Medicare Part D Data
Major Changes on the Horizon

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Background: The 3 primary administrative data sets developed by the Centers for Medicare and Medicaid services (CMS) to support the Medicare Part D program implementation represent a valuable source of data for health services researchers. This paper describes the structure of the Medicare Part D program and the related databases, and discusses their utilization for research purposes.

Results: The Medicare Part D administrative data include information on plan benefits (integrated into the Health Plan Management System), beneficiary enrollment files, and prescription drug event (PDE) claims-type data. The enrollment data may be of use in investigating the benefits and plan types that appeal to beneficiaries, but their application is limited by the fact that, although individual beneficiaries' enrollment choices are recorded, only summary enrollment data are currently publicly available. PDE data are likely to be of most interest to researchers as they are detailed (including beneficiary identifiers, contract identifiers pharmacy provider information on drugs provided, drug cost, and insurance status), beneficiary-specific (allowing them to be linked to beneficiary characteristics), and an unusual output for a program reimbursed under a capitation-based system. Because PDE data are highly sensitive, only summary data on the number of Part D prescriptions filled are publicly available.

Conclusions: Although the data collected in relation to the Medicare Part D program could be applied to many questions of interest to health services researchers, their utility is limited by the sensitive natures of many of these data, making it difficult currently to obtain access for research purposes.

Key Words: Medicare, Part D, pharmaceuticals

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The Medicare Part D benefit, established in the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (P.L. 108–173) represents arguably the largest expansion in Medicare benefits since the program's inception in 1965. In 2006, an estimated 43 million Medicare beneficiaries became eligible for "creditable" coverage under Part D, either through Part D drug plan coverage, or through employer or union retiree drug coverage that qualifies for the Medicare retiree drug subsidy. As of June 11, 2006, 38.2 million Medicare beneficiaries had such coverage.[1]

With this new program comes the possibility for prescription drug coverage for millions of Medicare beneficiaries. For researchers, the Medicare Part D program also introduces the potential for a comprehensive administrative prescription drug database for a large population, one that is linkable to other Medicare health care data. Although the potential for these data are great, numerous policy and regulatory issues will need to be addressed before research based on these new data can begin.

SOURCE AND STRUCTURE OF MEDICARE PART D DATA

When considering the use of Medicare Part D administrative data for future research projects, investigators need to understand the sources and likely structure of these data; this understanding will help in assessing the data's possible research limitations. Also critical is knowing the basic structure of the Part D program because the unique complexities of the program determine the type of data potentially available.

In 2006, the Medicare Part D defined the standard prescription drug benefit, with an average premium of about $32 per month for basic benefits; it includes an annual $250 deductible that the beneficiary is responsible for paying. Between $251 and the initial coverage limit of $2250, the Part D plan is responsible for 75% of costs and the beneficiary pays a 25% coinsurance. There is no coverage between $2251 and $5100. Beneficiaries are responsible for all costs between the initial coverage limit and the $5100 threshold, which corresponds to a $3600 threshold in true out-of-pocket costs. Catastrophic coverage begins at the attachment point or threshold of $3600 in true out-of-pocket costs. Costs in catastrophic coverage are split 3 ways: the government provides reinsurance equal to 80%; the Part D plan covers 15%, and the beneficiary pays a 5% coinsurance, or copayments of $2 for generic drugs and $5 for nongeneric drugs.

Coverage for the prescription drug benefit is provided under various types of prescription drug plans (PDPs). These can be stand-alone PDPs, which offer only prescription drug coverage, or Medicare Advantage (MA) prescription drug plans (MA-PDPs), which offer prescription drug coverage that is integrated with the health care coverage provided to Medicare beneficiaries under Medicare Part C. Stand-alone PDPs must offer a basic prescription drug benefit, and MA-

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PDPs must offer either a standard benefit or broader coverage for no additional cost. PDPs or MA-PDPs may also offer supplemental prescription drug benefits through enhanced alternative coverage for an additional premium, and MA-PDPs may use Part A and B rebate credits.

