Estimating the Effects of Consolidating Drugs under Part D or Part B

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EXECUTIVE SUMMARY

Although the Medicare Part D program has provided beneficiaries with coverage for pharmaceutical care since 2006, Medicare Part B still covers some drugs, generally those furnished "incident to a physician's service," administered using durable medical equipment (DME), and specifically covered by statute. As a result, a drug may be covered by Part B or Part D depending on the beneficiary's health condition or form of the drug. This report focuses on four drug categories that may have overlapping coverage in both programs:

Oral anticancer and antiemetic drugs: Part B covers oral anticancer and antiemetic drugs if they are associated with cancer treatment. Part D plans may cover these drugs in all other circumstances.

Vaccinations: Part B covers vaccinations for influenza and pneumonia for all beneficiaries and Hepatitis B for medium and high-risk beneficiaries. Part B covers other immunizations only if the beneficiary has been exposed to the relevant disease. Part D plans are required to provide coverage for many other vaccinations.

Insulin: The Medicare program that covers insulin depends on the form in which the drug is dispensed. Insulin solution is typically provided in a vial, which is then transferred to either a syringe or a pump. If the insulin is injected with a syringe, it is covered by Part D. If it is dispensed via a pump, Part B is the covering program.

Inhalants: Like insulin, coverage for inhalants depends on form. Metered Dose Inhalers (MDIs) are covered by Part D, while drugs dispensed via nebulizers are covered by Part B.

The overlapping coverage of these and other drugs by the Part B and Part D programs leads to two main problems. First, due to the programs' different payment structures, beneficiary out-of-pocket costs can vary drastically for the same or similar drug, which raises questions about whether prescribing decisions are affected by payment incentives. Second, these coverage rules can cause considerable administrative burden. Pharmacies must determine which program to bill; the Part B program and Part D plans must maintain systems edits to reject inappropriate claims; and beneficiaries may not receive important medications in a timely manner due to process complications.

These problems could be eliminated by consolidating drugs with coverage in Part B and Part D under one Medicare program. In 2007, Acumen LLC was contracted by CMS to study the financial impact of consolidation on Medicare, beneficiaries, Part D plans, and Medicaid. To this end, Acumen built a simulation framework to calculate prices and cost shares under both Part B and Part D, as well as changes in enrollment in Part D. Then, Acumen conducted

sensitivity analyses on the simulation to incorporate behavioral effects such as plan switching and drug substitution.

Comparison of Part B and Part D Benefit Structure

The financial impact of transitioning a drug from Part B to Part D, or vice versa, depends on differences in the Part B and Part D pricing models and benefit structures. These differences are quite substantial. In the Part B fee-for-service (FFS) program, Medicare decides what services should be covered and how much beneficiaries should pay and providers should be reimbursed for these services. As a result, pricing and benefit structures remain relatively consistent across beneficiaries. Part B employs two main strategies to price a drug, which are defined by a Healthcare Common Procedure Coding System (HCPCS) code. Prices are either 106 percent of the Average Sales Price (ASP) or, for DME-infused drugs (including insulin), 95% of the Average Wholesale Price (AWP). ASP and AWP do not vary by region or pharmacy; therefore, at a given point in time for a given drug, all pharmacies and physicians are reimbursed the same amount by the Part B program. Part B out-of-pocket costs for the beneficiary are also consistent across regions, pharmacies, and for the most part, beneficiaries. Once a deductible is met, Medicare covers 80 percent of Medicare-approved charges, and the beneficiary pays the remaining 20 percent.[1] Low-income beneficiaries have their deductible and their 20 percent share covered by Medicaid, as long as they see providers who accept Medicaid. Beneficiaries pay monthly premiums, which combined are required to cover 25 percent of Part B costs. Individual premiums vary by beneficiary income.

Part D benefits are administered by private health care organizations through stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage Drug Plans (MA-PDs). Part D beneficiaries can select from a variety of plans with varying premiums, copayments, drug coverage and pharmacy networks. Part D plans are able to negotiate prices for drugs, as defined by National Drug Codes (NDCs), with networked pharmacies, based on manufacturer rebates and discounts. In addition,the structure of beneficiary cost-sharing for Part D point-of-sale costs is designed by the beneficiary's plan, which can be a standard plan or one of three types of non-standard plans. For the standard plan, beneficiary cost for a given drug is strictly decided by the cost of the drugs and the benefit phase in which the drug falls. Benefit phase, in turn, is determined by the beneficiary's previous drug utilization. The standard plan has four benefit phases with different copayment amounts. Generally, the beneficiary pays 100 percent in the deductible phase, 25 percent in the initial coverage phase (ICP), 100 percent in the coverage gap, and 5 percent in the catastrophic coverage phase. Each phase has a threshold of utilization that must be hit before the beneficiary moves to another phase. For non-standard plans, the amount

[1] Influenza and pneumonoccal vaccines are covered by Medicare at 100 percent; deductibles and cost-sharing do not apply.

the beneficiary pays at the point of sale for a given drug is determined not only by drug cost and benefit phase, but also by drug tier, pharmacy type and status, and days supply. Beneficiaries who are eligible for low-income subsidies also receive some or all of their point of sale costs covered by Medicare. Beneficiaries pay plans monthly premiums, which are supplemented by Medicare's Reinsurance Subsidy to cover all beneficiary pharmaceutical costs. Premiums are determined by the plan's bid and thus, vary by beneficiary. Low income beneficiaries have their premiums covered by Medicare through the Low Income Premium Subsidy (LIPS).

Simulation Model

This analysis simulates the financial impacts of consolidating drugs under either the Part B or Part D program, using 2007 data. Through the simulation, we apply new coverage rules to the drug being consolidated. However, because the cost share of a Part D drug depends on previous drug utilization, removing or adding a drug to Part D affects the cost share of all subsequent drugs. Therefore, we must simulate the cost share of all Part D drugs given the additional or eliminated drug. We simulate the impact of consolidation for each drug individually and combined by program (for example, all drugs to be consolidated under Part D are combined). The below table summarizes the simulation model.

Simulation Steps for Each Drug in the Analysis

Phase	Step	Part B to Part D	Part D to Part B
Select cohort	1	Each cohort is composed of beneficiaries who took the analysis drug or any combination of analysis drugs in the originating program in 2007.	
Calculate pre-consolidation point-of-sale costs	2	For each beneficiary in the cohort, we calculate the Part B costs of the analysis drugs to the beneficiary, Medicare, and Medicaid. We also observe Part D costs incurred by Medicare, the beneficiary, and plans for *all* Part D drugs. We construct pre-consolidation costs by summing these amounts.	For each beneficiary in the cohort, we calculate the Part D costs incurred by Medicare, the beneficiary, and plans for *all* Part D drugs.
Construct post-consolidation point-of-sale costs	3	*Project Part D Prices:* We map each analysis drug's active ingredient to a set of National Drug Codes (NDCs) and define the median per unit price using Prescription Drug Event (PDE) data. .	*Project Part B Prices:* We map the active ingredient of each analysis drug to a HCPCS code and define the price using the CMS Part B fee schedule. If the fee schedule does not indicate a price, we use the median cost reported in Part B claims. If neither are available, we use the per unit median price of NDCs that map to that active ingredient across all PDEs.

Phase	Step	Part B to Part D	Part D to Part B
	4	*Construct Post-Consolidation Costs for Part D enrollees:* Using information on drug utilization, drug prices and Part D benefit schedules, we insert the Part B analysis drug claims into each beneficiary's sequence of PDE records and simulate the cost sharing amounts of each drug. *Construct Post-Consolidation Costs for Beneficiaries Not Enrolled in Part D:* We predict total pre-consolidation Part D costs of these beneficiaries based on diagnoses and demographic information. For beneficiaries with creditable coverage, we apply the standard benefit to simulate post-consolidation costs. We assume that beneficiaries without creditable coverage have lower expenditures and fit the distribution under an "enrollment indifference" threshold.	*Compute Post-Consolidation Costs:* We remove analysis drugs from a beneficiary's sequence of Part D drugs and apply the Part B cost sharing rules to those drugs.
	5	*Calculate Financial Impacts:* By subtracting pre-consolidation costs from post-consolidation costs at the beneficiary level, we calculate the average change in cost for the beneficiary, Medicare, Medicaid and the Part D plan.	
Calculate changes in plan bids and premiums	6	By aggregating the financial impact across beneficiaries, we calculate the change in average Part D costs and plan liability. These estimates are then used to calculate the impact on premiums.	
Calculate impact on total Medicare costs	7	We calculate the change in total Medicare costs with two main inputs: 1) changes in point of sale costs, calculated in steps 1-5, and 2) changes in Medicare's capitated monthly payments, calculated in step 6.	

We incorporate two sensitivity analyses into the simulation. First, we explore the impact of plan switching. Beneficiaries may respond to consolidation by changing Part D plans if consolidation changes the relative attractiveness of alternative plans. Second, we examine the possibility that beneficiaries substitute drugs after consolidation, based on changes in relative price.

Limitations

This analysis has several limitations. First, it does not take into consideration all potential effects of consolidation. Legislation mandates that certain drugs are covered under Part B with specific payment rules and that other drugs are excluded from the program. New legislation would need to pass in order to allow for consolidation under certain scenarios. In addition, we do not address the administrative costs of any systems changes needed to implement consolidation, such as adding drugs to or removing drugs from payment calculation methods or

disseminating information about changes to providers. We also do not take into consideration costs incurred by providers in adopting new coverage rules.

We also faced limitations related to drug pricing for MDIs and injectable insulin. Our simulation for moving MDIs from Part D to Part B uses Part D prices to impute the prices that would be paid in Part B. Because there are no claims for MDIs in Part B under current rules, Part D prices are the best available source of information. However, if post-consolidation Part B prices for MDIs were significantly different from those currently paid in Part D, the effects on beneficiaries, Medicare, and Part D plans would differ from those presented in the simulation findings. In addition, under current law, prices for insulin are significantly higher in Part D than in Part B. If injectable insulin moved to Part B with no increase in the allowable payment limit, providers may refuse to dispense the drug, creating access problems for beneficiaries. This may place pressure on Medicare to increase the reimbursement amount for insulin in Part B – for both injectable and pumped insulin. If the payment limit for insulin increased, the net increase in Medicare's costs resulting from consolidation under Part B would rise as well.

Findings

The key findings from this study are summarized as follows:

Part B and Part D per unit prices vary, affecting the financial impact of consolidation.

Consolidation results in a significant change in total cost for insulin drugs because the Part D per unit drug price is roughly 52 percent higher than the Part B price, due to the fact that Part B prices are set at the AWP in effect on October 1,2003. Nebulizers in Part D also cost substantially more than in Part B, with a 16 percent difference. Therefore, by moving pumped insulin and nebulizer inhalants from Part B to Part D, holding coverage rules constant, total cost would rise significantly. Costs for anticancer drugs and vaccines are comparable across the two programs. Because Part D prices are used to impute Part B prices for MDIs, costs for MDIs are very similar in the two programs by construction.

Table ES1: Comparison of Point-of-Sale Part B and D Costs, by Drug Type

Cohort	Total Costs under Part B	Total Costs under Part D Prices	Part D/Part B
B to D Drugs			
Anticancer	$169,253,702	$174,146,877*	1.03
	$10,864,039	$16,466,355*	1.52
Nebulizer Inhalant	$1,227,000,468	$1,424,907,959*	1.16
D to B Drugs			
Vaccine	$56,769,278*	$54,205,827	0.95
Injectable Insulin	$686,682,816*	$1,059,800,751	1.54
MDI	$2,334,224,423*	$2,354,910,321	1.01

*Simulated prices

On average, beneficiaries lose with B to D consolidations and gain with D to B consolidations.

The average increase in beneficiary out-of-pocket costs with B to D consolidation for all relevant drugs (i.e. anticancer, MDIs, and injectable insulin) is $267 (See Table ES2). Beneficiaries are adversely affected by B to D consolidation for two reasons. First, Part D cost sharing is less favorable compared to Part B. Second, beneficiaries would spend more with Part D consolidation because Part D prices are often higher than Part B reimbursement rates, as mentioned above. D to B consolidations (i.e. vaccines, pumped insulin, and nebulizer inhalants) reduce beneficiary burden because Part B drugs tend to cost less than the same drugs in Part D and beneficiaries enjoy more generous costsharing in Part B. On average, beneficiaries would spend $60 less if their drugs were moved to Part B.

Beneficiaries in the catastrophic phase experience the opposite effect.

Beneficiaries in the catastrophic coverage phase pay less with B to D consolidation because instead of paying the 20 percent coinsurance amount in Part B, they pay a 5 percent coinsurance amount in Part D. As demonstrated in Table ES3, which uses anticancer drugs as an example, the beneficiary in the catastrophic coverage phase pays $166 less, while a beneficiary in the ICP pays $454 dollars more. Conversely, beneficiaries in the catastrophic coverage phase are worse off under D to B consolidations. For example, beneficiaries with MDIs who end in the catastrophic phase pay an additional $10, while their counterparts who end in the gap see reductions of $138.

Table ES2: Average Change in Point-of-Sale Costs for Beneficiaries, Medicare, Medicaid, and Plans

Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
Combined B to D	1,177,717	$267*	-$296*	-$97*	$296*
Combined D to B	4,695,441	-$60*	$165*	$59*	-$252*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.

Table ES3: Average Change in Point-of-Sale Costs for Beneficiaries, Medicare, and Plans Based on Drug Utilization

Beneficiary Characteristics Related to Part D (Pre-Consolidation)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
Anticancer (B to D)					
Ended in Deductible	2,177	$326	-$911	-$176	$873
Ended in ICP	21,816	$454	-$938	-$123	$703
Ended in Gap	12,910	$353	-$403	-$169	$299
Ended in Catastrophic	7,936	-$166	$150	-$304	$382
MDIs (D to B)					
Ended in Deductible	2,049	-$6*	$9*	$6*	-$9*
Ended in ICP	58,565	$0*	$226*	$18*	-$244*
Ended in Gap	51,695	-$138*	$371*	$55*	-$293*
Ended in Catastrophic	28,431	$10*	-$57*	$163*	-$138*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for MDIs are based on a sample.
* Statistically significant at a 95% confidence level.

Consolidation slightly affects bids, with D to B consolidations having a greater impact.

Adding drugs to or removing drugs from Part D would lead to changes in plan costs, which would be passed onto Medicare and beneficiaries through an increase or decrease in plan bids. However, because such a small percentage of Medicare beneficiaries would be affected by

consolidations, the impact is low. Only one percent of beneficiaries are affected by B to D consolidations, resulting in a $0.76 increase in Part D bids (Table ES4). About 27 percent of all Part D beneficiaries are affected by D to B consolidations, but the average decrease in plan covered payments is only $252. Even in this case, the average national bid changes relatively little; it declines by just under $3, a change of four percent.

Table ES4: Expected Part D Premium Changes

Cohort	Average Plan Cost for Beneficiaries Pre-Consolidation	Average Plan Cost for Beneficiaries Post-Consolidation	Post-Pre Average Costs	Percent Change in Costs	Post-Consolidation Average Bid	Change in Average Bid
Combined B to D	$1,500	$1,764	$264*	1.0%	$76.33	$0.76*
Combined D to B	$1,589	$1,337	-$252*	-3.6%	$72.84	-$2.73*

Cost statistics for both cohorts are based on a sample.
* Statistically significant at a 95% confidence level.

Beneficiaries currently do not react to financial incentives by substituting drugs.

CMS is considering drug consolidation in part to reduce inappropriate prescribing incentives. For example, a beneficiary in the catastrophic coverage phase may request a prescription for an MDI to be covered by Part D instead of a nebulizer to be covered by Part B to reduce his coinsurance amount. However, we do not find evidence supporting substitution between nebulizer inhalants and MDIs, or pumped and injectable insulin, in response to changes in relative cost sharing rates across the two Medicare programs. First, beneficiaries are not more likely to use these drugs in their Part B form when they hit the coverage gap. Second, they are not more likely to use these drugs in their Part D form when they hit the catastrophic coverage phase. Third, non-LIS beneficiaries have similar consumptions patterns as Medicaid-eligible beneficiaries.

Consolidation does not substantially increase incentives for plan switching.

On average, beneficiaries could save about $140 by switching to a lower cost plan even before consolidation, and most beneficiaries would not save significantly more money by switching plans after consolidation. The largest impact was found in the anticancer B to D consolidation, where only ten percent of beneficiaries experience an increase in potential savings of $20 or more as a result of consolidation.

Overall, Medicare gains with B to D consolidation and loses with D to B consolidation.

Despite an increase in prices under Part D, Medicare gains with B to D consolidation because Part D has less generous coverage rules. In the combined simulation for all three drugs consolidated under Part D, consolidation reduces Medicare's total payments by $150 million, which is 0.4% percent of total Part D drug costs[2]. Almost 90 percent of eliminated Part B cost sharing is offset by the increased cost sharing for consolidated drugs in Part D. In the D to B simulation, Medicare's net payments increase by $52 million (See Table ES5). Almost all of the reduction in Part D costs from moving drugs to Part B is offset by the increase in Part B costs for consolidated drugs.

Table ES5: Total Financial Impact of Consolidation on Medicare

	Change in Medicare Payments (in thousands)					
		Part D				
Cohort	Part B	LICS	Reinsurance	Direct Subsidy	LIPS	Total
Combined B to D	-$1,140,230	$226,699*	$565,069*	$182,050*	$17,017*	-$149,395*
Combined D to B	$2,368,991	-$793,389*	-$802,357*	-$652,675*	-$68,693*	$51,877*

Cost statistics for both cohorts are based on a sample.
* Statistically significant at a 95% confidence level.

[2] In 2007, Medicare spent $42,158,957,140 in Part D costs.

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1 INTRODUCTION

Since its inception in 2006, the Medicare Part D program has provided beneficiaries with coverage for pharmaceutical care. However, Medicare Part B still covers certain types of prescription drugs, generally those furnished "incident to a physician's service," drugs administered using durable medical equipment (DME), and drugs specifically covered by statute, such as oral anticancer drugs and blood-clotting factors. These drugs were covered under Part B before the creation of Part D and have remained there since.

In some cases, the same drug is covered by Part B under certain circumstances and covered by Part D at all other times. This is the case for oral anticancer and antiemetic drugs. For instance, an antiemetic drug prescribed to a patient for use immediately following chemotherapy treatment would be covered by Part B. However, the same drug prescribed to the same patient one month after the conclusion of chemotherapy would be covered under Part D. The same is true for the hepatitis B vaccine. If the patient is considered "high risk", these vaccines are covered under Part B; in all other cases, they are covered under Part D. For other drugs, route of administration drives the covering program. For example, asthma medication dispensed in a metered dose inhaler (MDI) is covered under Part D, while the same medication dispensed through a nebulizer is covered under Part B. Finally, drugs within the same group can be split between the two programs. For example, influenza and pneumococcal vaccines are covered by Part B, while the herpes zoster vaccine is covered by Part D.

There are several potential problems with the overlapping coverage of drugs. First, drugs covered under Part B have different price determinations and payment structures than those covered under Part D. Therefore, the total cost of the drug and the beneficiary out-of-pocket cost share can vary drastically for the same drug depending on the program. In addition, administration fees may differ by program. This raises questions about whether prescribing decisions are affected by payment incentives and cost sharing impacts. Second, the rules governing coverage of these drugs can cause considerable administrative complexity. Navigating the system to correctly dispense and bill these overlap drugs is burdensome for the Centers for Medicare and Medicaid Services (CMS), claims adjudicators, pharmacists, physicians, plans, and beneficiaries. Third, quality of care is also a concern, especially regarding vaccinations. Because more beneficiaries are enrolled in Part B than in Part D and vaccinations are an important public health safeguard, advocates argue for coverage of all vaccines under Part B.

Some of these problems could be eliminated by consolidating coverage of the overlap drugs under one Medicare program. In some cases, drugs would move to Part D, while in other cases, they would move to Part B. In 2007, Acumen LLC was contracted by CMS to study the

financial impact of consolidation, in addition to assessing administrative impacts. This report does not include all drugs with overlapping coverage; instead it focuses on oral anticancer and antiemetic drugs, vaccines, insulin, and inhalants. A follow-up report will include findings for immunosuppressive drugs and parenteral nutrition. We present the baseline simulation of the financial impact of consolidating these drugs under one or both programs on beneficiaries, Part D plans, Medicare, and Medicaid. We also perform a sensitivity analysis to examine how the results would be affected by behavioral responses, as beneficiaries may switch Part D plans based on drug formulary placement or change patterns of drug consumption based on beneficiary cost share amounts.

