the point-of-sale price, but CMS states explicitly that this added element is not covered under the decision to release claims data.


31 Letter from Alissa Fox (Blue Shield Blue Cross Association) to Leslie Norwalk (CMS), December 18, 2006.

32 Hargrave and Hoadley, “Facilitating Access to Medicare Part D Drug Claims Data.”

33 Ibid.

About the author

Jack Hoadley, Ph.D., is a research professor in the Health Policy Institute at Georgetown University, where he has produced a series of studies on Medicare and Medicaid, giving particular attention to prescription drugs. Previously, he held positions at the Department of Health and Human Services in the Office of the Assistant Secretary for Planning and Evaluation; the Physician Payment Review Commission and its successor, the Medicare Payment Advisory Commission; the National Health Policy Forum at The George Washington University; and in the office of U.S. Rep. Barbara B. Kennelly. Dr. Hoadley received his Ph.D. in political science from the University of North Carolina at Chapel Hill.

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