Government payments to Part D plans are based on risk-adjusted per member per month capitated amounts. In addition to these basic rates, additional payments are made to plans through beneficiary premiums and low-income subsidies. Low-income subsidies are made to plans that enroll (or accept autoenrollment) of low-income eligible beneficiaries. Depending on income status, these low-income subsidies can range from 25% to full (100%) premium assistance. Therefore, monthly capitated payments to plans from Medicare consist of the following 4 components: (1) the direct subsidy equal to the standardized bid amount, adjusted for the risk characteristics of the enrollee, minus the monthly beneficiary premium for basic benefits; (2) reinsurance subsidies equal to 80% of the allowable reinsurance costs attributable to prescription drug costs after the Part D enrollee has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold; (3) low-income subsidies, which are government payments on behalf of certain beneficiaries based on their income and asset levels that cover part or all of the premium subsidy amount and plan cost sharing; and (4) risk-sharing arrangements involving symmetrical risk corridors in which the government either pays more of plan costs or recovers payments when a plan has allowable risk-corridor costs above or below a target amount by certain percentages.

Medicare Part D data are "administrative" data, meaning they derive from the actual operation of the prescription drug insurance program. The data fall into 3 broad categories:

1. Medicare Part D Plan (PDPs and MA-PDPs) Benefits Data;
2. Medicare Part D Enrollment Data (enrollment figures for Medicare Part D programs can be found at www.cms.gov. Figures for this article were accessed on September 22, 2006), and
3. Medicare Part D Prescription Drug Event (PDE) Data.

Historically, some Medicare administrative data have been made publicly available, and can often be obtained from the Centers for Medicare and Medicaid services (CMS) website. Other data may be available, but only released with a specific data use agreement (or DUA) which specifies the agreed upon analytic purposes. Benefits data files contain detail on plan benefit offerings and related cost sharing. These data are collected as part of the annual contract approval process for all plans offering prescription drug benefits. Data elements found in the benefits data sets are related to plan offerings and do not include information on characteristics of enrollees or utilization. The data are submitted directly by the plans and reside in the CMS Health Plan Management System (HPMS). Like benefits data from the other major Medicare capitated reimbursement program, Medicare Advantage, Part D benefit data are organized by benefit type rather than by plan or contract, although plan type and contract type summary information is available as part of the HPMS system. Table 1 illustrates the type of information currently available to the public.

Additional data not currently publicly available in database form include details on the use of formularies and use of drug "tiers" to encourage enrollees to use certain preferred drugs. For example, these files include detail on the specific drugs included in formularies used in each benefit plan, application of specific drugs to "tiers," and including corresponding copayment and coinsurance requirements. These benefits files also include information on the geographic service areas of individual plans, and provider networks.

TABLE 1. Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report—Monthly Summary (Data as of August 2006)

Current Contract Summary	No. Contracts	MA Only Enrollees	Drug Plan Enrollees	Total Enrollees
Total "prepaid" contracts*	512	985,441	6,419,886	7,405,327
Local CCPs	367	456,061	5,465,776	5,921,837
PFFS	25	296,681	505,387	802,068
Demos	31	3067	201,196	204,263
1876 cost	28	145,545	153,357	298,902
1833 cost (HCPP)	15	76,611		76,611
PACE	35		12,154	12,154
Regional PPOs	11	7476	82,016	89,492
Total PDPs	91			16,263,386
Employer/union only direct contract PDP	10		114,348	114,348
All other PDP*	81		16,149,038	16,149,038
TOTAL	603			23,668,713

Totals reflect enrollment as of the August 1, 2006 payment.

*Totals include beneficiaries enrolled in employer/union only group plans (contracts with "800 series" plan IDs). Where a beneficiary is enrolled in both an 1876 cost or PFFS plan and a PDP plan, both enrollments are reflected in these counts.

CCP indicates coordinated care plans; HCPP, healthcare prepayment plan; MA, Medicare Advantage; PACE, Program of All Inclusive Care for the Elderly; PDP, prescription drug plan; PFFS, Private Fee-For-Service; PPO, preferred provider organization.

Source: www.cms.gov.

HPMS data are not generally publicly available, although certain abstracts of the benefits data are available on the CMS website (www.cms.gov). In general, much of this data is not considered particularly sensitive, although working with these particular data files can be cumbersome.