In Section 2 of this report, we compare the Part B and Part D programs, including differences in drug pricing, premiums, and point of sale beneficiary cost share. Section 3 describes the Part B versus Part D determination process for the four drug categories. In Section 4, we explore the current utilization of these drugs under Part B and Part D. Section 5 explains the approach for our baseline simulation. Section 6 presents the financial impact of consolidation for drugs that move from Part B to Part D. Section 7 does the same for drugs that move from Part D to Part B. Section 8 discusses our methodology and findings of the sensitivity analyses, describing how beneficiaries and plans might respond to consolidation and how those behavioral changes affects simulation results on post-consolidation costs.

2 COMPARISON OF PART B AND PART D BENEFIT STRUCTURES

The financial impact of transitioning a drug from Part B to Part D, or vice versa, on Medicare, beneficiaries, and plans depends on differences in the Part B and Part D pricing models and benefit structures. These differences are quite substantial. In the Part B fee-for-service (FFS) program, Medicare decides what services should be covered and how much beneficiaries should pay and providers should be reimbursed for these services. As a result, pricing and benefit structures remain relatively consistent across beneficiaries. Part D benefits, on the other hand, are administered by private health care organizations through stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage Drug Plans (MA-PDs). Part D plans are able to negotiate prices with networked pharmacies, based on manufacturer rebates and discounts. In addition, they enjoy some flexibility in expanding coverage beyond the basic Part D benefits defined by Medicare, setting premiums, and determining point of sale beneficiary cost sharing amounts. Because Part D beneficiaries can choose from hundreds of plans with varying premiums, copayments, drug coverage and pharmacy networks, they would face different tradeoffs when Part B drugs are moved to Part D. In this section, we describe in detail Part B and Part D price-setting mechanisms and benefit structures.

2.1 Pricing

While the Part B program uses the Average Sales Price (ASP) to set drug prices, individual Part D plans base prices on negotiations and contractual agreements with pharmacies and drug manufactures. In the following discussion, we outline how each of these Medicare programs determines drug prices.

2.1.1 Part B Pricing Structure

The Part B pricing structure has changed significantly over the last several decades. In 1992, the program set outpatient drug prices to 100 percent of the Average Wholesale Price (AWP). Instead of corresponding to actual prices paid to drug manufacturers, AWP is more similar to a "manufacturer's suggested list price."[3] After criticism from the Office of the Inspector General (OIG) that Part B was paying significantly more for drugs than other health insurance programs, the program began paying 95 percent of AWP starting in 1997. In 2004, payments were decreased to 85 percent of AWP for most drugs. Part B pricing was modified once again in 2005 when the Average Sales Price (ASP) became the new mechanism for payment. The ASP more accurately reflects what medical and pharmaceutical providers pay for drugs because it represents actual payments made by purchasers to drug manufacturers,

[3] Chapter 9, "Medicare Payments for Outpatient Drugs Under Part B," in MedPAC's "Report to Congress: Variation and Innovation in Medicare," at http://medpac.gov/documents/June03_Entire_Report.pdf

accounting for rebates and discounts. The ASP pricing schedule is also timelier, as data are updated on a quarterly basis when manufacturers submit price data to Medicare. Part B currently pays providers 106 percent of the ASP. Drugs infused through DME, including insulin, are an exception; payment for DME-infused drugs is set at 95% of the AWP that was in effect on October 1, 2003.

Although the ASP changes over time, it does not vary by region or pharmacy. At a given point in time for a given drug, all pharmacies and physicians are reimbursed the same amount by the Part B program. For reimbursement, physicians submit the Healthcare Common Procedure Coding System (HCPCS) code on a Part B claim. Drugs within the same HCPCS code share the same active ingredient and strength, and each HCPCS is assigned a price. Pharmacies, on the other hand, typicallysubmit a National Drug Code (NDC), which uniquely identifies the drug by its active ingredient, strength, manufacturer, and packaging size. Because unit Part B prices are established for individual HCPCS codes, CMS maps the NDC code submitted by the pharmacy to a HCPCS code. CMS' HCPCS to NDC crosswalk is updated quarterly as new drugs enter the market and are approved for coverage by CMS.

2.1.2 Part D Pricing Structure

The pricing structure under Part D is similar to that of the commercial prescription drug plan industry. There are three components to the price of a drug: 1) the cost of the drug itself, or the "ingredient cost" charged by the manufacturer or wholesaler, 2) the dispensing fee charged by the pharmacy for its services, and 3) sales tax. The price of an individual drug can vary across Part D plans, as each independently negotiates costs with drug manufacturers and pharmacies. A plan typically negotiates two forms of discounts with manufacturers: 1) a flat per-unit percentage reduction of a drug's AWP that is given at the point of sale and 2) a rebate that is a varying percentage discount of AWP given at the end of the year and based on the volume sold through the plan's pharmacy network. Regulations allow plans to decide on their own how to pass on the savings from their negotiations; for example, they may do so directly through reductions in costs at the pharmacy counter or indirectly through reduced monthly premiums.[4] On the pharmacy side, plans may negotiate discounts on the dispensing fees by agreeing to include the pharmacy in its network.[5] Benefit Structure

For Part B and Part D benefits, beneficiaries pay monthly premiums and copayment/coinsurance amounts at the point of drug purchase. Whereas Medicare sets these

[4] The law requires that plans report the total amount of the savings they achieved through the negotiated discounts with manufacturers. Medicare's payments to plans for enrollees in the catastrophic phase are adjusted by the amount received by plans in the form of manufacturer rebates.

[5] If enrollees do not fill their prescriptions at pharmacies within their plan's network, their drugs may not be covered by the plan or beneficiaries may pay a higher copayment.

amounts for the Part B program, Part D plans can design their own cost sharing models with Medicare regulation. The structure of these premiums and point of sale costs within each Medicare program is described below.

2.1.3 Premiums

Part B and Part D benefits are financed through a combination of federal funding and beneficiary premiums. Unlike the premiums for the Part D program, which are set by private Part D plans, the amount of the Part B monthly premium is calculated each year by Medicare.

Part B

The law requires that funds collected during the year from monthly premiums are sufficient to cover 25 percent of all Part B program costs for beneficiaries, with the federal government covering the remaining 75 percent. Until 2007, Part B beneficiaries paid the same standard monthly premium amount regardless of their income. This changed with the passage of the Medicare Modernization Act (MMA), which mandated that beneficiaries in higher income brackets pay the standard 25 percent premium plus an adjustment amount, bringing their total premiums to range between 35 percent and 80 percent of Part B costs. As a result, in 2007, Medicare began a three-year process of phasing in premium increases for single beneficiaries with annual incomes over $80,000 and married beneficiaries with combined incomes over $160,000. This affected an estimated four percent of Part B beneficiaries. Beneficiaries would be responsible for paying 1/3 of the adjustment amount in 2007, 2/3 in 2008 and the full amount in 2009.[6] See Table 2-1 for a breakdown of the fully-implemented adjusted premium amounts by income level in 2009.

[6] SocialSecurityHop.com, Description of Medicare Part B Income-Related Monthly Adjustment Amount (IRMAA), http://socialsecurityhop.com/en/handbook/25/2500-description-of-medicare-part-b-income-related-monthly-adjustment-amount-irmaa

Table 2-1: Part B Premiums by Income Level, 2009

Annual Income		Total Monthly Premium
Individual Beneficiaries	**Married Beneficiaries**	
Not greater than $85,000	Not greater than $170,000	$96.40
Between $85,000 and $107,000	Between $170,000 and $214,000	$134.90
Between $107,000 and $160,000	Between $214,000 and $320,000	$192.70
Between $160,000 and $213,000	Between $320,000 and $426,000	$250.50
Greater than $213,000	Greater than $426,000	$308.30

Source: CMS Manual System Publication 100-01 Transmittal 56, http://www.cms.gov/Transmittals/downloads/R56GI.pdf

Low-income beneficiaries with limited assets can receive assistance with Part B expenses through the Medicare Savings Programs (MSPs), in which Medicaid pays their Part B premiums.

Beneficiaries can receive Part A and Part B benefits through managed care plans, referred to as Medicare Advantage (MA) plans. Beneficiaries continue to pay the standard Part B premium as they would under FFS Medicare (Part B).[7] For each beneficiary enrolled in an MA plan, Medicare pays the plan a monthly capitation rate, which is adjusted for the beneficiary's demographic and health characteristics. To determine the baseline amount of the monthly capitation rate, plans submit bids that reflect the expected costs of providing coverage to an average beneficiary. Bids include allowances for administrative costs and profits. Medicare compares plan bids to a CMS-determined benchmark, which is based on Part A and Part B costs and updated annually. If a plan's bid exceeds the benchmark, the plan is paid at the benchmark level and enrollees pay an additional premium to cover the cost difference. If a plan's bid is below the benchmark, Medicare pays the plan the bid amount plus a rebate.

Part D

Part D plans are either standard plans or one of three types of non-standard plans. These plans charge monthly premiums, which are determined by plan sponsors through market competition rather than fixed by Medicare. Hence, premiums can vary across plans. For each plan, the Part D sponsor submits a bid that reflects the expected revenues needed to cover the beneficiaries' drug costs under the plan's benefit design. All bids must include a minimum level of coverage mandated by the MMA, called the defined standard benefit. Medicare reviews each

[7] For additional coverage, beneficiaries can pay a premium amount to the MA plan.

bid and may negotiate with plan sponsors before approving them. These bids are used to calculate the national average bid, computed by taking an average of approved PDP and MA-PD plan bids, weighted by each plan's enrollment in a reference month of the previous year.

For each beneficiary enrolled in a Part D plan, Medicare pays a Direct Subsidy that covers a portion of the approved bid; the beneficiary pays the rest. Monthly premiums paid by a beneficiary are equal to the base beneficiary premium plus the difference between the plan's bid and the national average bid. For a bid equal to the national average, the beneficiary premium equals the beneficiary base premium. Plans with bids below the national average have lower beneficiary premiums; plans with bids above the national average have proportionally higher premiums.[8] A risk adjustment factor is added to increase the subsidy provided for beneficiaries with greater health needs that are expected to yield higher drug costs. Medicare subsidizes a portion of premium payments of low income beneficiaries,depending on their level of need, referred to as the Low Income Premium Subsidy (LIPS).

2.1.4 Beneficiary Point of Sale Costs

In addition to monthly premiums, Part B and Part D beneficiaries also pay a share of drug costs at the point of service. Whereas Part B cost sharing is generally consistent across all services, providers and beneficiary utilization, Part D cost sharing relies on many factors and varies widely.

Part B

For beneficiaries in Part B, point-of-service out-of-pocket costs come in the form of a deductible which must be met before Medicare starts paying. In 2006, the deductible was $124, and in 2007, it increased to $131. Once the deductible is met, Medicare covers 80 percent of Medicare-approved charges, and the beneficiary pays the remaining 20 percent.[9] Beneficiaries with MSP benefits have their deductible and their 20 percent share covered by Medicaid, as long as they see providers who accept Medicaid. However, if the state Medicaid program's reimbursement rate for the drug is lower than the beneficiary coinsurance amount, Medicaid pays its reimbursement rate. Providers must accept Medicare rates as payment in full.

To reduce their out-of-pocket expenses, beneficiaries have the option of purchasing Medicare Supplemental Insurance—Medigap—to cover the cost of deductibles, coinsurance payments, and provider balance billing. This coverage is sold through private health insurance

[8] A beneficiary's premium is also adjusted by an increase for any late enrollment penalty, a decrease for MA-PD plans that apply MA Part A and B rebates to buy down the Part D premium, and/or a decrease/elimination by a low-income premium subsidy.

[9] For certain drugs, such as influenza and pneumoncoccal vaccines, Medicare covers 100 percent of costs and beneficiaries pay no deducible or co-insurance.

companies. Standard Medigap policies must include coverage of the Part B 20 percent coinsurance, and have the option of covering deductible and balance billing charges.

Part D

Part D point of sale costs are designed by the beneficiary's plan, which can be a standard plan or one of three types of non-standard plans: actuarially equivalent plans, basic alternative plans, or enhanced plans. For the standard plan, beneficiary cost for a given drug is strictly decided by the cost of the drugs and the benefit phase in which the drug falls. The standard benefit has four phases: the deductible phase, the initial coverage phase (ICP), the coverage gap, and the catastrophic coverage phase. A more detailed description of each phase is below:

1. *Deductible Phase:* During this phase, the beneficiary pays 100 percent of drug costs; the plan and Medicare pay nothing. In 2007, the deductible for the standard plan was $265.
2. *ICP:* After paying $265 in the deductible phase, the beneficiary passes into the ICP. During this phase, the beneficiary pays 25 percent of drug costs, and the plan 75 percent.
3. *Coverage Gap:* A beneficiary passes into the coverage gap when Gross Drug Costs incurred in the ICP (paid by both the plan and the beneficiary) equal $2,400 (2007). This phase is referred to as the coverage gap because the beneficiary pays 100 percent of the costs; the plan and Medicare pay nothing.
4. *Catastrophic Coverage Phase:* A beneficiary passes into the catastrophic coverage phase after paying costs of $3,850 in the deductible phase, ICP, and coverage gap. In the catastrophic coverage phase, the beneficiary pays either 5 percent of drug costs or $2.15 (generic)/$5.35 (brand), whichever is greater. The plan pays 15 percent of drug costs, while Medicare is responsible for 80 percent. The payment made by Medicare is referred to as the Reinsurance Subsidy.

Beneficiaries can choose a plan that is actuarially equivalent to the standard plan or pay additional costs for an enhanced plan. *Actuarially equivalent standard plans* maintain the standard deductible but have a different ICP and catastrophic cost structure. *Basic alternative plans* are also actuarially equivalent to the defined standard plan, but in addition to having different ICP and catastrophic cost structures, these plans also reduce or eliminate the deductible requirement. The value of the third plan type, *enhanced alternative plans*, must actuarially exceed that of the defined standard plans. The enhanced benefits can include expanded formularies, lower deductibles, reduced cost sharing, increase initial coverage levels, or coverage in the gap. Enhanced alternative plans charge higher premiums, covered by the beneficiary.

For non-standard plans, the amount the beneficiary pays at the point of sale for a given drug is determined not only by drug cost and benefit phase, but by within-phase differences in

cost sharing due to drug tier, pharmacy type and status, and days supply. Beneficiaries who are LIS eligible also receive some or all of their point of sale costs covered by Medicare, referred to as Low Income Cost Share (LICS) Subsidy.

In conclusion, beneficiary payments are determined very differently in Part B and Part D. In Part B, beneficiary premiums are calculated by Medicare and point-of-sale cost share is set at 20 percent of the Medicare payment limit. Subsidies for premiums and cost-sharing for low-income beneficiaries are the primary source of variation in the actual out-of-pocket costs paid by beneficiaries. Higher income beneficiaries pay higher premiums; beneficiaries eligible for Medicaid or MSPs pay no premium or point of sale costs at all. Part D beneficiary payments, on the other hand, depend on many more factors and therefore vary greatly. For a given drug, in addition to beneficiary income, Part D beneficiary cost share is determined by the drug's tier, the pharmacy in which the drug is dispensed, and the beneficiary's plan type and previous drug utilization.

3 PART B VERSUS PART D DETERMINATION

Medicare is considering consolidating certain drugs under either the Part B program or the Part D program partially because of the administrative complexity of the B versus D determination process for pharmacies and medical providers. In the following section, we describe the current process and how this would change as a result of consolidation for each drug in the analysis. We have developed the following narrative based on CMS documentation and interviews with pharmacists and medical providers.

3.1 Oral Anticancer and Antiemetic Drugs

The coverage of oral anticancer and antiemetic drugs by Part B or Part D depends on the beneficiary's condition and treatment. If the beneficiary has cancer, Part B covers oral anticancer drugs. To be covered by Part B, oral antiemetic drugs must approved by the FDA for use as an antiemetic, administered by the physician as a part of cancer treatment, prescribed for use within 48 hours of cancer treatment, and be in replacement for IV antiemetic drugs. Part D plans may cover oral anticancer and antiemetic drugs that do not meet the conditions for Part B coverage; examples include anticancer drugs prescribed for non-cancer-related usage and antiemetic drugs not for use within 48 hours of cancer treatment.

3.1.1 Current Determination Process

The anticancer B versus D determination process places a burden on pharmacies, the Part B and Part D programs, and beneficiaries. Pharmacies must determine which program to bill; the Part B program and Part D plans must maintain systems edits to reject inappropriate claims; and beneficiaries may not receive important medications in a timely manner due to process complications.

As the use of anticancer drugs became more common in the nineties, the dispensing of these drugs shifted away from physicians' offices and cancer treatment centers towards pharmacies. Because relatively few prescriptions covered by Part B are filled in retail settings, pharmacists have little experience with billing Part B and often bill prescriptions for anticancer drugs to Part D by default. Although the Part D plan's Plan Benefit Manager (PBM) often rejects the claim via the use of extensive edits, some Part D plans do not have sufficient edits, causing the claims of cancer beneficiaries to be billed to Part D instead of Part B.

If the claim is rejected by Part D, the pharmacist bills Part B, a process which pharmacies find burdensome. If the prescription does not have the appropriate ICD-9 code, the pharmacist must call the prescribing physician to confirm that the beneficiary has cancer. This code should be submitted with the drug information in the claim. If the oral antiemetic drug will not be taken

within the permitted time period or does not fulfill the other requirements for coverage, the drug cannot be covered by Part B. Like Part D plans, the Part B program must maintain edits to ensure that anticancer drugs are properly approved or rejected. However, even with these edits in place, one interviewee reported that the system does not effectively reject oral antiemetic drugs that should not be covered by Part B. DME Medicare Administrative Contractors seldom conduct audits to recover inappropriate payments because they are not a large enough share of total payment to warrant this time-intensive exercise.

Perhaps the most important stakeholders in this discussion are the beneficiaries. It is possible that a beneficiary with cancer who is undergoing treatment and thus experiencing nausea may not receive antiemetic drugs because of the statutory and regulatory Part B requirements. In addition, beneficiaries often do not know which program is paying for their drugs and why. Therefore, they may have difficulty monitoring whether drugs are being properly billed. For example, due to lack of knowledge, a beneficiary may not protest that his anticancer drug was inappropriately covered by Part D, pushing him into the coverage gap.

Throughout the remainder of this report, oral anticancer and antiemetic drugs are consolidated and referred to as anticancer drugs.

3.1.2 Benefits of Consolidation

Consolidating all anticancer drugs under Part D would facilitate pharmacy drug processing and billing and eliminate the necessity of maintaining systems edits for Part D plans and Part B, which could improve beneficiary access.

3.2 Vaccines

Part B only covers vaccinations for influenza and pneumonia for all beneficiaries and Hepatitis B for medium and high-risk beneficiaries.[10] Part B covers other immunizations only if the beneficiary has been exposed to a disease or condition (e.g. a tetanus shot for an individual who has stepped on a rusted nail). The MMA requires Part D to provide coverage for many other vaccinations.

[10] "High risk groups currently identified include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B Virus (HBV) carrier; homosexual men; illicit injectable drug abusers. Intermediate risk groups include: staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work." See Medicare Part B Versus D Coverage Issues, http://www.cms hhs.gov/prescriptiondrugcovgenin/downloads/partbandpartddoc_07.27.05.pdf .

3.2.1 Current Determination Process

The vast majority of vaccines are dispensed at physician's offices, although it is more and more common for pharmacies to offer vaccines, depending on state regulations and administration practices. Because physicians are familiar with the Part B billing processes (just as pharmacies are more familiar with the Part D billing processes), the current process for flu and pneumonia vaccines is not problematic. Part B covers these vaccines in all circumstances, and providers commonly bill Part B.

Other vaccinations are more complicated because the physician must determine whether Part B or Part D should be billed based on the beneficiary's health characteristics. To demonstrate that Part B should pay for a drug typically covered under Part D, the physician must submit diagnosis codes with the Part B claim.

More importantly, complications arise when the beneficiary is not eligible for Part B coverage of the vaccine. Because physician offices are out of a Part D plan's pharmacy network, beneficiaries receiving a vaccine covered by Part D at a doctor's office must often pay for the cost of the vaccine at the point of service. The beneficiary may then submit a paper claim to the Part D plan to receive reimbursement. This applies even to low income beneficiaries, for whom paying these extra costs at the point of service likely serves as a barrier to procuring certain vaccinations. To improve beneficiary access, CMS promotes other reimbursement strategies.[11] Physicians can prescribe the vaccine to the beneficiary, who then takes the prescription to and receives the vaccine from a pharmacist. In cases where the state or administrative complexities of the vaccine prohibit the pharmacist from injecting the vaccine, the pharmacy can mail (or the beneficiary can transport) the vaccine to the prescribing physician. This may reduce the effectiveness of vaccines such as zoster that should be kept frozen until administration. CMS also encourages plans to mail beneficiaries a description of the process through which the physician can bill Part D, which the beneficiary then provides to the physician. This process involves the submission of a physician paper or electronic claim. Physicians can also use a web-based system based on the National Council for Prescription Drugs Program (NCPDP) standard.

Pharmacies and physicians have also faced obstacles in receiving reimbursement for administration fees, which has led to several policy changes over the years. In the Part B and Part D claims data, the administration fee for vaccines is approximately $19.33 regardless of vaccine type. After the inception of Part D, CMS decided not to reimburse physicians under Part B for the administration costs of Part D-covered vaccines, so the burden of the administration cost fell on the beneficiary. Therefore, Congress included a provision in the Tax Relief and

[11] Reimbursement strategies in the remainder of this paragraph are based on Section 60.2 in Chapter 5 (Benefit and Beneficiary Protection) of the Prescription Drug Benefit Manual (2010), accessed at http://www.cms hhs.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf.

Health Care Act of 2006 (P.L. 109-432) requiring Part B coverage of Part D vaccine administration during 2007. Beginning in 2008, Part D plans assumed responsibility for covering these costs.

3.2.2 Benefits of Consolidation

Due to the obstacles physicians face in billing Part D and concerns regarding beneficiary access, MedPAC recommended in 2007 that all vaccines and administration fees be paid under Part B. Furthermore, 22 medical organizations including the American Medical Association (AMA) drafted a letter to members of the US House of Representatives expressing their support for H.R. 4992, the Medicare Improvement Act of 2007, which, had it passed, would have shifted the payment for all preventative vaccines to Part B. In addition to improving access and reducing billing burden, consolidation under Part B would mean that the Part B program and Part D plans would not have to maintain their systems' edits to avoid inappropriate coverage.

3.3 Insulin

The Medicare program that covers insulin depends on the form in which the drug is taken. Insulin solution is typically provided in a vial, which is then transferred to either a syringe or a pump. If the insulin is injected with a syringe, it is covered by Part D. If it is dispensed via a pump, Part B is the covering program.

3.3.1 Current Determination Process

Insulin vials are typically dispensed by a pharmacy. The pharmacy must then use information on the physician's prescription, which indicates how the drug should be administered, to determine whether to bill Part B or Part D. Insulin delivered through an ambulatory pump is covered by Part B through the DME benefit, while insulin delivered through an implanted pump is covered by Part B FFS. Part D covers insulin administered by injection, which is statutorily excluded from coverage under Part B. If the specific delivery method is not indicated on the prescription, the pharmacy must contact the prescribing physician for clarification. This extra step places a burden on the pharmacies. Additionally, as discussed above in reference to anticancer drugs, pharmacies are less familiar with and more resistant to billing Part B.

Beneficiaries are required to have a separate prescription for the syringe (covered by Part D) and a pump (covered by Part B). The actual syringe and pump are not considered in this analysis.

3.3.2 Benefits of Consolidation

Moving all insulin, regardless of dispensing form, to Part D would facilitate pharmacy billing by removing the B versus D determination process. The pharmacy would not have to interpret information on the prescription, nor contact the physician, to determine coverage. In addition, the pharmacy would not have to utilize a less familiar billing process. Finally, the need for the Part B program or Part D plans to maintain systems edits would be removed. While moving insulin dispensed by pump to Part D would mean that insulin solution and pumps would be covered under different programs, a beneficiary receives the pump from a separate provider, not the pharmacy, so covering the two under separate programs should not create additional complexity. This analysis also considers moving insulin administered via a syringe to Part B. Because pharmacies fill prescriptions for insulin vials, however, consolidation under Part B would not address the issues associated with pharmacy billing of Part B. In addition, the current payment limit for insulin in Part B is significantly lower than the median price for insulin in Part D, as discussed further below. If insulin were consolidated under Part B and the payment limit remained unchanged, providers may be resistant to provide the drug at the lower rate.

3.4 Inhalants

There are two main routes for dispensing inhalants: Metered Dose Inhalers (MDIs) and nebulizers. MDIs, which are statutorily excluded from coverage under Part B but may covered by Part D, are hand-held devices that quickly dispense medication to a patient's lungs through inhalation. Nebulizers, which dispense a medicated mist, are typically administered in a hospital setting for patients that are not able to use MDIs; less often, they are used at home. Generally, Part B covers nebulizers under the DME benefit, and medication dispensed in a nebulizer is covered under the same benefit as a supply for the effective use of the equipment.

3.4.1 Current Determination Process

The current determination and billing process for inhalants is straightforward. MDIs are primarily dispensed in pharmacies and covered under Part D, thus facilitating pharmacy billing. Similarly, nebulizer inhalants are typically dispensed in hospital settings, and thus are more easily billed to Part B. In some cases, a beneficiary uses a nebulizer at home and receives the solution from a pharmacy. In these cases, the pharmacy must bill Part B, which as mentioned above, is more complex than the more-familiar Part D process.

3.4.2 Benefits of Consolidation

If MDIs and nebulizer inhalants were consolidated under one program, either pharmacies or hospitals and physicians would have to use a less-familiar billing process. Overall, pharmacies are better positioned to accommodate consolidation of MDIs under Part B because they tend to bill Part B more than hospitals and physicians bill Part D. If nebulizer inhalants were to move to Part D instead, hospitals and physicians would be required to adopt cumbersome billing strategies similar to those used for vaccinations. For inhalants, there are no gains from consolidation for Part B and Part D processing systems. MDIs and inhalants dispensed via nebulizers are easily distinguishable by HCPCS and NDC codes and no edits are required under the current system to reject a given code under some situations and accept it under others.

4 PRE-CONSOLIDATION UTILIZATION PATTERNS

In this chapter, we review pre-consolidation utilization in terms of the number of beneficiaries potentially affected by consolidation, total drug costs, number of annual claims per beneficiary, and annual costs per beneficiary. This section also reviews formulary placement of Part D-covered drugs.

4.1 Overview of Pre-Consolidation Utilization and Costs

Utilization of the drugs considered in this analysis varies, with the number of beneficiaries potentially affected by consolidation ranging from 12,000 beneficiaries taking insulin via a pump to over 3.5 million beneficiaries taking MDIs (Table 4-1).[12] Less than one percent of beneficiaries taking drugs potentially affected by consolidation under Part D take more than one of the drugs; the total number of beneficiaries potentially affected, adjusting for this overlap, is 1.2 million. Six percent of beneficiaries take some combination of the three drug types that would be moved from Part D to Part B. Overall, 4.7 million individual beneficiaries could be affected by consolidation under Part B.

Because the per unit costs of these drugs vary considerably, a large number of beneficiaries taking a particular drug does not necessarily imply that total costs for that drug are high. For example, there are significantly more beneficiaries taking vaccines than anticancer drugs in Part B, but because anticancer drugs tend to be more expensive than vaccines, total Part B costs for these drugs are almost equal. As expected, we tend to see more costs in the program that currently covers the drug. For example, there are no costs of MDIs in Part B because this program currently rejects any such claims. Nebulizer inhalants and injectable insulin should follow this same pattern, but some claims for these drugs are appearing in the inappropriate program. Because anticancer drugs and vaccines are covered by both programs, costs are also split.

[12] The number of beneficiaries potentially affected is defined by the number of beneficiaries taking the drug covered by the program from which the drug will be moved. For example, there are 68,082 beneficiaries taking oral anticancer drugs under Part B.

Table 4-1: Summary of Consolidation Scenarios and Pre-Consolidation Utilization, 2007

Cohort	Current Coverage	Coverage After Consolidation	Number of Beneficiaries Potentially Affected	Total Part B Costs	Total Part D Costs
B to D Drugs					
Anticancer	B	D	68,082	$169,253,702	$174,405,441
Pumped Insulin	B	D	12,269	$10,864,039	$0
Nebulizer Inhalant	B	D	1,101,622	$1,227,000,468	$101,214,796
Combined	B	D	1,177,717	$1,407,118,209	$275,620,237
D to B Drugs					
Vaccine	D	B	353,158	$171,942,067	$54,205,827
Injectable Insulin	D	B	1,096,140	$13,359	$1,059,800,751
MDI	D	B	3,516,650	$0	$2,354,910,321
Combined	B	B	4,695,441	$171,955,426	$3,468,916,899

Source: 2007 Standard Analytical Files: Carrier and DME, 2007 Prescription Drug Event Data

4.2 Part B Utilization

Table 4-2 summarizes the utilization of each type of drug in Part B, including the number of beneficiaries with claims, the average number of claims per beneficiary, and the average cost per beneficiary. Because Part B currently covers the influenza and pneumonia vaccines, it is not surprising that the number of beneficiaries taking vaccines in Part B is almost 13 million. Very few beneficiaries have claims for injectable insulin or MDIs in Part B due to coverage rules. As the conditions treated by anticancer drugs, insulin, and inhalants tend to be chronic, beneficiaries taking these drugs average between four and seven claims a year. Claims for vaccines, on the other hand, average one per beneficiary per year. Beneficiaries taking anticancer drugs incur the highest average cost, at just under $2,500 a year. Average Part B costs for beneficiaries taking inhalants dispensed via a nebulizer and insulin dispensed via a pump are also relatively large.

Table 4-2: Part B Utilization, 2007

Cohort	Number of Beneficiaries Taking the Drug	Average Number of Claims per Beneficiary	Average Annual Cost per Beneficiary
B to D Drugs			
Anticancer	68,082	4.1	$2,486
Pumped Insulin	12,269	5.4	$885
Nebulizer Inhalant	1,101,622	6.5	$1,114
Combined	1,177,717	6.4	$1,194
D to B Drugs			
Vaccine	12,732,079	1.0	$14
Injectable Insulin	267	1.4	$50
MDI	0	0.0	$0
Combined	12,722,264	1.0	$14

Source: 2007 Standard Analytical Files: Carrier and DME

4.3 Part D Coverage and Utilization

To illustrate how formularies would need to expand if Part B drugs were moved to Part D, Table 4-3 presents the average percentage of reference National Drug Codes (NDCs) covered by Part D sponsors for each drug class. With the exception of nebulizer inhalants, the remaining drug classes have coverage rates above 75 percent. Not surprisingly, enhanced plans have higher rates of coverage across drugs.

Table 4-3: Average Percentage of Reference NDCs in Formulary by Plan Type, 2007

Cohort	Standard	Actuarial Equivalent	Basic Alternative	Enhanced
B to D Drugs				
Anticancer	80.4%	80.7%	81.6%	85.7%
Pumped Insulin	78.8%	84.2%	81.5%	86.4%
Nebulizer Inhalant	54.0%	58.7%	59.6%	65.4%
D to B Drugs				
Vaccine	82.1%	83.5%	85.0%	87.2%
Injectable Insulin	78.8%	84.2%	81.5%	86.4%
MDI	74.8%	75.5%	78.3%	82.3%

Source: 2007 Part D Formulary Files

The number of beneficiaries taking each analysis drug in Part D, along with the average number of claims and average annual costs, appear in Table 4-4. Of the analysis drugs, MDIs, anticancer drugs, and injectable insulin are the most common, with over a million beneficiaries taking each. Because antiemetics, which are grouped with anticancer drugs, are commonly used for many other conditions, they appear in Part D even though the program does not cover them for cancer treatment. Table 4-4 also demonstrates that the vaccines covered by Part D are utilized by significantly fewer beneficiaries than those covered by Part B. Vaccines in Part D are considerably more expensive than vaccines in Part B, primarily due to differences in the types of vaccine covered by the programs. The average annual cost for vaccines per beneficiary is $153 in Part D, where the majority of claims are for the herpes zoster vaccine, compared to just $14 in Part B, where most claims are for the relatively inexpensive influenza and pneumonia vaccines. Once again, because health conditions treated by insulin and inhalants tend to be chronic, beneficiaries fill multiple claims for those drugs in a year. Injectable insulin is the most frequently filled, with an average of seven claims per beneficiary per year.

Table 4-4: Part D Utilization, 2007

Cohort	Number of Beneficiaries Taking the Drug	Average Number of Claims per Beneficiary	Average Annual Cost per Beneficiary
B to D Drugs			
Anticancer	1,552,231	3.1	$112
Pumped Insulin	0	0.0	$0
Nebulizer Inhalant	365,360	5.2	$277
Combined	1,872,486	3.6	$147
D to B Drugs			
Vaccine	353,158	1.0	$153
Injectable Insulin	1,096,140	7.0	$967
MDI	3,516,650	5.8	$670
Combined	4,695,441	6.0	$738

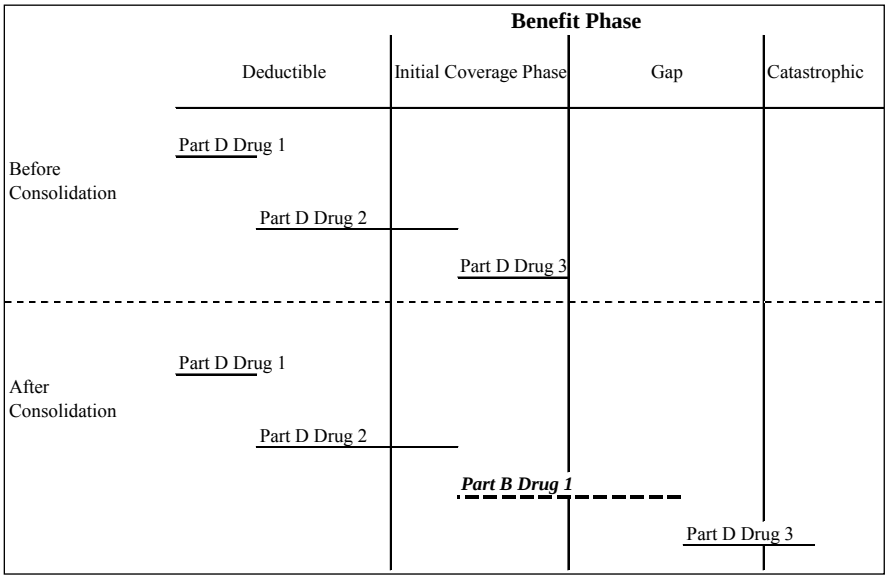
Source: 2007 Prescription Drug Event Data

5 SIMULATION FRAMEWORK

We use a simulation model to assess the financial impact of consolidating the analysis drugs under either the Part B or Part D program. For each cohort of beneficiaries taking these drugs in 2007, the model simulates how much beneficiaries, Medicare, and Part D plans would have paid at point-of-sale had these drugs been covered exclusively under either Part D or Part B. To construct the differences in cost sharing amounts for a given drug as it switches from one program to another, we use as inputs the utilization of the drug in the current program, part B cost sharing, utilization of *other* drugs in Part D, and Part D plan benefit schedules. We also calculate how the additional costs for Part D plans are passed on to beneficiaries and Medicare in the form of higher premiums.

Figure 5-1 illustrates the simulation methodology for cost sharing under Part D. In this example, a beneficiary enrolled in Part D has one Part B drug purchase and three Part D drug purchases. The Part B drug is covered under Part D after consolidation. The beneficiary receives a Part B drug immediately after the second Part D prescription. Before consolidation (top panel), the benefit phase in which each Part D drug occurs does not depend on the Part B drug. After consolidation (bottom panel), however, every Part D drug purchased after the Part B drug is shifted to a higher level in the benefit schedule. In this example, the Part D drug 3 falls into the ICP before consolidation, but would straddle the gap and catastrophic phase once the Part B drug is integrated in the sequence. This changes the point-of-sale amounts that the beneficiary, plan, and Medicare must pay, not only for the newly integrated Part B drug, but also for other Part D drugs.

Figure 5-1: Effects of Consolidation on Benefit Phase, Example



Using information on the benefit structure, as captured in formulary and beneficiary cost files from the Health Plan Management System, and drug prices, which are imputed as described below, the simulation calculates the change in the amount that the beneficiary, the plan, Medicare, and Medicaid pay for drugs after consolidation. We perform these simulations for beneficiaries who took any or a combination of the drugs being assessed, exploiting realized data on their Part D and Part B drug events. Table 5-1 presents the seven major steps of the simulation. The following subsections discuss each step in more detail.

Table 5-1: Simulation Steps for Each Drug in the Analysis

Phase	Step	Part B to Part D	Part D to Part B
Select cohort	1	Each cohort is composed of beneficiaries who took the analysis drug or any combination of analysis drugs in the originating program in 2007.	
Calculate pre-consolidation point-of-sale costs	2	For each beneficiary in the cohort, we calculate the Part B costs of the analysis drugs to the beneficiary, Medicare, and Medicaid. We also observe Part D costs incurred by Medicare, the beneficiary, and plans for *all* Part D drugs. We construct pre-consolidation costs by summing these amounts.	For each beneficiary in the cohort, we calculate the Part D costs incurred by Medicare, the beneficiary, and plans for *all* Part D drugs.
Construct post-consolidation point-of-sale costs	3	*Project Part D Prices:* We map each analysis drug's active ingredient to a set of National Drug Codes (NDCs) and define the median per unit price using Prescription Drug Event (PDE) data. .	*Project Part B Prices:* We map the active ingredient of each analysis drug to a HCPCS code and define the price using the CMS Part B fee schedule. If the fee schedule does not indicate a price, we use the median cost reported in Part B claims. If neither are available, we use the per unit median price of NDCs that map to that active ingredient across all PDEs.

Phase	Step	Part B to Part D	Part D to Part B
	4	*Construct Post-Consolidation Costs for Part D enrollees:* Using information on drug utilization, drug prices and Part D benefit schedules, we insert the Part B analysis drug claims into each beneficiary's sequence of PDE records and simulate the cost sharing amounts of each drug. *Construct Post-Consolidation Costs for Beneficiaries Not Enrolled in Part D:* We predict total pre-consolidation Part D costs of these beneficiaries based on diagnoses and demographic information. For beneficiaries with creditable coverage, we apply the standard benefit to simulate post-consolidation costs. We assume that beneficiaries without creditable coverage have lower expenditures and fit the distribution under an "enrollment indifference" threshold.	*Compute Post-Consolidation Costs:* We remove analysis drugs from a beneficiary's sequence of Part D drugs and apply the Part B cost sharing rules to those drugs.
	5	*Calculate Financial Impacts:* By subtracting pre-consolidation costs from post-consolidation costs at the beneficiary level, we calculate the average change in cost for the beneficiary, Medicare, Medicaid and the Part D plan.	
Calculate changes in plan bids and premiums	6	By aggregating the financial impact across beneficiaries, we calculate the change in average Part D costs and plan liability. These estimates are then used to calculate the impact on premiums.	
Calculate impact on total Medicare costs	7	We calculate the change in total Medicare costs with two main inputs: 1) changes in point of sale costs, calculated in steps 1-5, and 2) changes in Medicare's capitated monthly payments, calculated in step 6.	

5.1 Selecting the Cohort of Beneficiaries

To identify beneficiaries taking one of the six analysis drugs, we define related HCPCS and NDC codes and extract all claims associated with those codes. We use the CMS Claims Processing Manual[13] to identify the HCPCS codes associated with B to D drugs (i.e. anticancer drugs, pumped insulin, and nebulizer inhalants) and extract all associated claims from the 2007 DME, Carrier or Outpatient (OP) claims files. We use information in Medispan and First Data Bank (FDB) to identify NDCs related to D to B drugs (i.e. vaccines, insulin, and MDIs). For vaccines, we identify the NDCs that correspond to the relevant therapeutic classes.[14] We then

[13] CMS Claims Processing Manual: https://www.cms.gov/manuals/downloads/clm104c17.pdf

[14] The therapeutic classes used were W7F (mumps and related virus), W7H (enteric virus), W7J (neurotoxic virus), W7K (antisera), W7L (gram positive cocci), W7M (gram negative bacilli non-enteric), W7N (toxin producing bacilli), W7P (rickettsial), W7Q (gram negative cocci), W7S (antivenins), W7T (antigenic skin tests), W7U

exclude any Part D claims for influenza, pneumonia, and hepatitis B vaccines because they are primarily billed under Part B. To identify insulin drugs, we include NDCs that are labeled insulin by the therapeutic class or the third party restriction code (both are elements of the Generic Product Identifier, GPI, which is defined by the active ingredient, dosage form, and concentration). Finally, to identify MDIs, we include NDCs that have a route of administration of inhalation and a dosage form specifying aerosols, powder, caps, or inhaler. Appendix A lists the HCPCS codes that correspond to each of the drug cohorts.[15] Appendix B shows the active ingredients corresponding to each drug class.