Medicare Part D enrollment data may also be of interest to researchers investigating the benefits and plan types that appeal to Medicare beneficiaries. Comprehensive data on beneficiary-specific enrollment in Medicare Part D options are necessary to process appropriate payments to PDPs and MA-PDPs. To this end, specific enrollment choices of individual beneficiaries (and corresponding dates of coverage) are recorded. Although such information is of potential interest to researchers, this beneficiary identifiable enrollment information is sensitive and not publicly available. Some summary enrollment information is currently available on the CMS website (www.cms.gov). Table 2 shows an example of the type of enrollment data available.

The Part D data that will probably be of greatest interest to researchers will be the PDE data. PDE data are claims-like records of beneficiary-specific records submitted by the Part D plans (both PDPs and MA-PDPs) for every prescription filled. PDE data is to be submitted by Part D plans on a monthly basis to a designated CMS intermediary. Normally, these claims-like data would not be an output of a program reimbursed under a capitation-based system (recall that under capitated payment systems, plans do not submit "claims" because reimbursement is not based on specific services provided but is instead based on a monthly amount). However, the complex structure of the Medicare Part D program requires the collection of PDE data mainly for the following purposes: (1) calculate and verify true out-of-pocket costs; (2) reconcile low-income cost sharing and reinsurance; (3) implement risk-sharing provisions; and (4) in future years, make beneficiary-level risk adjustments. The PDE data have a number of key data elements:

1. Plan identifiers (including contract and benefit package identifiers which describe the Part P plan and specific benefits offered);
2. Beneficiary identifiers (health identification claim [HIC], which can be linked to other claims; patient date of birth, and gender);
3. Date of service and date of payment by the Part D plan;
4. Pharmacy provider information;
5. Drugs provided (including the National Drug Classification [NDC] code, compound code, and quantity dispensed);
6. Drug costs (including ingredient cost, dispensing fees, and taxes); and
7. Insurance and coverage status (including beneficiary copays).

PDE data may have the most potential for research purposes because of the level of detail available and also because the beneficiary-specific basis means that the data can be linked to beneficiary characteristics, Medicare service utilization, and diagnoses. Unfortunately, the PDE files are also the most highly sensitive and may be the most difficult to gain access to. Currently, no publicly available access to these beneficiary-specific data exists except for summary data on the number of Part D prescriptions filled. An example of those summary data appears in Table 3.

TABLE 2. Total Medicare Beneficiaries With Drug Coverage as of June 11, 2006

Description	June (Millions)
Drug coverage from Medicare or former employer	
Stand-alone prescription drug plan (PDP voluntary enrollment)	10.37
Medicare advantage with prescription drugs (MA-PDP)	6.04
Medicare-Medicaid (automatically enrolled)	6.07
Medicare retiree drug subsidy	6.90
FEHB retiree coverage	1.60
TRICARE retiree coverage	1.86
Total	32.84
Additional sources of creditable drug coverage	
Veteran's administration coverage	2.01
Indian health service coverage	0.11
Active workers with Medicare secondary payer	2.57
Other retiree coverage, not enrolled in RDS	0.10
State pharmaceutical assistance programs	0.59
Total	5.38

MA indicates Medicare advantage; PDP, prescription drug plan; RDS, Medicare retiree drug subsidy; VA, Veterans Administration.
Source: www.cms.gov.

BENEFITS AND DRAWBACKS OF PART D DATA

The enormous complexities of the Part D program benefit and payment design require far more data to be submitted by Part D plans than other capitated plan programs (eg, the MA program) have to generate. Unlike Medicare Advantage, the design and payment mechanisms of the Part D benefit requires that CMS monitor specific drug claims on a beneficiary level. Beneficiary-specific service-level data are required, for example, to monitor when Part D enrollees have met true out-of-pocket cost requirements and, therefore, have become eligible for a different level of benefits. That this level of data is required for important program implementation and payment is good news because, as an integral part of the payment system, such information is more likely to be timely and accurate than nonpayment or voluntary submission data. Also, prescription drug insurance systems, many of which are administered by prescription benefit managers (PBMs), have a long history of submitting electronic claims information. This may increase the accuracy of even "new" data such as the PDE files.