The cohorts for each of the six drug-specific simulations include all beneficiaries who took the drug in 2007 (see Table 4-2 and Table 4-4); that is, a beneficiary may appear in more than one drug-specific cohort. We restrict the cohort size to a maximum of 120,000 individuals obtained by randomly sampling fractions of the population taking a particular drug. This restriction applies to beneficiaries using vaccines, injectable insulin, nebulizer inhalants and MDIs.

Because beneficiaries in the drug cohorts overlap when a beneficiary takes more than one drug, simulation results for each individual drug cohort are not additive. We therefore perform two combined simulations: 1) for all drugs being consolidated under Part D and 2) for all drugs being consolidated under Part B. For a given combined simulation, we create seven cohorts, one for each of the possible combinations of the three drugs being consolidated. A beneficiary appears in only one cohort so that total program effects can be calculated by summing effects for each drug-combination-specific cohort. We again restrict each cohort size to a maximum of 120,000 individuals, obtained by randomly sampling fractions of the relevant population. The populations taking combinations of drugs are generally small relative to the populations taking any particular drug. Therefore, for the combined Part B to Part D simulation, the restricted cohort size applies only for beneficiaries with nebulizer inhalants alone. For the combined Part D to Part B simulation, the restriction applies to beneficiaries using vaccines, injectable insulin, and MDIs individually as well as beneficiaries who use both injectable insulin and MDIs. These beneficiaries were assigned sample weights for the calculation of the combined results.

5.2 Calculating Pre-Consolidation Point-of-Sale Costs

For the purpose of tracking financial impacts, pre-consolidation costs include all payments made by beneficiaries, Medicaid, Medicare and Part D plans for: 1) Part B drugs to be consolidated under D, 2) Part D drugs to be consolidated under B, and 3) *all other* Part D drugs.

(hymenoptera-derived agents), W7V (rhus extracts), W7W (allergenic extracts), and W7Z (vaccine/toxoid preparations, combinations).

[15] We exclude the generic Not Otherwise Classified (NOC) HCPCS values, since they can map to multiple active ingredients.

That is, our measure for pre-consolidation costs excludes all Part B drugs that are not being consolidated. Because the benefit schedule in Part B is linear (the beneficiary pays 20 percent, except for a small deductible), the cost share of other Part B drugs does not change post-consolidation, and therefore this exclusion has no effect on cost changes. The discussion below describes in detail the calculation of pre-consolidation Part B and Part D costs.

5.2.1 Pre-consolidation Part B Costs

For each Part B drug to be consolidated under D (anticancer, pumped insulin, and nebulizer inhalants), we extract all simulation drug claims found in the DME, OP, and Carrier files of the 2007 Summary Analytical Files (SAFs). The Carrier and DME files provide claim-level information on drug quantity, which we multiply by ingredient cost per unit found in a commercial database, First Data Bank, to establish the total ingredient cost of each claim. However, OP claims, which make up approximately 38 percent of total Part B anticancer drug claims, do not contain drug quantity.[16] For these claims, we impute the median quantity based on the distribution of the DME and Carrier claims under the assumption that quantity does not vary by claim type. First Data Bank per unit prices are based on 106 percent of ASP and reflect Medicare' methods for calculating prices (See Section 2.1 for more details). As this file is updated every quarter, we use the date of service on the claim to identify which price within 2007 should be used. After calculating ingredient costs, we add pharmacy supply fees when applicable (anticancer drugs[17]) and administration fees (vaccines[18]).

The total cost of each drug claim is now divided between Medicare, Medicaid, and the beneficiary based on Medicare regulations. The beneficiary pays 20 percent of the Gross Drug Cost (GDC), unless he/she is eligible for Medicaid, in which case Medicaid pays the full beneficiary coinsurance amount. Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the lesser of the 20 percent coinsurance amount and the state's reimbursement rate. To identify which beneficiaries are eligible for Medicaid we use the Enrollment Database (EDB). We aggregate beneficiary, Medicaid, and Medicare claim-level costs to calculate pre-consolidation beneficiary-level costs for each payer under Part B.

5.2.2 Pre-consolidation Part D Costs

Pre-Consolidation Part D costs are calculated from the financial information reported in Prescription Drug Event (PDE) data. We calculate beneficiary costs for each PDE as the sum of

[16] OP claims are 3% of claims for pumped insulin and 0.2% of claims for nebulizer inhalants.
[17] The pharmacy supply fee is found on the Part B claim. It is $24 for the first claim in a 30-day period and $16 for subsequent claims.
[18] $19.93 for 2007.

'patient pay amount' and 'other True Out-of-pocket (TrOOP) amount'. For non-catastrophic claims, Medicare is responsible for paying Low-Income Cost Sharing (LICS) subsidy amounts, which are also reported on the claim. For these claims, the GDC is only shared between the beneficiary and the Part D plan; hence the liability of the plan equals the difference between GDC and the sum of beneficiary costs and patient liability reduction due to other payer amount (PLRO).

In the catastrophic range, the beneficiary generally pays 5 percent of GDC, with the plan covering 15 percent, and Medicare covering 80 percent. In the cases when the beneficiaries pay the alternative minimum amount of $2.15/$5.35, we reduce the plan's liability first, and start reducing Medicare's share if the alternative minimum is greater than 20 percent of GDC.

5.3 Projecting Post-Consolidation Prices

We now must simulate what beneficiaries would have paid if the drugs had been covered under a different program. To do so, we must first infer Part D prices for drugs currently covered under Part B and assign Part B prices for drugs currently covered under Part D. We then use new prices to calculate post-consolidation drug costs. Finally, we follow the corresponding benefit structure to allocate costs across beneficiaries, Medicare and Medicaid.

5.3.1 Pricing Part B Drugs under Part D Coverage

To determine drug prices (i.e., ingredient costs) under Part D for each Part B to D drug, we use the active ingredient and strength information for HCPCS codes and their corresponding NDCs. Because NDC codes are more specific than HCPCS codes in certain dimensions (e.g., NDCs are specific to brand/generic, manufacturer and package size), one HCPCS code generally maps to multiple NDCs. Therefore, we must map each HCPCS to a group of NDCs that share the same active ingredient and strength. To do so, we first map HCPCS to Generic Sequence Numbers (GCN-SEQNO), which are unique descriptions of active ingredient, strength, route of administration, and form. We then remove the GCN-SEQNOs that do not correspond to the route of administration defined by the HCPCS code. We also exclude compound GCN-SEQNOs; we require that the active ingredient in the HCPCS description be the only active ingredient. Table 5-2 provides an example of the HCPCS to GCN-SEQNO mapping for an anti-cancer drug. The HCPCS is originally mapped to three GCN-SEQNOs; two are removed because they are not oral. After creating a list of GCN-SEQNOs, we use First Data Bank to map them to individual NDCs. We then extract all 2007 PDEs with a Product Service ID corresponding to this list.

Table 5-2: Example of HCPCS to GCN-SEQNO Mapping

HCPCS Description	Potential GCN-SEQNOs	Description of Potential GCN-SEQNOs	Meets Inclusion Criteria
J8510: Busulfan 2 mg	008777	Busulfan Tablet Oral 2 mg	yes
	041626	Busulfan Ampul (Ml) Intravenous 60 mg/10 ml	no
	063053	Busulfan Vial (Sdv, Mdv Or Additive) (ml) Intravenous 60 mg/10 Ml	no

Based on this mapping and information found in the Part B claims, we now assign a Gross Drug Cost (GDC) to each Part B claim being moved to Part D based on Part D pricing as observed in PDE data. Each claim's GDC is calculated by summing the ingredient cost – which is the product of the quantity, strength and unit price per milligram – with the dispensing fee. This amount is then multiplied by 1 plus the sales tax rate.

$$GDC_i = \left(quantity_b * strength_b * p_j^D + df\right) * (1 + tax)$$

Where

Quantity is reported in the Part B claim. For OP claims, since quantity is not reported, we take the median quantity of Carrier and DME claims for each drug.

Strength is taken from the HCPCS description.

p_j is the median unit price per milligram obtained from PDE data.

df is the dispensing fee as reported in PDE data. Because there is practically no variation in dispensing fee across NDCs, for every HCPCS, we take the median dispensing fee among all PDE records within that HCPCS.

tax is the sales tax rate charged at the state level. Because sales tax is seldom charged for these drugs, we assume a sales tax of zero.

We use the product of quantity, strength, and unit price per milligram as the ingredient cost, instead of the one reported on the PDE record, because the HCPCS strength does not necessarily correspond to the strength of all NDCs that are mapped to that particular HCPCS. Therefore, we calculate the HCPCS distributions of unit price by pooling the prices per milligram from all 2007 PDE records that correspond to each HCPCS code.

5.3.2 Pricing Part D Drugs under Part B Coverage

We construct post-consolidation prices under Part B by using the published Part B Payment Allowance Limit for the HCPCS that corresponds to the Part D claim NDC, whenever possible.[19] Insulin and most vaccines are priced in this fashion. In cases where the HCPCS does not appear in the pricing file, we construct the post-consolidation price as the observed median price in Part B data distributions for the specific HCPCS code. This is the method used for the Zoster vaccine, which accounts for more than 95 percent of Part D vaccine GDCs in 2007. Because MDIs are not currently covered by Part B, neither a Payment Allowance Limit nor Part B claims are available. In the absence of this information, we assume that Part B prices determined after consolidation would be similar to those in Part D and price the claim at the median per unit GDC within active ingredient, across all PDE data.

5.3.3 Post-Consolidation Pricing Effects

To assess the implications of the pricing simulation methods on total costs, Table 5-3 compares total drug costs under Part B and under Part D for all simulation drugs. For each drug type, an asterisk indicates total costs are predicted using the pricing methods described above. The last column in Table 5-3 shows the ratio of Part D to B costs. For example, anticancer drugs cost three percent more under Part D compared to Part B. Except for insulin, Part D prices are comparable to Part B rates. Insulin prices under Part D are about 52 percent higher compared to Part B reimbursement rates, because Part B rates for all infusion drugs provided through DME, including insulin, are set by statue at the AWP that was in effect on October 1, 2003.

Table 5-3: Comparison of Part B and D Costs, by Drug Type

Cohort	Total Costs under Part B	Total Costs under Part D Prices	Part D/Part B
B to D Drugs			
Anticancer	$169,253,702	$174,146,877*	1.03
Pumped Insulin	$10,864,039	$16,466,355*	1.52
Nebulizer Inhalant	$1,227,000,468	$1,424,907,959*	1.16
D to B Drugs			
Vaccine	$56,769,278*	$54,205,827	0.95
Injectable Insulin	$686,682,816*	$1,059,800,751	1.54
MDI	$2,334,224,423*	$2,354,910,321	1.01

*Simulated prices

[19] ASP Pricing files for 2007 are available at http://www.cms.gov/McrPartBDrugAvgSalesPrice/01b_2007aspfiles.asp#TopOfPage.

5.4 Computing Beneficiary Cost Share, Plan Covered Payments and Medicare Costs

With the reconstructed sequence of drug events and associated prices, we compute the new beneficiary, plan and Medicare costs for each beneficiary and drug event. For beneficiaries enrolled in Part D this exercise involves integrating information from the benefit structure of the Part D plan in which the beneficiary is enrolled, along with his/her LIS status, to recalculate costs. For beneficiaries not enrolled in Part D, this exercise requires the estimation of unobserved drug costs and assumptions about unobserved drug coverage. Because these conjectures depend on whether a beneficiary has creditable coverage, we consider those two groups of non-Part D beneficiaries separately. That is, we use a different method for calculating post-consolidation cost share for each one of the following three groups: 1) Part D enrollees, 2) not enrolled in Part D, with creditable coverage, and 3) not enrolled in Part D, without creditable coverage. We describe each method in detail below.

5.4.1 Part D Enrollees

For the beneficiaries enrolled in Part D, the calculation of post-consolidation financial impacts for B to D simulations is straightforward. We add the simulation drugs to the sequence of original Part D drugs for the beneficiary. We then re-compute payments by the beneficiary, the Part D plan, and Medicare. Appendix C provides details on our methods for using Part D benefit structure, formulary and pharmacy data to recalculate beneficiary cost share, plan covered payments and Medicare costs for any sequence of drug events.

The calculation of post-consolidation costs for the D to B simulations merely involves removing the simulation claims from Part D and recalculating the cost shares of the beneficiary, the Part D plan, and Medicare. Additionally, the PDEs that are deleted from Part D appear in Part B, where we apply the Part B cost sharing rules between the beneficiary, Medicare, and Medicaid. Finally, we aggregate the amounts paid under Part B and Part D to obtain total post-consolidation for each party.

5.4.2 Beneficiaries With Creditable Coverage

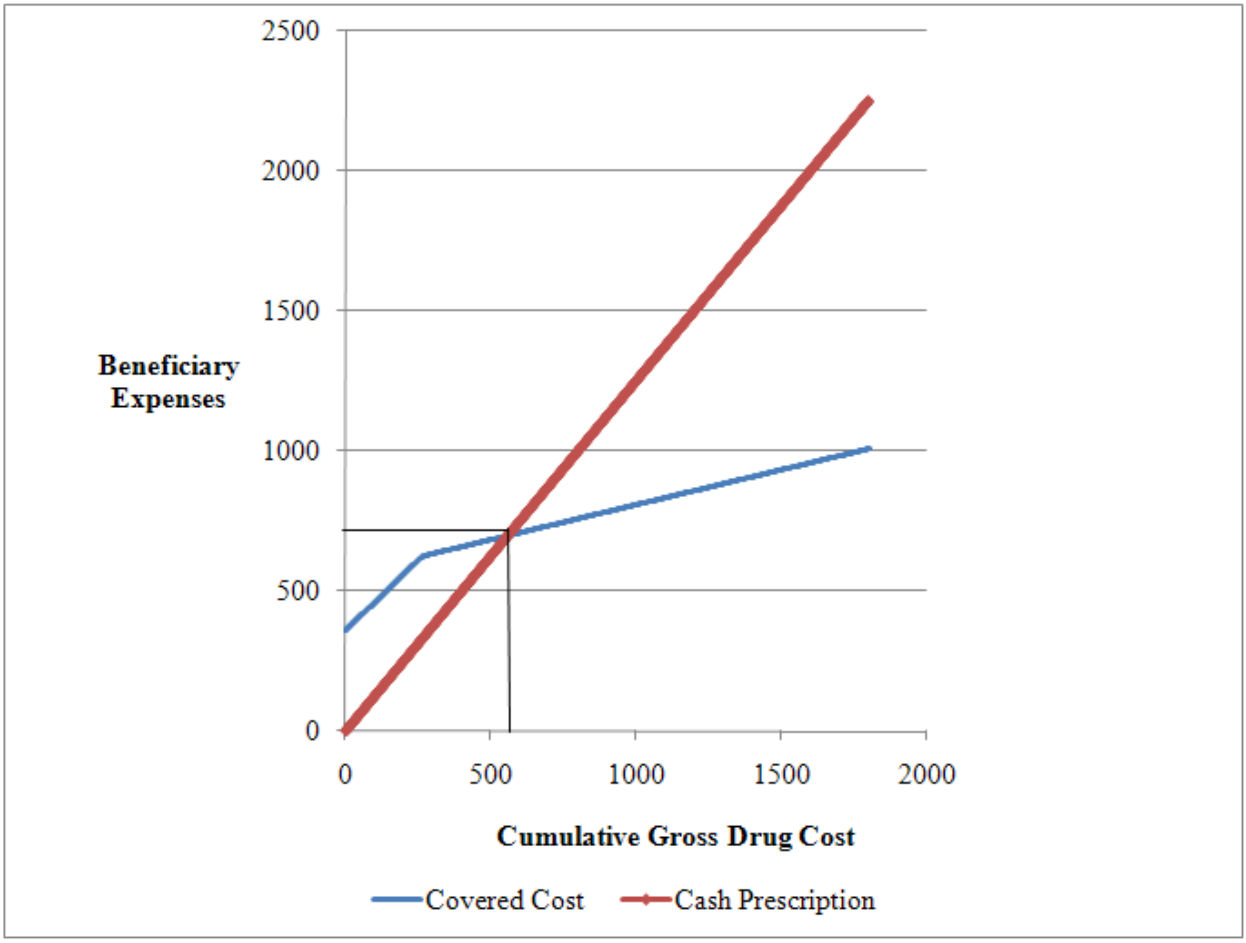
For these beneficiaries, we resolve the problem of unobserved annual drug costs by extrapolating results from an OLS regression on a sample of Part D beneficiaries who were not eligible for LIS in 2007. More specifically, we regress the natural logarithm of annual beneficiary gross drug costs on demographic characteristics (gender, bracketed values of age) and diagnostic data (RxHCC indicator variables, which are included in Medicare's Part D risk adjustment model). We run separate regressions for each cohort. We then obtain predicted

annual GDC for the creditable coverage beneficiaries, which serves as the base for pre-consolidation calculations for this group of beneficiaries. Since creditable coverage plans need to be at least actuarially equivalent to the standard Part D plan, we use the standard benefit structure to approximate the cost sharing of benefits under Part D. We further assume that creditable coverage beneficiaries will continue to use their current health insurance instead of enrolling into a PDP plan after B to D consolidation.

5.4.3 Beneficiaries Without Creditable Coverage

We also do not observe pre-consolidation prescription drug GDC for beneficiaries without creditable coverage. We assume that the decision not to enroll or obtain creditable coverage is due to very low prescription drug needs. Figure 5-2 illustrates the identification of the maximum amount of GDC for which not enrolling is cheaper than enrolling in a standard plan. The covered cost curve plots the relationship between GDC and TrOOP for a non-LIS beneficiary. It is a stepwise linear function with a knot at the beginning of the initial coverage phase, where GDC is $265. The cash prescription curve presents the linear relationship between GDC and no-insurance out-of-pocket costs, accounting for the fact that the GDC of a prescription is higher if the person does not have prescription drug insurance. By using the commercial database Verispan, we found that in 2007, pharmacy prices of drugs were on average 25 percent higher in the absence of insurance. The slope of the cash prescriptions curve is adjusted accordingly. With an annual premium of $360, the indifference point between enrolling and not enrolling falls in the ICP at $559. We use predicted GDC values from the OLS regression described above, rescaling them so that their distribution is bounded in the range (0,559). This approach ensures that beneficiaries with higher risk scores are imputed to incur higher prescription costs. After the addition of the Part B drugs under Part D, we assess whether it is more beneficial to enroll in Part D than to remain without coverage. The costs of enrolling also include late enrollment penalties. A beneficiary's premium increases by one percent of the average premium for each month of non-enrollment.

Figure 5-2: Relationship between GDC and Beneficiary Expenses



5.5 Calculating the Financial Impact on Beneficiaries

For each beneficiary in the simulation sample, we calculate beneficiary-level post-consolidation cost sharing amounts by simply summing costs for the beneficiary, Medicare, and the plan across all of the beneficiary's drugs. By subtracting each beneficiary's pre-consolidation costs, calculated in Step 4, from post-consolidation costs, we calculate the change in costs for the beneficiary, Medicare, and Part D plans.

5.6 Calculating Changes in Premiums

When drugs are consolidated under Part D, Part D plans begin to cover drugs previously provided under Part B. We assume that plans cover the increased costs by increasing their Part D bids. Since we do not observe manufacturer rebates to plans, which affect drug costs, we also assume that the increase in the Part D bid for each plan is proportional to the increase in plan liability after consolidation. The pre- and post-consolidation Part D plan expenditures for each beneficiary are computed by our benefit administration algorithm. On the other hand, as coverage of some drugs shifts away from Part B, Part B premiums fall. We assume that the relative change in Part B premiums equals the relative change in total Part B costs. Analogously, in D to B simulations, Part B premiums increase and Part D premiums fall due to the changes in coverage.

5.7 Calculating the Overall Financial Impact on Medicare

The financial impact on Medicare is derived from changes in 1) point-of-sale costs and 2) changes in monthly capitated payments made to Part D plans. Changes in point of sale costs, which are calculated in steps 1-5, refer to changes in LICS payments, reinsurance payments, and Medicare's cost share in Part B. Changes in monthly capitated payments include changes in Direct Subsidies and LIPS and are based on the change in bids caused by consolidation.

5.8 Limitations

This analysis has several limitations. First, it does not take into consideration all potential effects of consolidation. Legislation mandates that certain drugs are covered under Part B with specific payment rules and that other drugs are excluded from the program. New legislation would need to pass in order to allow for consolidation under certain scenarios. In addition, we do not address the administrative costs of any systems changes needed to implement consolidation, such as adding drugs to or removing drugs from payment calculation methods or disseminating information about changes to providers. We also do not take into consideration costs incurred by providers in adopting new coverage rules.

We also faced limitations related to drug pricing for MDIs and injectable insulin. Our simulation for moving MDIs from Part D to Part B uses Part D prices to impute the prices that would be paid in Part B. Because there are no claims for MDIs in Part B under current rules, Part D prices are the best available source of information. However, if post-consolidation Part B prices for MDIs were significantly different from those currently paid in Part D, the effects on beneficiaries, Medicare, and Part D plans would differ from those presented in the simulation findings. In addition, under current law, prices for insulin are significantly higher in Part D than in Part B. If injectable insulin moved to Part B with no increase in the allowable payment limit, providers may refuse to dispense the drug, creating access problems for beneficiaries. This may place pressure on Medicare to increase the reimbursement amount for insulin in Part B – for both injectable and pumped insulin. If the payment limit for insulin increased, the net increase in Medicare's costs resulting from consolidation under Part B would rise as well.

6 THE IMPACT OF CONSOLIDATION UNDER PART D

In this section, we describe our findings from the simulations that move drugs from Part B to Part D. In Section 6.1, we present the pre-consolidation costs for the beneficiary, Medicare, Medicaid, and Part D plans. Section 6.2 discusses post-consolidation costs for each stakeholder and the change in cost by a variety of beneficiary characteristics. The overall financial impact of consolidation under Part D on total Medicare costs is discussed in Section 6.3.

6.1 Pre-Consolidation Costs of Beneficiaries, Medicaid, Medicare, and Part D Plans

Part B costs for anticancer drugs, insulin dispensed by pump, and nebulizer inhalants are split between beneficiaries, Medicare, and, for beneficiaries who are dual-eligible, Medicaid. Table 6-1 describes how Part B average drug costs for beneficiary cohorts taking drugs currently covered by Part B are divided among those stakeholders. Because Part B costs for non-analysis drugs are the same before and after consolidation, they are omitted. The first three rows of the table separate beneficiaries into cohorts based on consumption of each individual drug. The total number of beneficiaries affected by consolidation, displayed in the final row of the table, is less than the sum of the beneficiaries in each specific cohort because a beneficiary may take more than one of the analysis drugs. Average costs per beneficiary in Part B are highest for beneficiaries taking anticancer drugs; the average cost per beneficiary affected by consolidation is $2,487. Consistent with program rules, Medicare pays about 80 percent of Part B costs for all beneficiaries in these cohorts, with the remainder paid by the beneficiary and, for dual-eligibles, Medicaid.

Table 6-1: Part B Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicaid and Medicare, by Cohort, 2007

Cohort	Number of Beneficiaries	Part B Costs		
		Beneficiary	Medicaid	Medicare
Anticancer	68,082	$385	$113	$1,989
Pumped Insulin	12,269	$137	$40	$708
Nebulizer Inhalant	1,101,622	$126	$95	$886
Combined	1,177,717	$145	$97	$968

Source: 2007 Standard Analytical Files
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.
Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.

Part D cost sharing for non-analysis drugs may change as a result of consolidation. Part D costs for all drugs taken by the beneficiary are therefore included in Table 6-2, which describes the breakdown of Part D point-of-sale costs for the beneficiary, Medicare, and the Part D plan. Note that Plan Covered Payments for point-of-sale costs are ultimately covered by the premiums paid by the beneficiary and Medicare. Medicaid does not make payments under Part D and is omitted. Medicare Part D point-of-sale costs are separated into LICS payments (payments made by Medicare on behalf of LIS eligible beneficiaries) and reinsurance payments for beneficiaries who end in the catastrophic coverage phase (where Medicare covers 80 percent of the costs). Part D average costs per beneficiary for beneficiaries in each of the specific drug cohorts fall into a relatively narrow range between $3,049 and $3,450. Of the three specific drug groups, Medicare pays the largest share of point-of-sale costs for beneficiaries with insulin dispensed by pump, at 50 percent. Those beneficiaries pay 16 percent of their point-of-sale Part D costs and the plan covers 34 percent. Medicare pays about 49 percent of pre-consolidated Part D costs for all beneficiaries taking a drug or combination of drugs to be consolidated under Part D.

Table 6-2: Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by Cohort, 2007

Cohort	Number of Beneficiaries	Part D Costs			
		Beneficiary	Medicare: LICS	Medicare: Reinsurance	Plan Covered Payments
Anticancer	68,082	$678	$477	$962	$1,032
Pumped Insulin	12,269	$692	$672	$603	$1,082
Nebulizer Inhalant	1,101,622	$562	$1,001	$722	$1,165
Combined	1,177,717	$613	$964	$754	$1,161

Source: 2007 Standard Analytical Files
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.

Table 6-3 presents the combined Part B and Part D average pre-consolidation costs paid by the beneficiary, Medicare, and the Part D plans. Total costs are highest for those who took anticancer drugs ($5,905) and lower for beneficiaries with nebulizer inhalants ($4,748) and pumped insulin ($4,172). Total costs covered by Medicare range from 48 percent of total drug costs for all beneficiaries with pumped insulin to 58 percent of total drug costs for all beneficiaries with cancer. On average, Medicare covers 55 percent of combined point-of-sale Part B and Part D drug costs for beneficiaries potentially affected by consolidation.

Table 6-3: Combined Part B and Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, Medicaid and Plans, by Cohort, 2007

Cohort	Number of Beneficiaries	Part B and Part D Costs	Part B and Part D Pre-Consolidation Costs				
			Beneficiary	Medicare	Medicaid	Plan	Creditable Coverage Insurance Plan
Anticancer	68,082	$5,905	$1,152	$3,428	$113	$1,032	$181
Pumped Insulin	12,269	$4,172	$908	$1,984	$40	$1,082	$158
Nebulizer Inhalant	1,101,622	$4,748	$750	$2,609	$95	$1,165	$129
Combined	1,177,717	$4,911	$821	$2,686	$97	$1,161	$147

Source: 2007 Standard Analytical Files
Creditable coverage insurance amounts reflect estimated, not actual, data.
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.
Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.

The distribution of pre-consolidation Part B costs across beneficiaries is presented in Table 6-4. Costs for beneficiaries with anticancer drugs are considerably more skewed than those for beneficiaries with pumped insulin or nebulizer inhalants. The distribution of combined Part B costs is also significantly skewed, which implies that the effect of consolidation will vary considerably across beneficiaries.

Table 6-4: The Distribution of Part B Pre-Consolidation Point-of-Sale Costs for Beneficiaries with B to D Drugs, 2007

Cohort	Number of Beneficiaries	Cost at 25th percentile	Cost at 50th percentile	Cost at 75th percentile	Mean
Anticancer	68,082	$245	$808	$2,595	$2,486
Pumped Insulin	12,269	$296	$754	$1,208	$885
Nebulizer Inhalant	1,101,622	$170	$498	$1,290	$1,108
Combined	1,177,717	$171	$519	$1,340	$1,210

Source: 2007 Standard Analytical Files
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.

6.2 Post-Consolidation Costs under Part D

After inserting Part B drug claims in each beneficiary's Part D drug sequence, the share of total costs attributed to beneficiaries, Medicare, and Part D plan sponsors will change. This section presents results for post-consolidation costs for each stakeholder. It also discusses how

the change in cost varies among beneficiaries with different levels of Plan D utilization and LIS status.

6.2.1 Change in Costs for Beneficiaries, Medicare, Medicaid, and Part D Plans

We present the post-consolidation costs for each stakeholder in Table 6-5. In Table 6-6, we present the average change in cost for each stakeholder from simulations for each type of drug, followed by the average change in cost for each stakeholder in the combined simulation in the last row. The average change in cost is defined as post-consolidation cost less pre-consolidation cost.

The average cost per beneficiary rises for each drug cohort moving from Part B to Part D, increasing by two percent for all beneficiaries taking anticancer drugs, 12 percent for pumped insulin, and four percent for nebulizer inhalants. In the combined simulation, the average cost per beneficiary rises by five percent. Consolidation under Part D reduces Medicare's share of the average cost per beneficiary for all three types of drugs individually and in the combined simulation. Medicare's share of point-of-sale costs per beneficiary falls from 58 to 43 percent for anticancer drugs, from 48 to 35 percent for pumped insulin, from 55 to 47 percent for nebulizer inhalants, and from 55 to 47 percent for the combined simulation. Increases in payments from beneficiaries finance about 40 percent of the decline in Medicare's share of point-of-sale costs for anticancer drugs and insulin pumps and slightly more than half of the decline for nebulizers. About half of the decline in Medicare's share of point-of-sale costs in the combined simulation is covered by the increase in the beneficiary's share of costs.

Table 6-5: Total Post-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare and Plans, by B to D Cohort

Cohort	Number of Beneficiaries	Cost Per Beneficiary Post-Consolidation	Beneficiary	Medicare: LICS	Medicare: Reinsurance	Plan Covered Payments	Creditable Coverage Insurance Plan
Anticancer	68,082	$6,034	$1,543	$672	$1,942	$1,588	$289
Pumped Insulin	12,269	$4,689	$1,334	$802	$831	$1,531	$193
Nebulizer Inhalant	1,101,622	$4,960	$1,037	$1,283	$1,087	$1,387	$165
Combined	1,177,717	$5,134	$1,088	$1,156	$1,234	$1,456	$199

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Creditable coverage insurance amounts reflect estimated, not actual, data.
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.

Table 6-6: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for B to D Drugs, by Cohort

Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
Anticancer	68,082	$391	-$814	-$113	$556
Pumped Insulin	12,269	$426	-$351	-$40	$448
Nebulizer Inhalant	1,101,622	$287*	-$239*	-$95*	$223*
Combined	1,177,717	$267*	-$296*	-$97*	$296*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.
* Statistically significant at a 95% confidence level.

6.2.2 Change in Costs by Part D Characteristics

Table 6-7 illustrates how the change in costs due to consolidation varies by Part D characteristics, including Part D enrollment status, Part D utilization, Part D benefit type and LIS eligibility. We use anticancer drugs as an example.

By construction, the costs for beneficiaries who are not currently enrolled in Part D and do not enroll after consolidation change relatively little. In contrast, the costs for beneficiaries who enroll after consolidation shift from Medicare to beneficiaries and plans, while the costs for beneficiaries with other coverage shift to beneficiaries and the creditable coverage plans.

We observe significant variation in the change in costs for beneficiaries with different initial levels of utilization in Part D. The beneficiaries' original benefit phase affects cost change because the inclusion of the Part B drugs can push them into different phases, where they experience different cost sharing amounts. For example, beneficiaries who end in the catastrophic coverage phase see payment reductions, whereas most beneficiaries in all other phases experience payment increases. This is consistent with the fact that instead of paying the 20 percent coinsurance amount in Part B, the beneficiary is consuming more drugs in the catastrophic coverage phase with a five percent coinsurance amount. Medicare, on the other hand, pays more point-of-sale costs for these catastrophic beneficiaries, with a $150 increase in payments for beneficiaries taking anticancer drugs. Similar patterns are observed when consolidating pumped insulin and nebulizer inhalants under Part D (see Table F- 1 and Table F-2 in Appendix F).

Table 6-7: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for Anticancer Drugs, by Part D characteristics

Beneficiary Characteristics Related to Part D (Pre-Consolidation)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
All	68,082	$391	-$814	-$113	$556
Part D Enrollment Status					
Enrolled in Part D	44,839	$309	-$590	-$171	$538
Not Enrolled in Part D, No Creditable Coverage; Not Enrolling after Reform	5,461	$125	-$136	$0	$0
Not Enrolled in Part D, No Creditable Coverage; Enrolling after Reform	11,835	$872	-$1,662	$0	$1,212
Not Enrolled in Part D, Creditable Coverage	5,947	$371	-$1,578	$0	$0
Part D Utilization					
Ended in Deductible (Low)	2,177	$326	-$911	-$176	$873
Ended in ICP (Low)	21,816	$454	-$938	-$123	$703
Ended in Gap (Medium)	12,910	$353	-$403	-$169	$299
Ended in Catastrophic (High)	7,936	-$166	$150	-$304	$382
Part D Benefit Type					
Standard	6,631	$272	-$504	-$214	$550
Alternative Basic	19,669	$292	-$501	-$200	$484
Actuarially Equivalent	5,374	$67	-$85	-$370	$472
Enhanced	10,948	$444	-$1,000	-$27	$683
800 Series Plans	1,934	$489	-$795	-$4	$375
Unknown Type	283	$448	-$1,085	-$54	$785
LIS Eligibility Status					
Not Eligible	27,371	$520	-$1,023	$0	$590
Eligible	17,459	-$23	$89	-$439	$456

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Creditable coverage amounts reflect estimated, not actual, data.

LIS eligibility status is also a strong determinant of post-consolidation changes in payments for the beneficiary and Medicare. LIS eligible beneficiaries are very likely Medicaid eligible under Part B, and are only responsible for a small fraction of total cost of their drugs under either Part B or Part D. In our sample, LIS beneficiaries' average payment decreases by $23. Medicare payments for point-of-sale costs increase for these beneficiaries because they are taking on costs that were previously covered by Medicaid. In contrast to LIS beneficiaries, non-eligible beneficiaries on average spend $520 more after consolidation as they face higher coinsurance rates under Part D and do not receive cost sharing subsidies.

Table 6-8 presents the distribution of cost changes across beneficiaries by LIS status. The average increase in beneficiary payments for drugs consolidated under Part D comes from a distribution with large payment increases for beneficiaries at the high end of the distribution in the LIS ineligible groups. For anticancer drugs, non-LIS beneficiaries up to the 25th percentile have small changes in payments, while 24 percent of beneficiaries have payment increases of $1000 or more. Cost changes for beneficiaries with pumped insulin and nebulizer inhalants have a similar distribution, with 25 and 21 percent of beneficiaries paying more than $1000 more post-consolidation. For the combined simulation, 21 percent of non-LIS beneficiaries pay more than $1000 in increased costs after consolidation. LIS beneficiaries experience small changes since the vast majority of them are also Medicaid eligible and hence bear a small fraction of the cost under either Part B or Part D.

Table 6-8: Distribution of Beneficiary Point-of-Sale Cost Change for B to D Drugs, by Cohort

Cohort	Number of Beneficiaries	Average Change in Beneficiary Costs	Distribution of Cost Change			Percent of Beneficiaries With Change Over $1,000
			25th	50th	75th	
Anticancer	68,082	$391	$0	$67	$495	17%
Non-LIS	27,371	$520	$0	$139	$1,020	25%
LIS	17,459	-$23	-$4	$3	$9	1%
Pumped Insulin	12,269	$426	$5	$198	$665	15%
Non-LIS	4,721	$586	$40	$383	$981	24%
LIS	3,625	$9	$0	$5	$23	0%
Nebulizer Inhalant	1,101,622	$287	-$1	$6	$233	10%
Non-LIS	317,089	$553	-$7	$78	$744	21%
LIS	499,555	-$13	-$11	$1	$4	0%
Combined	1,177,717	$267	$0	$8	$241	10%
Non-LIS	348,526	$487	-$2	$91	$728	21%
LIS	518,122	-$11	$1	$4	-$14	0%

Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.

6.2.3 Price and Coverage Effects

Since total change in cost may be a reflection of change in coverage or price, we decompose the change of cost into the amount resulting from the price change (the shift from the Part B price to the typical Part D price) and the amount resulting from the change of coverage rules. Table 6-9 presents these findings for drugs consolidated under Part D. For anticancer drugs, almost all of the change in cost is explained by the change in coverage. For pumped insulin, the increase in price under Part D explains about 40 percent of the total change in cost. The price effect also contributes to the change in cost for nebulizer inhalants; that effect is driven primarily by an increase in spending on one inhalant[20] under Part D.

Price and coverage effects affect stakeholders differently, although those patterns are common to all three of the Part B to D drugs. Table 6-10 presents the disaggregated price and coverage effects by Part D characteristics for anticancer drugs as a representative example. Both the price and coverage factors tend to increase beneficiary spending, except for those beneficiaries who originally end in the coverage gap, who originally end in the catastrophic coverage phase, and who are LIS eligible. In most cases, Medicare payments increase because of the price effect, but decrease because of the coverage effect.

Table 6-9: Disaggregated Price and Coverage Effects for B to D Drugs, by Drug Cohort

Cohort	Beneficiary			Medicare			Plan Covered Payments		
	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect
Anticancer	$391	-$1	$392	-$814	$64	-$879	$556	$1	$554
Pumped Insulin	$426	$175	$251	-$351	$136	-$487	$448	$137	$312
Nebulizer Inhalants	$287	$52	$235	-$239	$104	-$342	$223	$5	$218

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for the nebulizer inhalant cohort are based on a sample.

[20] Ipratropium/Albuterol, which is sold under the brand name Combivent and is unavailable as a generic, accounts for about 25 percent of total spending on nebulizer inhalants in Part B, but rises to 40 percent of spending on nebulizer inhalants in Part D at typical Part D prices.

Table 6-10: Disaggregated Price and Coverage Effects of Change in Point-of-Sale Costs by Beneficiary Characteristics, Anticancer Drugs

Beneficiary Characteristics Related to Part D (Pre)	Beneficiary			Medicare			Plan Covered Payments		
	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect
All	$391	-$1	$392	-$814	$64	-$879	$556	$1	$554
Part D enrollment Status									
Enrolled in Part D	$309	$1	$308	-$590	$77	-$667	$538	$8	$530
Not Enrolled in Part D, No Creditable Coverage; Not Enrolling after Reform	$125	-$30	$155	-$136	-$17	-$118	$0	$0	$0
Not Enrolled in Part D, No Creditable Coverage; Enrolling after Reform	$872	$50	$822	-$1,662	$18	-$1,680	$1,212	$31	$1,181
Not Enrolled in Part D, Creditable Coverage	$371	-$21	$393	-$1,578	$0	-$1,578	$0	$0	$0
Part D Utilization									
Ended in Deductible (Low)	$326	$16	$310	-$911	$89	-$1,000	$873	$7	$865
Ended in ICP (Low)	$454	$8	$445	-$938	$85	-$1,023	$703	$3	$700
Ended in Gap (Medium)	$353	-$13	$366	-$403	$77	-$481	$299	$16	$284
Ended in Catastrophic (High)	-$166	$0	-$167	$150	$51	$100	$382	$10	$371
Part D Benefit Type									
Standard	$272	$6	$266	-$504	$88	-$592	$550	$9	$540
Alternative Basic	$292	-$3	$295	-$501	$71	-$573	$484	$7	$478
Actuarially Equivalent	$67	$0	$66	-$85	$76	-$161	$472	$7	$464
Enhanced	$444	$4	$440	-$1,000	$82	-$1,082	$683	$14	$670
800 Series Plans	$489	$5	$484	-$795	$73	-$868	$375	-$13	$388
Unknown Type	$448	$16	$432	-$1,085	$71	-$1,156	$785	$8	$778
LIS Eligibility Status									
Not Eligible	$520	$2	$518	-$1,023	$78	-$1,101	$590	$7	$583
Eligible	-$23	-$1	-$22	$89	$76	$14	$456	$9	$447

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.

6.2.4 Changes in Bids and Premiums

We assume that changes in plan liabilities due to consolidation are fully passed on to Part D plan bids. Under this assumption, the percent change in bids is equal to the percent change in plan liability. To calculate the percent change in plan liability, we use the change in average plan-covered costs, presented in Table 6-11. The change in average costs is largest for anticancer drugs and lowest for pumped insulin. The beneficiaries that are potentially affected represent a small share of all Part D participants—less than one percent for anticancer drugs and pumped insulin and about five percent for nebulizer inhalants. Plan liability for the average beneficiary therefore changes relatively little, by less than one percent in all three cases. Accordingly, average national bids are mostly unchanged.

For the combined simulation, the change in average plan-covered costs is $264. The percentage of beneficiaries affected remains around five percent, so the change in average plan liabilities is one percent. The increase in the average bid is therefore less than one dollar for the consolidation of all three types of drugs.

Table 6-11: Expected Part D Premium Changes for B to D Consolidation, by Cohort

Cohort	Average Plan Cost for Beneficiaries Pre-Consolidation	Average Plan Cost for Beneficiaries Post-Consolidation	Post-Pre Average Costs	Percent Change in Costs	Post-Consolidation Average Bid	Change in Average Bid
Anticancer	$1,567	$2,106	$539	0.1%	$75.66	$0.09
Pumped Insulin	$1,571	$1,735	$164	0.0%	$75.57	$0.00
Nebulizer Inhalant	$1,703	$1,981	$278*	0.9%	$76.23	$0.66*
Combined	$1,500	$1,764	$264*	1.0%	$76.33	$0.76*

Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.
* Statistically significant at a 95% confidence level.