Another promising feature of Medicare Part D data relates to the large numbers of Medicare beneficiaries who are currently enrolled in Part D, indicating a large population for which data are available. As of June 11, 2006, more than 20 million beneficiaries were enrolled in a Medicare Part D plan (CMS, 2006[1]); specifically, these include 10.4 million in a PDP; 6 million in an MA-PDP, and 6.1 million beneficiaries

TABLE 3. Estimated Prescriptions Filled for Medicare Beneficiaries With Drug Coverage

	Stand-Alone Prescription Drug Plan	Medicare Advantage With Prescription Drugs	Medicare-Medicaid (Automatically Enrolled)	Medicare Retiree Drug Subsidy	Estimated Federal Retirees (Tricare, FEHB)*	Estimated Alternative Creditable Coverage*	Total
January, 2006	11,448,945	14,841,225	29,258,415	19,505,610	9,752,805	16,395,200	101,202,200
February, 2006	15,282,320	15,282,320	29,665,680	19,777,120	9,888,560	16,126,500	106,022,500
March, 2006	19,708,500	15,954,500	29,093,500	18,770,000	10,323,500	16,074,265	109,924,265
April, 2006†	21,793,356	14,528,904	27,968,587	18,161,130	9,340,010	14,010,014	105,802,000
May, 2006	24,024,330	15,288,210	28,528,869	19,110,262	9,828,135	14,196,195	110,976,000
Total	92,257,450	75,895,158	144,515,051	95,324,122	49,133,009	76,802,174	533,926,965

*Estimated normalized monthly prescription drug claims are based on adjusting extrapolated data on total claims for the 65 and over population to reflect what would be expected for the population of beneficiaries with drug coverage, based on actual monthly enrollment and adjusted historical utilization rates.

†According to experts, there has historically been a 5.5% decrease in prescription drug claims volume between March and April due to seasonality. This decrease was partially offset by an increase in enrollment.

Source: www.cms.gov.

dually eligible for Medicare and Medicaid who were automatically enrolled.

An additional major benefit to researchers of the Medicare Part D data is the ability to link them to other Medicare claims data. This ability to link prescription drug with claims for other services (provided under the fee-for-service program, such as hospitalizations, postacute care, physician office visits, and procedures), in addition to other beneficiary demographic and diagnostic information, will enable researchers to conduct a wide range of cost, cost-effectiveness, outcome, and quality of care analyses.

There are, however, some substantial limitations with respect to using Medicare Part D data for such research efforts. Part D data—particularly details of plan formularies and beneficiary-level data—may be difficult to access, even for CMS contractors and congressional agencies. This is the case for a few reasons. The most important factor potentially limiting access to Part D data relates to interpretation of the mandate under which the data, specifically the PDE data, are required and submitted by plans. One proposed interpretation is that the PDE data are required only for payment and program implementation. Therefore, the ability to use these data for nonpayment purposes—such as research—is very unclear. CMS issued a proposed rule that would allow for research use of the PDE data on October 18, 2006; public comments were due to the agency in December. A final rule on this issue is pending.

Another roadblock to the research use of Part D data may be more temporary. As a new program, many of the data format and systems related to Part D, as well as processes for data access and sharing, have yet to be fully developed. Furthermore, the agency responsible for determining these data use systems—CMS—is not primarily a research agency. Research needs (particularly as CMS resources are currently severely stretched) cannot always be a priority.

Finally, there continues to be extreme political sensitivity regarding the implementation of the Part D program. As the program unfolds, successes and particularly perceived failures of Part D become highly public debates between key Medicare stakeholders. For this reason, the continued concern surrounding any evaluation or assessment of the Part D program makes the likelihood of routine access to Part D data for research purposes unclear at best, particularly in the short run. Researchers may need to be content with either the summary information available through the CMS website or limited private data sources.

SUMMARY

Medicare Part D data sources have enormous potential for research purposes. PDE data, in particular, theoretically provide beneficiary claims-level data that could be linked to beneficiary characteristics and other utilization and diagnoses. This possibility allows for analyses that could assess the impacts of prescription drug use on health care costs and quality for a large population. Gaining access to these data for research purposes—aside from aggregate and summary information—may take some time. However, potential research applications of these data (including the ability to analyze patterns of prescription drug utilization over a large, nationally-based population) are very promising.

REFERENCE

1. Centers for Medicare and Medicaid Services (CMS), 2006. Press release, June14, 2006. Available at: www.cms.gov. Accessed September 22, 2006.