The same methodology can be applied to calculate post-consolidation Part B premiums, assuming that the change in premiums is proportional to the change in costs. As demonstrated in Table 6-12, the estimated changes in Part B premiums are minimal. With over $176 billion spent on Part B overall in 2007,[21] the impact of changing the coverage status of these drugs is small.

[21] 2008 Annual Report of the Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, accessed at http://www.cms.gov/ReportsTrustFunds/downloads/tr2008.pdf.

Table 6-12: Expected Part B Premium Changes for B to D Consolidation, by Cohort

Cohort	Total Part B Costs	Percent Change in Costs	Post-Consolidation Part B Premium	Change in Post-Consolidation Part B Premium
Anticancer	$135,415,098	-0.1%	$93.43	-$0.07
Pumped Insulin	$8,691,237	0.0%	$93.50	-$0.00
Nebulizer Inhalant	$976,378,595	-0.6%	$92.98	-$0.52
Combined	$1,120,484,930	-0.6%	$92.90	-$0.60

Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.

6.3 Total Financial Impact on Medicare

The total financial impact on Medicare is derived from the changes in point of sale costs presented in section 6.2.1 and the changes in capitated payments presented in 6.2.4. For Part D, point of sale costs are divided into LICS and reinsurance payments; capitated payments are separated into those for direct subsidies and LIPS payments. The effect of consolidation on each of these payment mechanisms will vary. For example, consolidation will have a larger effect on LICS and LIPS when the share of LIS-eligible beneficiaries is large, while the effect on direct subsidies will rise with the number of beneficiaries affected.

Medicare's share of point-of-sale costs is greater in Part B than in Part D for all beneficiaries except those in the catastrophic coverage phase. Because of that benefit structure, consolidation under Part D would tend to reduce Medicare's total payments at given drug prices unless a large share of beneficiary costs is in the catastrophic phase. We find that consolidation under Part D does reduce Medicare's total payments for each drug type and for the combined simulation (see Table 6-13). Of the individual drugs, moving nebulizer inhalants to Part D causes the largest reduction in net Medicare costs primarily because of the large number of beneficiaries affected. In the combined simulation for all three drugs consolidated under Part D, consolidation reduces Medicare's total payments by $150 million, or 0.4% percent of total Part D spending on prescription drugs in 2007.

Medicare's total payments fall after consolidation because the elimination of Part B cost sharing for these drugs is not completely offset by increases in Part D costs. Almost 90 percent of eliminated Part B cost sharing is offset by increased costs in Part D. The majority, nearly 60 percent, of the increase in Part D costs comes from increased reinsurance payments for beneficiaries in the catastrophic phase; the remaining 40 percent is split almost equally between payments for low-income cost-sharing and direct subsidies.

Table 6-13: Total Financial Impact of B to D Consolidation on Medicare

Cohort	Change in Medicare Payments (in thousands)					
		Part D				
	Part B	LICS	Reinsurance	Direct Subsidy	LIPS	Total
Anticancer	-$135,403	$13,262	$66,705	$20,614	$0	-$34,822
Pumped Insulin	-$8,691	$1,588	$2,792	$3,332	$0	-$979
Nebulizer Inhalant	-$976,379	$310,823*	$402,753*	$157,987*	$14,377*	-$90,439*
Combined	-$1,140,230	$226,699*	$565,069*	$182,050*	$17,017*	-$149,395*

LICS refers to Low-Income Cost Sharing; LIPS refers to Low-Income Premium Subsidies.
Cost statistics for the nebulizer inhalant and combined cohorts are based on samples.
* Statistically significant at a 95% confidence level.

7 THE IMPACT OF CONSOLIDATION UNDER PART B

In this section, we describe our findings from the simulations that move drugs currently covered by Part D to Part B. In Section 6.1, we present the pre-consolidation costs for the beneficiary, Medicare, and plans. Section 6.2 discusses change in costs for each stakeholder. Finally, Section 6.3 describes how consolidation under Part B would affect total Medicare spending for beneficiaries taking these drugs.

7.1 Pre-Consolidation Costs of Beneficiaries, Medicare, and Part D Plans

Part D costs for vaccines, injectable insulin, and MDIs are shared between beneficiaries, Medicare, and Part D plan sponsors. Again, because changes in Part D coverage affects cost sharing for all Part D drugs, the costs for all of the Part D drugs taken by a beneficiary are included. The first three rows of Table 7-1 report the pre-consolidation average cost of all Part D drugs for beneficiaries in each individual drug cohort. Beneficiary payments in Part D can be decomposed into spending on the analysis drug and spending on other drugs. Beneficiary cost is lowest for vaccines and highest for injectable insulin; beneficiary spending on other drugs is highest for beneficiaries with injectable insulin, but is within a relatively narrow range for all three drug cohorts. Total Medicare costs are lowest for beneficiaries with vaccines both in terms of dollar value and percentage of total costs paid; Medicare pays 25 percent of costs for beneficiaries with vaccines in Part D but almost 50 percent of costs for beneficiaries with injectable insulin and MDIs. Part D plan payments range from just under 40 percent of average costs for beneficiaries with injectable insulin and MDIs to 50 percent for beneficiaries with vaccines.

The final row of the table presents the average pre-consolidation costs for all beneficiaries in the combined simulation. Medicare pays about 45 percent of the average cost for all beneficiaries potentially affected by consolidation. Plan payments are about 40 percent of average costs in the combined simulation.

Table 7-1: Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by Cohort, 2007

Cohort	Number of Beneficiaries	Total Cost Per Beneficiary Pre-Consolidation	PRE-Consolidation Costs				
			Beneficiary: Simulation Drug	Beneficiary: Non Simulation Drug	Medicare: LICS	Medicare: Reinsurance	Plan
Vaccine	353,158	$2,405	$36	$571	$353	$238	$1,207
Injectable Insulin	1,096,140	$5,243	$160	$597	$1,509	$1,104	$1,872
MDI	3,516,650	$4,093	$118	$491	$1,087	$815	$1,582
Combined	4,695,441	$4,067	$129	$508	$1,076	$765	$1,589

Source: 2007 Standard Analytical Files
Cost statistics for all cohorts are based on samples.

Table 7-2 presents the distribution of costs for vaccines, injectable insulin, and MDIs. Most beneficiaries spend relatively little on vaccines, resulting in a negatively skewed distribution. Costs for MDIs and injectable insulin are positively skewed, as are costs in the combined simulation.

Table 7-2: The Distribution of Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries with D to B Drugs, 2007

Cohort	Number of Beneficiaries	25%	50%	75%	Mean
Vaccine	353,158	$156	$162	$166	$154
Injectable Insulin	1,096,140	$297	$671	$1,276	$967
MDI	3,516,650	$89	$287	$954	$667
Combined	4,695,441	$128	$346	$1,037	$734

Source: 2007 Standard Analytical Files
Cost statistics for all cohorts are based on samples.

7.2 Post-Consolidation Costs Under Part B

After moving Part D claims for vaccines, injectable insulin, and MDIs from each beneficiary's Part D drug sequence to Part B, the share of total costs attributed to beneficiaries, Medicare, and Part D plan sponsors changes. This section presents results for post-consolidation costs for each stakeholder. We also discuss how the change in cost varies among beneficiaries with different pre-consolidation levels of Plan D utilization and LIS status.

7.2.1 Change in Costs for Beneficiaries, Medicare, and Part D Plans

Table 7-3, Table 7-4, and Table 7-5 report the Part B, Part D, and combined Parts B and D post-consolidation costs for beneficiaries taking drugs consolidated under Part B. Moving drugs from Part D to Part B generates either little change or a decrease in overall average cost per beneficiary (see Table 7-5). Because spending on MDIs and vaccines is small relative to total spending, average costs for beneficiaries in those drug cohorts remain essentially unchanged after consolidation. After consolidation, the cost per beneficiary of injectable insulin falls by six percent compared to pre-consolidation. However, Medicare's share of total costs per beneficiary rises by four to six percent for all three types of drugs. In the combined simulation, the average cost per beneficiary falls by two percent, and Medicare's share of Part B and Part D costs falls by about five percent.

Table 7-3: Part B Post-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by Cohort

Cohort	Number of Beneficiaries	Part B		
		Beneficiary	Medicaid	Medicare
Vaccine	353,158	$31	$4	$126
Injectable Insulin	1,096,140	$76	$65	$486
MDI	3,516,650	$83	$61	$518
Combined	4,695,441	$83	$59	$505

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Cost statistics for all cohorts are based on samples.

Table 7-4: Part D Post-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by Cohort

Cohort	Number of Beneficiaries	Part D			
		Beneficiary	Medicare: LICS	Medicare: Reinsurance	Plan Covered Payments
Vaccine	353,158	$565	$342	$230	$1,113
Injectable Insulin	1,096,140	$585	$1,280	$807	$1,605
MDI	3,516,650	$478	$934	$669	$1,345
Combined	4,695,441	$494	$907	$594	$1,337

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.

Table 7-5: Total Post-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by D to B Cohort

Cohort	Number of Beneficiaries	Total Cost Per Beneficiary Post-Consolidation	Total Post-Consolidation Costs			
			Beneficiary	Medicare	Medicaid	Plan Covered Payments
Vaccine	353,158	$2,412	$597	$698	$4	$1,113
Injectable Insulin	1,096,140	$4,903	$661	$2,572	$65	$1,605
MDI	3,516,650	$4,087	$560	$2,121	$61	$1,345
Combined	4,695,441	$3,980	$577	$2,006	$59	$1,337

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.

The change in costs for each stakeholder is presented in Table 7-6. For MDIs and vaccines consolidated under Part B, relatively small decreases in beneficiary payments and larger decreases in plan liabilities are offset by small increases in payments from Medicaid and larger increases in payments from Medicare. This pattern also holds in the combined simulation. The decline in average cost per beneficiary for injectable insulin is composed of decreases in payments from Medicare and beneficiaries, plus a decline in plan liabilities. These are partially offset by an increase in payments from Medicaid.

Table 7-6: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for D to B Drugs, by Cohort

Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
Vaccine	353,158	-$10*	$107*	$4*	-$93*
Injectable Insulin	1,096,140	-$96*	-$41*	$65*	-$268*
MDI	3,516,650	-$49*	$219*	$61*	-$237*
Combined	4,695,441	-$60*	$165*	$59*	-$252*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.

7.2.2 Change in Costs by Part D Characteristics

For drugs consolidated under Part B, the change in cost by Part D utilization also varies, but with different patterns than observed for drugs consolidated under Part D. The breakdown of these costs by Part D characteristics for MDIs is presented in Table 7-7. Payments from beneficiaries with claims for vaccines and MDIs tend to decline for those in the low and medium utilization categories, while rising for those with high utilization. Medicare payments follow the opposite pattern. Most of the change in cost for vaccines and MDIs for LIS eligible beneficiaries is picked up by Medicaid under Part B, while lower coinsurance rates under Part B compared to Part D mean that non-LIS beneficiaries tend to pay less and Medicare more after consolidation.

Table 7-7: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for MDIs, by Part D characteristics

Beneficiary Characteristics Related to Part D (Pre-consolidation)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
All	3,516,650	-$49*	$219	$61*	-$237*
Enrollment					
FFS	2,413,830	-$66*	$191*	$74*	-$211*
HMO	1,008,919	-$59*	$334*	$34*	-$306*
Neither	93,901	$500*	-$306*	$0*	-$176*
Part D Utilization					
Ended in Deductible (Low)	51,198	-$6*	$9*	$6*	-$9*
Ended in ICP (Low)	1,463,355	$0	$226*	$18*	-$244*
Ended in Gap (Medium)	1,291,696	-$138*	$371*	$55*	-$293*
Ended in Catastrophic (High)	710,401	$10*	-$57*	$163*	-$138*
Part D Benefit Type					
Standard	489,792	-$27*	$97*	$90*	-$168*
Alternative Basic	1,295,893	-$48*	$160*	$73*	-$195*
Actuarially Equivalent	475,200	$11*	$33*	$112*	-$168*
Enhanced	1,021,263	-$98*	$360*	$20*	-$285*
800 Series Plans	230,629	-$8*	$572*	$3*	-$549*
Unknown Type	3,873	-$17*	$23*	$139*	-$160*
LIS Eligibility Status					
Not Eligible	1,685,588	-$126*	$445*	$0*	-$317*
Eligible	1,831,062	$22*	$11*	$117*	-$163*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.

The pattern of change in cost for beneficiaries with injectable insulin by Part D characteristics is slightly different and is presented in Table 7-8. As for the other Part D to B drugs, beneficiaries pay slightly less after consolidation and the decline is largest for those who were initially in the gap. Medicare payments fall substantially for those who end in the catastrophic phase, but rise for most other beneficiaries. Medicare payments for LIS eligible beneficiaries fall by much more for these beneficiaries than for the other Part D to B drugs, but the changes for non-LIS eligible beneficiaries are similar.

Table 7-8: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for Injectable Insulin, by Part D characteristics

Beneficiary Characteristics Related to Part D (Pre)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan Covered Payments
All	1,096,140	-$96*	-$41*	$65*	-$268*
Enrollment					
FFS	780,496	-$107*	-$99*	$77*	-$229*
HMO	284,116	-$146*	$155*	$38*	-$380*
Neither	31,528	$621*	-$390*	$0*	-$208*
Part D Utilization					
Ended in Deductible (Low)	3,589	-$6*	-$22*	$7*	-$7*
Ended in ICP (Low)	269,560	-$14*	$177*	$19*	-$337*
Ended in Gap (Medium)	482,388	-$208*	$138*	$43*	-$293*
Ended in Catastrophic (High)	340,603	-$3*	-$469*	$133*	-$179*
Part D Benefit Type					
Standard	161,284	-$41*	-$204*	$94*	-$195*
Alternative Basic	404,386	-$71*	-$153*	$80*	-$198*
Actuarially Equivalent	159,094	$9*	-$274*	$104*	-$186*
Enhanced	312,164	-$216*	$217*	$20*	-$350*
800 Series Plans	57,741	-$69*	$448*	$5*	-$746*
Unknown Type	1,471	-$20*	-$149*	$107*	-$151*
LIS Eligibility Status					
Not Eligible	452,950	-$264*	$332*	$0*	-$389*
Eligible	643,190	$23*	-$304*	$110*	-$183*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.

Table 7-9 shows the distribution of beneficiary cost changes for the three drugs consolidated under Part B. Some beneficiaries with claims for injectable insulin benefit from a decline in payments, but payments for most beneficiaries are changed very little. In the combined simulation, the average change in beneficiary cost declines for non-LIS beneficiaries and increases slightly for LIS beneficiaries. Eleven percent of non-LIS beneficiaries benefit from a decline of more than $500.

Table 7-9: Distribution of Beneficiary Point-of-Sale Cost Change for D to B Drugs, by Cohort

Cohort	Number of Beneficiaries	Average Change in Beneficiary Costs	25th	50th	75th	Percent of Beneficiaries With Change Under $500
Vaccine	353,158	-$10	-$20	$0	$10	0%
Non-LIS	292,757	-$15	-$25	$0	$15	0%
LIS	60,401	$12	-$3	$0	$0	0%
Injectable Insulin	1,096,140	-$96	-$75	-$10	$0	8%
Non-LIS	452,950	-$264	-$393	-$110	-$15	20%
LIS	643,190	$23	-$16	-$2	$0	0%
MDI	3,516,650	-$49	-$33	-$6	$0	5%
Non-LIS	1,685,588	-$126	-$113	-$19	$3	9%
LIS	1,831,062	$22	-$12	-$3	$0	0%
Combined	4,695,441	-$60	-$40	-$6	$1	5%
Non-LIS	2,356,286	-$141	-$138	-$22	$5	11%
LIS	2,339,155	$23	-$14	-$3	$0	0%

Cost statistics for all cohorts are based on samples.

7.2.3 Price and Coverage Effects

Because the total change in cost reflects changes in both coverage and price, we decompose the change in cost into the portion associated with the price change and the portion associated with the coverage change. Table 7-10 presents the disaggregated changes for the three drugs consolidated under Part B. For vaccines and MDIs, the effect comes almost entirely from changes in coverage. For injectable insulin, the price effect of moving to the lower prices in Part B accounts for a substantial share of the total change in cost for both beneficiaries and Medicare. However, for beneficiaries, the coverage effect also lowers payments, while for Medicare, the coverage effect leads to an increase in payments that almost completely offsets the price effect.

Table 7-10: Disaggregated Price and Coverage Effects for D to B Drugs, by Drug Cohort

Cohort	Beneficiary			Medicare			Plan Covered Payments		
	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect
Vaccine	-$10	$2	-$12	$107	$5	$102	-$93	$0	-$93
Injectable Insulin	-$96	-$31	-$65	-$41	-$273	$232	-$268	$0	-$268
MDI	-$49	$1	-$49	$219	-$5	$224	-$237	$0	-$237

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.

Table 7-11 shows the disaggregated changes for beneficiaries with vaccines by Part D characteristics. The price effect of moving from Part D to Part B lowers beneficiary payments for all levels of utilization; as expected, the coverage effect is largest for beneficiaries who were originally in the gap in Part D. The coverage effect increases Medicare payments for beneficiaries originally in the ICP and gap, but decreases payments for beneficiaries in the catastrophic phase. The price effect increases Medicare payments.

Table 7-11: Disaggregated Price and Coverage Effects of Change in Point-of-Sale Costs by Beneficiary Characteristics, Vaccines

Beneficiary Characteristics Related to Part D (Pre)	Beneficiary			Medicare			Plan Covered Payments		
	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect
All	-$10	$2	-$12	$107	$5	$102	-$93	$0	-$93
Enrollment									
FFS	-$26	$1	-$26	$103	$4	$99	-$78	$0	-$78
HMO	$0	$2	-$2	$120	$7	$113	-$113	$0	-$113
Neither	$163	$26	$137	-$52	$0	-$52	-$84	$0	-$84
Part D Utilization									
Ended in Deductible (Low)	-$31	$3	-$34	$101	$8	$93	-$61	$0	-$61
Ended in ICP (Low)	$4	$2	$2	$124	$6	$119	-$123	$0	-$123
Ended in Gap (Medium)	-$51	$1	-$53	$97	$5	$92	-$45	$0	-$45
Ended in Catastrophic (High)	$13	$1	$12	-$4	$5	-$9	-$19	$0	-$19
Part D Benefit Type									
Standard	-$27	$1	-$28	$103	$4	$99	-$76	$0	-$76
Alternative Basic	-$5	$2	-$7	$101	$5	$95	-$93	$0	-$93
Actuarially Equivalent	$0	$2	-$2	$36	$5	$31	-$46	$0	-$46
Enhanced	-$26	$1	-$27	$124	$5	$119	-$93	$0	-$93
800 Series Plans	$9	$2	$7	$124	$7	$117	-$123	$0	-$123
Unknown Type	-$1	$0	-$1	-$6	$7	-$14	-$7	$0	-$7
LIS Eligibility Status									
Not Eligible	-$15	$2	-$17	$126	$5	$121	-$104	$0	-$104
Eligible	$12	$2	$10	$16	$6	$10	-$42	$0	-$42

Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums. Cost statistics for all cohorts are based on samples.

7.2.4 Changes in Bids and Premiums

We calculate the change in Part D bids as discussed above, by assuming that changes in plan liabilities due to consolidation are fully passed on. Therefore, the percent change in bids is equal to the percent change in plan liability. To calculate the percent change in plan liability, we again use the change in average costs, presented in Table 7-12. The projected decrease in average costs for consolidation of individual drug types ranges from $94 for vaccines to $267 for injectable insulin. Patients with claims for vaccines and injectable insulin represent a relatively small share of all Part D participants, and plan liability for those beneficiaries therefore changes by less than one percent. About 20 percent of Part D participants have claims for MDIs, but plan liability for the average beneficiary still changes relatively little, by less than three percent. Accordingly, average national bids are mostly unchanged. The decrease in the average bid is less than $1 for vaccines and injectable insulin and about $2 for MDIs.

The average change in costs for combined consolidation of all three drug types under Part B is $252. About 27 percent of all Part D beneficiaries would be affected by consolidation of all three drugs; the total increase in plan liability is under four percent. Even in this case, the average national bid changes relatively little; it declines by just under $3.

Table 7-12: Expected Part D Premium Changes for D to B Consolidation, by Cohort

Cohort	Average Plan Cost for Beneficiaries Pre-Consolidation	Average Plan Cost for Beneficiaries Post-Consolidation	Post-Pre Average Costs	Percent Change in Costs	Post-Consolidation Average Bid	Change in Average Bid
Vaccine	$1,207	$1,113	-$94*	-0.1%	$75.47	-$0.10*
Injectable Insulin	$1,872	$1,605	-$267*	-0.8%	$75.00	-$0.57*
MDI	$1,582	$1,345	-$237*	-2.6%	$73.64	-$1.93*
Combined	$1,589	$1,337	-$252*	-3.6%	$72.84	-$2.73*

Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.

Using the assumption that Part B premiums would increase in the same proportion to cost changes, we estimate that changes in Part B premiums are also relatively small, as shown in Table 7-13. For any single drug type, the change in Part B costs is never larger than one percent. Changes in Part B premiums are therefore quite small.

Table 7-13: Expected Part B Premium Changes for D to B Consolidation, by Cohort

Cohort	Total Part B Costs	Percent Change in Costs	Post-Consolidation Part B Premium	Change in Post-Consolidation Part B Premium
Vaccine	$44,338,987	0.0%	$93.52	$0.02
Injectable Insulin	$532,724,040	0.3%	$93.78	$0.28
MDI	$1,820,780,704	1.0%	$94.47	$0.97
Combined	$2,368,990,848	1.4%	$94.76	$1.26

Cost statistics for all cohorts are based on samples.

7.3 Total Financial Impact on Medicare

The overall impact of consolidation under Part B on Medicare's total payments is derived from the changes in point of sale costs presented in section 7.2.1 and the changes in capitated payments presented in 7.2.4. Medicare pays a smaller share of drug costs in Part D than in Part B unless a beneficiary is in the catastrophic coverage phase. Thus, for given drug prices, consolidation under Part B will tend to increase Medicare's total payments unless current costs are concentrated in the catastrophic phase. In the simulations for vaccines and MDIs, Medicare's payments increase as a result of consolidation under Part B (see Table 7-14). For vaccines, the fall in all Part D costs offsets almost 70 percent of the increase in Part B costs, while for MDIs the offset is closer to 90 percent.

Consolidating insulin under Part B would reduce Medicare's total payments. Moving to the lower mandated price of insulin in Part B has a larger effect on total Medicare costs for injectable insulin than does Medicare's increased cost sharing in that program. Because the Part B payment limit for insulin is significantly lower than insulin prices in Part D, the consolidation of insulin under Part B could lead to pressure for increases in the payment allowance, which would reduce Medicare's cost savings from consolidation. For example, if all insulin consolidated under Part B was priced at the median Part D price, a reasonable upper bound for an updated payment limit, the new price would be 54 percent more expensive than the current Part B payment limit. The change in Part B payments for injectable insulin would thus increase by that amount, while the change in Part D costs would remain the same. Medicare's Part B payments for insulin delivered via pump would also increase. Overall, consolidating insulin under Part B at the median Part D price would increase Medicare's total payments for insulin by $96 million, compared to a decrease of $196 million in total payments if the Part B price is used.

Table 7-14: Total Financial Impact of D to B Consolidation on Medicare

Cohort	Change in Medicare Payments (in thousands)					
		Part D				
	Part B	LICS	Reinsurance	Direct Subsidy	LIPS	Total
Vaccine	$44,339	-$3,719*	-$2,779*	-$24,041*	$0*	$13,800*
Injectable Insulin	$532,724	-$251,838*	-$325,904*	-$137,385*	-$13,641*	-$196,045*
MDI	$1,820,781	-$537,590*	-$512,763*	-$463,682*	-$47,557*	$259,189*
Combined	$2,368,991	-$793,389*	-$802,357*	-$652,675*	-$68,693*	$51,877*

LICS refers to Low-Income Cost Sharing; LIPS refers to Low-Income Premium Subsidies.
Cost statistics for all cohorts are based on samples.
*Statistically significant at a 95% confidence level.

In the combined simulation of consolidating all three drugs, Medicare's net payments increase by $52 million, 0.1 percent of total Part D prescription drug spending (see Table 7-14). Consolidating under Part B increases payments for Part B cost sharing, but 98 percent of the increase in payments under Part B is offset by reductions in Part D costs. Reduced reinsurance payments for beneficiaries in the catastrophic coverage phase and reduced low-income cost sharing each account for about 35 percent of the fall in Part D payments and declines in direct subsidies to Part D plans account for another 28 percent.

The choice of price for insulin in Part B does not affect the change in Part D payments, but total payments for cost-sharing in Part B would rise by 12 percent in the combined simulation if the price for all insulin was set at the median price in Part D rather than at the Part B payment limit. Thus, the increase in Medicare's net payments as a result of consolidation would be larger. In the combined simulation, Medicare's net payments would increase by $344 million if the median Part D price is used for insulin, in contrast to $52 million with insulin at the current Part B price.

8 SENSITIVITY ANALYSIS

Consolidation under either Part B or Part D would affect the relative attractiveness of different plans in Part D for beneficiaries. Moving drugs between programs would also alter the relative prices of drugs that may be clinically substitutable in some cases. This section explores some of the ways in which beneficiaries could respond to these changes and how such responses affect the results of the simulation.

8.1 Plan Switching

Because moving coverage from Part B to Part D changes the drug basket of beneficiaries already enrolled in Part D, these beneficiaries may be encouraged to change plans. The plan chosen by the beneficiary may have been a good choice before consolidation, but provide unattractive cost sharing, relative to alternative plans, for the newly added simulation drugs.

To assess the financial incentive for beneficiaries to switch plans, we use all of a beneficiary's drug claims from 2007 to recalculate liability under all of the alternative plans in the PDP region of residence, for each non-LIS beneficiary. We perform these calculations using the pre-consolidation basket and then using the post-consolidation basket. Before consolidation, only about ten percent of beneficiaries choose the plan that provides the lowest cost given their observed drug consumption. Because beneficiaries may not be able to predict their drug consumption, this does not necessarily imply that plan choice is irrational. The average beneficiary chooses a plan that is cheaper than about 70 percent of available plans, which provides some evidence that plan choice is sensitive to costs. However, the average saving that a beneficiary could realize from switching to a cheaper plan before consolidation is about $140.

After coverage consolidation, drug consumption patterns in Part D change, and so do relative beneficiary costs under alternative plans. As alternative plans become more attractive, a beneficiary is more likely to switch. To account for the observed patterns of beneficiary plan choice, we assume that a beneficiary switches plans if the average amount that could be saved by enrolling in the available cheaper plans increases by more than a certain threshold. For example, consider a beneficiary who could save an average of $200 by switching to one of the other available plans. When the threshold is $20, this beneficiary switches plans if consolidation increases the average saving from alternative plans to more than $220; this implies that beneficiaries are extremely sensitive to increases in average saving. When the threshold is $100, the beneficiary switches plans if consolidation increases the average saving from alternatives to more than $300. Thus, as the threshold increases, fewer beneficiaries switch plans. For beneficiaries that switch, we calculate the post-consolidation cost based on an alternative plan chosen randomly from the set of cheaper plans.

Table 8-1 presents the number and percentage of beneficiaries who switch plans in the simulation for three different choices of the threshold. The table also includes the average savings from alternative plans before and after consolidation. The increase in average savings from choosing a cheaper plan is larger under consolidation from Part B to Part D than from Part D to Part B, so beneficiaries are more likely to switch plans under consolidation from Part B to Part D. For consolidation under Part D, the proportion of beneficiaries who would change Part D plans after consolidation is 5 percent when the average increase in saving required to induce a switch must be greater than $100 and 10 percent when the average increase in saving must be greater than $20. For consolidation under Part B, only one percent of beneficiaries would change plans when the average increase in saving required to cause a switch must be greater than $100. With a more aggressive threshold of $20, the percentage who switch rises to 6 percent. The average beneficiary who switches after Part D to B consolidation generally saves less than the average beneficiary who switches after Part B to D consolidation.

Table 8-1: Effect of Threshold Choice on Beneficiary Plan Switching After Consolidation

Cohort	Increase in Potential Savings Required to Induce Switch	Number of Beneficiaries Switching	Percent of All Beneficiaries Switching	Average Savings for Switching Beneficiaries	
				Pre-Consolidation (Potential)	Post-Consolidation (Simulated)
Combined B to D	$20	124,081	10%	$121	$299
	$50	91,789	8%	$118	$356
	$100	63,970	5%	$117	$438
Combined D to B	$20	298,479	6%	$133	$201
	$50	133,636	3%	$150	$274
	$100	50,711	1%	$174	$395

Source: 2007 Standard Analytical Files
Cost statistics for all cohorts are based on samples.

We use these results to explore the effect of plan switching on the change in Medicare's total payments caused by consolidation. For the combined consolidation of anticancer drugs, pumped insulin, and nebulizer inhalants under Part D, allowing beneficiaries to switch plans increases the change in Part D costs as a result of consolidation. By switching plans, beneficiaries are able to pass more of the additional cost to plans, which implies higher premiums paid by Medicare and all Medicare beneficiaries. With a threshold of $100, the increase in total post-consolidation Part D costs is eight percent larger than the increase without switching (see Table 8-2). As the threshold falls and more beneficiaries switch plans, the change in post-consolidation Part D costs rises; with a threshold of $20, the increase in Part D costs is

nine percent larger than the increase without switching (see Table 8-2). Plan switching increases the offsetting rise in Part D costs but does not affect the decline in Medicare's costs from eliminating Part B cost sharing, so the overall impact of switching is to decrease the total financial impact of consolidation under Part D. With plan switching, the decline in Medicare's payments from moving these drugs from Part B to D is smaller. As a share of total Part D costs, however, the effect is small. Medicare's total payments decline by 0.1 percent when the simulation includes plan switching with a threshold of $20, compared to 0.4 percent when the switching effect is excluded.

Table 8-2: Total Financial Impact of B to D Consolidation on Medicare, Including Plan Switching

Cohort	Increase in Potential Savings Required to Induce Switch	Change in Medicare Payments (in thousands)					
			Part D				
		Part B	LICS	Reinsurance	Direct Subsidy	LIPS	Total
Combined B to D	$20	-$1,140,230	$226,699	$547,898	$278,244	$25,019	-$62,371
	$50	-$1,140,230	$226,699	$547,721	$274,836	$24,816	-$66,159
	$100	-$1,140,230	$226,699	$548,722	$268,003	$24,187	-$72,620
	no switching	-$1,140,230	$226,699	$565,069	$182,050	$17,017	-$149,395

LICS refers to Low-Income Cost Sharing; LIPS refers to Low-Income Premium Subsidies.
Cost statistics for all cohorts are based on samples.
Medicare's payments for low-income cost-sharing remain the same under all thresholds because the beneficiaries eligible for that subsidy are not permitted to change plans in the simulation.

In the combined consolidation of vaccines, injectable insulin, and MDIs under Part B, allowing plan switching lowers the decrease in Part D costs that results from consolidation, but the effect of switching is small. Because switching reduces drug costs in the catastrophic phase of coverage, Medicare's payments for reinsurance fall by more with switching. However, when beneficiaries choose plans with more attractive cost sharing from their perspective, Medicare's payments for direct plan subsidies increase by more than in simulations without switching, and this effect is larger than the effect on reinsurance. For all choices of threshold, the change in the decline in Part D costs is less than one percent (see Table 8-3). Incorporating plan switching thus has a minimal impact on the overall change in Medicare's payments from consolidation under Part B. Because the financial impact of consolidation under Part B is very small relative to total Part D costs even when plan switching is not included, the effect of plan switching is negligible.

Table 8-3: Total Financial Impact of D to B Consolidation on Medicare, Including Plan Switching

Cohort	Increase in Potential Savings Required to Induce Switch	Change in Medicare Payments (in thousands)					
			Part D				
		Part B	LICS	Reinsurance	Direct Subsidy	LIPS	Total
Combined D to B	$20	$2,368,991	-$793,389	-$822,890	-$625,217	-$66,065	$61,430
	$50	$2,368,991	-$793,389	-$813,532	-$638,872	-$67,052	$56,146
	$100	$2,368,991	-$793,389	-$810,950	-$642,342	-$67,653	$54,657
	no switching	$2,368,991	-$793,389	-$802,357	-$652,675	-$68,693	$51,877

LICS refers to Low-Income Cost Sharing; LIPS refers to Low-Income Premium Subsidies.
Cost statistics for all cohorts are based on samples.
Medicare's payments for low-income cost-sharing remain the same under all thresholds because the beneficiaries eligible for that subsidy are not permitted to change plans in the simulation.

8.2 Drug Substitution

Consolidation could also affect a beneficiary's or provider's choice of how to administer a drug. Part B currently covers insulin administered through pumps, while Part D covers injectable insulin. If the insulin drugs were consolidated under Part B or Part D, the relative costs of using pumped and injectable insulin would change post-consolidation. As discussed above, insulin is 52 percent more expensive in Part D because Part B payments for insulin administered through DME are set by statute. After consolidation, some beneficiaries might switch from pumped insulin to injectable insulin because of the decline in the relative cost of injectables. A similar effect could arise in the case of nebulizer inhalants and MDIs, since the Part B and Part D drugs share active ingredients and hence might in some circumstances be clinically substitutable. We also explore whether consolidation reduces financial incentives to substitute for a drug in a different form. For example, with current coverage rules, a beneficiary who reaches catastrophic coverage would have an incentive to request an MDI instead of a nebulizer inhalant, if possible, in order to pay the lower cost share in Part D.

We explore whether beneficiaries respond to changes in relative prices and use the cheaper drug by comparing insulin utilization patterns between two groups of beneficiaries. The first group consists of non-LIS eligible beneficiaries who reached the catastrophic benefit phase and used insulin in either Part B or Part D in each of three phases: before reaching the coverage gap, while being in the coverage gap, and in the catastrophic coverage phase. This group of beneficiaries faces a constant 20 percent coinsurance rate under Part B, while the cost sharing under Part D varies by benefit phase: 25 percent in the ICP, 100 percent in the coverage gap, and 5 percent in the catastrophic phase. If financial incentives affect a patient's decision to choose a

Part B or Part D drug, we should observe substitution away from the Part D drugs while the beneficiary is in the coverage gap, and increased use of the Part D drug relative to the Part B drug in the catastrophic phase.

The second group of beneficiaries is chosen similarly, but is comprised of beneficiaries who are Medicaid eligible. The switching incentives at the benefit phase seams do not exist for this group, which makes it a good comparison group. Table 8-4 reports the percentages of beneficiaries using only the Part B drug, only the Part D drug, and using both, by benefit phase.

Table 8-4: Part B and Part D Insulin Utilization by Benefit Phase and LIS Status

Beneficiary Status	Deductible/ICP			Coverage Gap			Catastrophic			Total Beneficiaries
	B Only	D Only	B and D	B Only	D Only	B and D	B Only	D Only	B and D	
Non-LIS	0.2%	99.7%	0.1%	0.2%	99.6%	0.2%	0.3%	99.5%	0.2%	134,078
LIS-Medicaid	0.5%	99.4%	0.2%	0.5%	99.3%	0.2%	0.6%	99.2%	0.2%	26,663

Source: 2007 Standard Analytical Files

The share of non-LIS beneficiaries only using injectable insulin slightly decreases from 99.7 percent in the Deductible/ICP phases to 99.6 percent in the coverage gap. Even though the direction of the change is consistent with the higher relative cost of Part D insulin, the magnitude is small. We also observe the same pattern for Medicaid-eligible beneficiaries. Further, the number of beneficiaries who only use Part D insulin in the catastrophic phase goes down relative to the coverage gap for both groups. We therefore conclude that the data do not support the presence of the expected effects discussed above for insulin.

We repeated the analysis for nebulizer inhalants and MDIs, comparing patterns between non-LICS and Medicaid-eligible beneficiaries. Again, we found no evidence of drug use shifts between the two types of medications. Table E- 1 and Table E- 2 in Appendix E provide the utilization summaries, by active ingredient. The lack of evidence for significant cost-based drug substitution in the data may imply that there are relatively few cases in which these drugs are in fact clinically substitutable. It also indicates that drug substitution is unlikely to increase as a result of consolidation.

9 SUMMARY OF FINDINGS

The key findings from this study can be summarized as follows:

Part B and Part D per unit prices vary, affecting the financial impact of consolidation.

Consolidation results in a significant change in total cost for insulin drugs because the Part D per unit drug price is roughly 52 percent higher than the Part B price, due to the fact that Part B prices are set at the AWP in effect on October 1, 2003. Nebulizers in Part D also cost substantially more than in Part B, with a 16 percent difference. Therefore, by moving pumped insulin and nebulizer inhalants from Part B to Part D, holding coverage rules constant, total cost would rise significantly. Costs for anticancer drugs and vaccines are comparable across the two programs. Because Part D prices are used to impute Part B prices for MDIs, costs for MDIs are very similar in the two programs by construction.

On average, beneficiaries lose with B to D consolidations and gain with D to B consolidations.

The average increase in beneficiary out-of-pocket costs with B to D consolidation for all relevant drugs (i.e. anticancer, MDIs, and injectable insulin) is $267. Beneficiaries are adversely affected by B to D consolidation for two reasons. First, Part D cost sharing is less favorable compared to Part B. Second, beneficiaries would spend more with Part D consolidation because Part D prices are often higher than Part B reimbursement rates, as mentioned above. D to B consolidations (i.e. vaccines, pumped insulin, and nebulizer inhalants) reduce beneficiary burden because Part B drugs tend to cost less than the same drugs in Part D and beneficiaries enjoy more generous cost-sharing in Part B. On average, beneficiaries would spend $60 less if their drugs were moved to Part B.

Beneficiaries in the catastrophic phase experience the opposite effect.

Beneficiaries in the catastrophic coverage phase pay less with B to D consolidation because instead of paying the 20 percent coinsurance amount in Part B, they pay a 5 percent coinsurance amount in Part D. For example, a beneficiary taking anticancer drugs who ends in the catastrophic coverage phase pays $166 less after consolidation, while a beneficiary in the ICP pays $454 dollars more. Conversely, beneficiaries in the catastrophic coverage phase are worse off under D to B consolidations. For example, beneficiaries with MDIs who end in the catastrophic phase pay an additional $10, while their counterparts who end in the gap see reductions of $138.

Consolidation slightly affects bids, with D to B consolidations having a greater impact.

Adding drugs to or removing drugs from Part D would lead to changes in plan costs, which would be passed onto Medicare and beneficiaries through an increase or decrease in plan bids. . However, because such a small percentage of Medicare beneficiaries would be affected by consolidations, the impact is low. Only one percent of beneficiaries are affected by B to D consolidations, resulting in a $0.76 increase in Part D bids. About 27 percent of all Part D beneficiaries are affected by D to B consolidations, but the average decrease in plan covered payments is only $252. Even in this case, the average national bid changes relatively little; it declines by just under $3, a change of four percent.

Beneficiaries currently do not react to financial incentives by substituting drugs.

CMS is considering drug consolidation in part to reduce inappropriate prescribing incentives. For example, a beneficiary in the catastrophic coverage phase may request a prescription for an MDI to be covered by Part D instead of a nebulizer to be covered by Part B to reduce his coinsurance amount. However, we do not find evidence supporting substitution between nebulizer inhalants and MDIs, or pumped and injectable insulin, in response to changes in relative cost sharing rates across the two Medicare programs. First, beneficiaries are not more likely to use these drugs in their Part B form when they hit the coverage gap. Second, they are not more likely to use these drugs in their Part D form when they hit the catastrophic coverage phase. Third, non-LIS beneficiaries have similar consumptions patterns as Medicaid-eligible beneficiaries.

Consolidation does not substantially increase incentives for plan switching.

On average, beneficiaries could save about $140 by switching to a lower cost plan even before consolidation, and most beneficiaries would not save significantly more money by switching plans after consolidation. The largest impact was found in the anticancer B to D consolidation, where only ten percent of beneficiaries experience an increase in potential savings of $20 or more as a result of consolidation.

Overall, Medicare gains with B to D consolidation and loses with D to B consolidation.

Despite an increase in prices under Part D, Medicare gains with B to D consolidation because Part D has less generous coverage rules. In the combined simulation for all three drugs consolidated under Part D, consolidation reduces Medicare's total payments by $150 million, which is 0.4% percent of total Part D drug costs. Almost 90 percent of eliminated Part B cost sharing is offset by the increased cost sharing for consolidated drugs in Part D. In the D to B simulation, Medicare's net payments increase by $52 million. Almost all of the reduction in Part

D costs from moving drugs to Part B is offset by the increase in Part B costs for consolidated drugs.

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APPENDIX A: HCPCS CODES AND DESCRIPTIONS

Table A- 1: HCPCS Codes for Oral Anticancer and Antiemetic Drugs

HCPCS	Description
J8501	Aprepitant, 5 mg
WW020,J8510	Busulfan, 2 mg
J8520,WW089,WW090,WW091	Capecitabine, 150 mg
J8521,WW093,WW094,WW096	Capecitabine, 500 mg
Q0171	Chlorpromazine, 10 mg
Q0172	Chlorpromazine, 25 mg
J8530,WW010,WW014,WW017	Cyclophosphamide, 25 mg
WW011,WW013,WW015,WW016	Cyclophosphamide, 50 mg
Q0180	Dolasetron mesylate, 100 mg
Q0167	Dronabinol, 2.5 mg
Q0168	Dronabinol, 5 mg
J8560,WW030,WW031,WW032	Etoposide, 50 mg
J8565	Gefitinib, 250 mg
Q0166	Granisetron hydrochloride, 1 mg
J8600,WW080,WW081	Melphalan, 2 mg
WW034,WW040,WW044,WW052,WW053,WW054	Methotrexate, 2.5 mg
WW060,WW064,WW068,WW075,WW076,J8610	Methotrexate, 2.5 mg
J8650	Nabilone, 1 mg
Q0179	Ondansetron hydrochloride, 8 mg
Q0165	Prochlorperazine maleate, 10 mg
Q0164	Prochlorperazine maleate, 5 mg
Q0169	Promethazine hydrochloride, 12.5 mg
Q0170	Promethazine hydrochloride, 25 mg
WW005,WW008	Temozolomide, 100 mg
WW006,WW007	Temozolomide, 20 mg
WW003,WW004	Temozolomide, 250 mg
J8700,WW002,WW009	Temozolomide, 5 mg
Q0174	Thiethylperazine maleate, 10 mg
Q0173	Trimethobenzamide, 250 mg
Q0163	Diphenhydramine hydrochloride, 50 mg
Q0175	Perphenazine, 4 mg
Q0176	Perphenazine, 8 mg
Q0177	Hydroxyzine pamoate, 25 mg
Q0178	Hydroxyzine pamoate, 50 mg

Table A- 2: HCPCS Codes for Pumped and Injectable Insulin

HCPCS	Description
J1817	Insulin Pump, 50 Units
J1815	Insulin Injections, 5 Units

Table A- 3: HCPCS Codes for Nebulizer Inhalants

HCPCS	Description
J2545	Pentamidine isethionate, 300 mg
J7603	Albuterol per 1mg or levabuterol per 0.5 mg
J7607	Levalbuterol, 0.5 concentrated mg compounded
J7608	Acetylcysteine, 1000 mg
J7609	Albuterol, 1 unit mg compounded
J7610	Albuterol, 1 concentrated mg compounded
J7611	Albuterol, 1 concentrated mg non-compounded
J7612	Levalbuterol, 0.5 concentrated mg non-compounded
J7613	Albuterol, 1 unit mg non-compounded
J7614	Levalbuterol, 0.5 unit mg non-compounded
J7615	Levalbuterol, 0.5 unit mg compounded
J7620	Albuterol up to 2.5 mg, ipratropium up to 0.5 mg
J7626	Budesonide, 0.5 unit mg non-compounded
J7627	Budesonide, 0.5 unit mg compounded
J7631	Cromolyn, 10 unit mg
J7633	Budesonide, 0.25 concentrated mg non-compounded
J7634	Budesonide, 0.25 concentrated mg compounded
J7639	Dornase, 1 mg
J7640	Formoterol, 0.012 mg
J7644	Ipratropium, 1 unit mg non-compounded
J7645	Ipratropium, 1 unit mg compounded
J7668	Metaproterenol, 10 concentrated form mg
J7669	Metaproterenol, 10 unit dose form mg non-compounded
J7670	Metaproterenol, 10 unit dose form mg compounded
J7674	Methacholine, 1 mg
J7682	Tobramycin, 300 unit mg non-compounded
J7685	Tobramycin, 300 unit mg compounded
Q4080	Iloprost, 0.02 mg
Q4093	Albuterol, 1 with levabuterol concentrated form mg
Q4094	Albuterol, 1 with levabuterol unit dose form mg

Table A- 4: HCPCS Codes for Vaccines

HCPCS	Description
90586	Bacillus Calmette-Guerin 1 each
90632	Hepatitis A adult, 1 ml
90633	Hepatitis A children, 1 ml
90636	Hepatitis A Hepatitis B, 1 each
90645	Hemophilus flu B HbOC, 1 each
90647	Hemophilus flu B PRP-OMP, 0.5 ml
90649	HPV, 1 each
90675	Rabies, 1 ml
90680	Rotavirus, 1 each
90690	Typhoid oral , 1 each
90691	Typhoid intramuscular 90691, 1 ml
90700	Diphtheria adult acellular, 0.5 ml
90702	Diphtheria children, 0.5 ml
90703	Tetanus, 0.5 ml
90704	Mumps, 0.5 ml
90705	Measles, 0.5 ml
90706	Rubella, 0.5 ml
90707	Measles, Mumps, Rubella, 0.5 ml
90713	Poliovirus Inactivated, 0.5 ml
90714	Tetanus Diphtheria, 0.5 ml
90715	Tetanus Diphtheria, 0.5 ml
90716	Varicella, 0.5 ml
90717	Yellow Fever, 0.5 ml
90718	Tetanus Diphtheria Children, 0.5 ml
90721	Tetanus Diphtheria, 1 each
90733	Meningococcal Polysaccharide, 0.5 ml
90734	Meningococcal Conjugate, 1 each
90735	Japanese Encephalitis, 1 ml
90736	Zoster, 0.5 ml

APPENDIX B: ACTIVE INGREDIENTS FOR DRUGS ASSIGNED TO EACH COHORT

Table B- 1: Active Ingredients for Oral Anticancer and Antiemetic Drugs

Active Ingredients	Description
Aprepitant	Aprepitant Capsule 125 MG
Aprepitant	Aprepitant Capsule 40 MG
Aprepitant	Aprepitant Capsule 80 MG
Aprepitant	Aprepitant Capsule Therapy Pack 80 & 125 MG
Busulfan	Busulfan Tab 2 MG
Capecitabine	Capecitabine Tab 150 MG
Capecitabine	Capecitabine Tab 500 MG
Chlorpromazine	Chlorpromazine HCl Tab 10 MG
Chlorpromazine	Chlorpromazine HCl Tab 25 MG
Cyclophosphamide	Cyclophosphamide Tab 25 MG
Cyclophosphamide	Cyclophosphamide Tab 50 MG
Diphenhydramine HCL	Diphenhydramine HCl (Sleep) Cap 50 MG
Diphenhydramine HCL	Diphenhydramine HCl Cap 50 MG
Diphenhydramine HCL	Diphenhydramine HCl Tab 50 MG
Dolasetron Mesylate	Dolasetron Mesylate Tab 100 MG
Dronabinol	Dronabinol Cap 2.5 MG
Dronabinol	Dronabinol Cap 5 MG
Etoposide	Etoposide Cap 50 MG
Granisetron	Granisetron HCl Tab 1 MG
Hydroxyzine Pamoate	Hydroxyzine Pamoate Cap 25 MG
Hydroxyzine Pamoate	Hydroxyzine Pamoate Cap 50 MG
Melphalan	Melphalan Tab 2 MG
Methotrexate Sodium	Methotrexate Sodium Tab 2.5 MG (Antirheumatic)
Methotrexate Sodium	Methotrexate Sodium Tab 2.5 MG (Base Equiv)
Ondansetron	Ondansetron HCl Tab 8 MG
Ondansetron	Ondansetron Orally Disintegrating Tab 8 MG
Perphenazine	Perphenazine Tab 4 MG
Prochlorperazine Maleate	Prochlorperazine Maleate Tab 10 MG
Prochlorperazine Maleate	Prochlorperazine Maleate Tab 5 MG
Promethazine HCl	Promethazine HCl Tab 12.5 MG
Promethazine HCl	Promethazine HCl Tab 25 MG
Temozolomide	Temozolomide Cap 100 MG

Active Ingredients	Description
Temozolomide	Temozolomide Cap 20 MG
Temozolomide	Temozolomide Cap 250 MG
Temozolomide	Temozolomide Cap 5 MG
Thiethylperazine Maleate	Thiethylperazine Maleate Tab 10 MG
Trimethobenzamide hcl	Trimethobenzamide hcl 250 MG

Table B- 2: Active Ingredients for Nebulizer Inhalants

Active Ingredients	Description
Acetylcysteine	Acetylcysteine Inhal Soln 10%
Acetylcysteine	Acetylcysteine Inhal Soln 10%
Acetylcysteine	Acetylcysteine Inhal Soln 20%
Albuterol Sulfate	Albuterol Sulfate Soln Nebu 0.083%
Albuterol Sulfate	Albuterol Sulfate Soln Nebu 0.083% (2.5 MG/3ML)
Albuterol Sulfate	Albuterol Sulfate Soln Nebu 0.5% (5 MG/ML)
Albuterol Sulfate	Albuterol Sulfate Soln Nebu 0.63 MG/3ML (Base Equiv)
Albuterol Sulfate	Albuterol Sulfate Soln Nebu 1.25 MG/3ML (Base Equiv)
Albuterol-Ipratropium	Albuterol-Ipratropium Nebu Soln 2.5(3)-0.5 MG/3ML
Arformoterol Tartrate	Arformoterol Tartrate Soln Nebu 15 MCG/2ML (Base Equiv)
Budesonide	Budesonide Inhalation Susp 0.25 MG/2ML
Budesonide	Budesonide Inhalation Susp 0.5 MG/2ML
Budesonide	Budesonide Inhalation Susp 1 MG/2ML
Cromolyn Sodium	Cromolyn Sodium Soln Nebu 20 MG/2ML
Dornase	Dornase Alfa Inhal Soln 1 MG/ML
Formoterol	Formoterol Fumarate Soln Nebu 20 MCG/2ML
Iloprost	Iloprost Inhalation Solution 10 MCG/ML
Ipratropium Bromide	Ipratropium Bromide Inhal Soln 0.02%
Levalbuterol HCl	Levalbuterol HCl Soln Nebu 0.31 MG/3ML (Base Equiv)
Levalbuterol HCl	Levalbuterol HCl Soln Nebu 0.63 MG/3ML (Base Equiv)
Levalbuterol HCl	Levalbuterol HCl Soln Nebu 1.25 MG/3ML (Base Equiv)
Levalbuterol HCl	Levalbuterol HCl Soln Nebu Conc 1.25 MG/0.5ML (Base Equiv)
Metaproterenol	Metaproterenol Sulfate Soln Nebu 0.4%
Metaproterenol	Metaproterenol Sulfate Soln Nebu 0.6%
Methacholine Chloride	Methacholine Chloride Inhal For Soln 100 MG
Pentamidine Isethionate	Pentamidine Isethionate For Nebulization Soln 300 MG
Tobramycin	Tobramycin Nebu Soln 300 MG/5ML

Table B- 3: Active Ingredients for Vaccines

Active Ingredients	Description
Bacillus Calmette-Guerin	BCG Vaccine (Intravesical) For Susp 50 MG
Bacillus Calmette-Guerin	BCG Vaccine (Intravesical) For Susp 81 MG/VIAL
Candida	Candida Albicans Skin Test Antigen
Diphtheria , Tetanus, Haemophilus B	Diph, Acell Pert, Tet Tox & Haemophilia B Poly Vac For Inj Kit
Diphtheria , Tetanus	Diph, Acellular Pert & Tet Tox Inj 15 LF-10 MCG-5 LF/0.5ML
Diphtheria , Tetanus	Diph, Acellular Pert & Tet Tox Inj 25 LF-58 MCG-10 LF/0.5ML
Diphtheria , Tetanus	Diph, Acellular Pert & Tet Tox Inj 6.7 LF-46.8 MCG-5LF/0.5ML
Diphtheria , Tetanus	Diphtheria-Tetanus Toxoids (DT) Inj 6.7-5 LFU/0.5ML
Haemophilus B	Haemophilus B Oligosaccharide Conjugate Vaccine Inj
Haemophilus B	Haemophilus B Polysac Conj-Hepatitis B (Recomb) Vac IM Susp
Haemophilus B	Haemophilus B Polysaccharide Conjugate Vaccine For Inj
Haemophilus B	Haemophilus B Polysaccharide Conjugate Vaccine Inj
Hepatitis A & Hepatitis B	Hepatitis A (Inact)-Hep B (Recomb) Vac Inj 720-20 ELU-MCG/ML
Hepatitis A	Hepatitis A Vaccine Inj 1440 EL Unit/ML
Hepatitis A	Hepatitis A Vaccine Inj 25 Unit/0.5ML
Hepatitis A	Hepatitis A Vaccine Inj 50 Unit/ML
Hepatitis A	Hepatitis A Vaccine Inj 720 EL Unit/0.5ML
Hepatitis A	Hepatitis A Vaccine Inj intramuscular
Japanese Encephalitis Virus	Japanese Encephalitis Virus Vaccine For Inj
Measles	Measles Virus Vaccine For Inj
Measles, Mumps & Rubella	Measles, Mumps & Rubella Virus Vaccines For Inj
Measles, Mumps & Rubella	Measles-Mumps-Rubella-Varicella Virus Vaccines For Inj
Meningococcal	Meningococcal (A, C, Y, and W-135) ConjugaIe Vaccine Inj
Meningococcal	Meningococcal Vaccine A, C, Y, and W-135 Inj
Mumps	Mumps Virus Vaccine Live Inj
Poliovirus	Poliovirus Vaccine, IPV Inj

Active Ingredients	Description
Quadrivalent Human Papillomavirus (HPV)	Quadrivalent Human Papillomavirus (HPV) Recombinant Vac Inj
Rabies	Rabies Vaccine, PCEC For Inj
Rabies	Rabies Virus Vaccine, HDC Inj
Rotavirus	Rotavirus Vaccine, Live Oral Pentavalent Susp
Rubella	Rubella Virus Vaccine Inj
Diphtheria , Tetanus	Tet Tox-Diph-Acell Pertuss Ad Inj 5-2-15.5 LF-LF-MCG/0.5ML
Diphtheria , Tetanus	Tet Tox-Diph-Acell Pertuss Ad Inj 5-2.5-18.5 LF-LF-MCG/0.5ML
Tetanus	Tetanus Inj 250 Unit/ML
Tetanus	Tetanus Toxoid Adsorbed Inj 10 LF
Tetanus	Tetanus Toxoid Adsorbed Inj 5 LF
Tetanus	Tetanus Toxoid Fluid Inj 5 LF
Tetanus	Tetanus toxoid,adsorbed
Tetanus	Tetanus toxoid,fluid
Tetanus	Tetanus-Diphtheria Toxoids (Td) Inj 2-2 LF/0.5ML
Diphtheria , Tetanus	Tetanus-Diphtheria Toxoids (Td) Inj 5-2 LFU
Tuberculin PPD	Tuberculin PPD Inj 5 Unit/0.1ML
Typhoid	Typhoid VI Polysaccharide Intramuscular Vac Inj 25 MCG/0.5ML
Typhoid	Typhoid Vaccine Cap Delayed Release
Varicella	Varicella Virus Vaccine Live Subcutaneous Inj
Yellow Fever	Yellow Fever Vaccine Subcutaneous Inj
Zoster	Zoster Vaccine Live For Inj 19400 Unit/0.65ML

Table B- 4: Active Ingredients for Metered Dose Inhalers

Active Ingredients	Description
Albuterol	Albuterol Inhal Aerosol 90 MCG/ACT
Albuterol sulfate	Albuterol Sulfate Inhal Aero 108 MCG/ACT (90MCG Base Equiv)
Albuterol-Ipratropium	Albuterol-Ipratropium Aerosol 103-18 MCG/ACT (120-20MCG/ACT)
Beclomethasone Dipropionate	Beclomethasone Dipropionate Inhal Aero Soln 40 MCG/ACT
Beclomethasone Dipropionate	Beclomethasone Dipropionate Inhal Aero Soln 80 MCG/ACT
Budesonide	Budesonide Inhal Aero Powd 200 MCG/INH (Breath Activated)
Budesonide	Budesonide Inhal Powder 180 MCG/ACT

Active Ingredients	Description
Budesonide	Budesonide Inhal Powder 90 MCG/ACT
Budesonide-Formoterol	Budesonide-Formoterol Fumarate Dihyd Aerosol 160-4.5 MCG/ACT
Budesonide-Formoterol	Budesonide-Formoterol Fumarate Dihyd Aerosol 80-4.5 MCG/ACT
Cromolyn	Cromolyn Sodium Inhal Aerosol Soln 800 MCG/ACT (1 MG/Valve)
Flunisolide	Flunisolide Inhal Aerosol 250 MCG/ACT
Fluticasone Propionate	Fluticasone Propionate Aer Pow BA 50 MCG/BLISTER
Fluticasone Propionate	Fluticasone Propionate HFA Inhal Aerosol 110 MCG/ACT
Fluticasone Propionate	Fluticasone Propionate HFA Inhal Aerosol 220 MCG/ACT
Fluticasone Propionate	Fluticasone Propionate HFA Inhal Aerosol 44 MCG/ACT
Fluticasone Propionate	Fluticasone Propionate Inhal Aerosol 220 MCG/ACT (250/Valve)
Fluticasone-Salmeterol	Fluticasone-Salmeterol Inhal Aerosol 115-21 MCG/ACT
Fluticasone-Salmeterol	Fluticasone-Salmeterol Inhal Aerosol 230-21 MCG/ACT
Fluticasone-Salmeterol	Fluticasone-Salmeterol Inhal Aerosol 45-21 MCG/ACT
Fluticasone-Salmeterol	Fluticasone-Salmeterol Powder Disks 100-50 MCG/DOSE
Fluticasone-Salmeterol	Fluticasone-Salmeterol Powder Disks 250-50 MCG/DOSE
Fluticasone-Salmeterol	Fluticasone-Salmeterol Powder Disks 500-50 MCG/DOSE
Formoterol Fumarate	Formoterol Fumarate Inhal Cap 12 MCG
Insulin Powder	Insulin Regular (Human) Inhalation Powder 1 & 3 MG/BLISTER
Insulin Powder	Insulin Regular (Human) Inhalation Powder 1 MG/BLISTER
Insulin Powder	Insulin Regular (Human) Inhalation Powder 3 MG/BLISTER
Ipratropium Bromide	Ipratropium Bromide HFA Inhal Aerosol 17 MCG/ACT
Levalbuterol Tartrate	Levalbuterol Tartrate Inhal Aerosol 45 MCG/ACT (Base Equiv)
Metaproterenol Sulfate	Metaproterenol Sulfate Inhal Aerosol Pow 0.65 MG/ACT
Mometasone Furoate	Mometasone Furoate Inhal Powd 220 MCG/INH (Breath Activated)
Nedocromil Sodium	Nedocromil Sodium Inhal Aerosol 1.75 MG/ACT
Pirbuterol	Pirbuterol Acetate Breath Activated Inhal Aerosol 200MCG/INH
Salmeterol Xinafoate	Salmeterol Xinafoate Aer Pow BA 50 MCG/DOSE (Base Equiv)

Active Ingredients	Description
Tiotropium Bromide Monohydrate	Tiotropium Bromide Monohydrate Inhal Cap 18 MCG (Base Equiv)
Triamcinolone Acetonide	Triamcinolone Acetonide Inhal Aerosol 100 MCG/ACT(200/Valve)

APPENDIX C: ASSIGNING COST SHARE AND DECISION RULES FOR PREDICTING BENEFIT STRUCTURE

A.1 Assigning Cost Share

We assign the share of GDC paid by the beneficiary, Medicare, and the Part D plan to each drug using PDE data elements and data sources that provide information on drug characteristics and plan benefits. Cost sharing amounts for a given drug depend on the beneficiary's plan benefits and previous drug utilization, in addition to drug characteristics, such as tier, days supply and delivery channel. In this section, we describe our methods for assigning cost sharing amounts.

Data Sources

The main data fields in the PDE record we use to calculate beneficiary cost are:

- Drug characteristics: Days Supply and Product Service ID – or NDC
- Gross Drug Cost (GDC): Sum of Ingredient Cost, Dispensing Fee, and Sales Tax
- Delivery channel: Service Provider ID (either NCPDP or NPI) and Qualifier

In addition to these PDE data elements, we calculate beneficiary cost with non-PDE data sources that contain information about plan benefit structures. These data sources are used by Medicare to calculate plan bids, provide benefit information to beneficiaries, and conduct quality assurance. There are three main types of non-PDE Medicare files used in the analysis: Health Plan Management System (HPMS) data, Part D Plan Finder Files, and enrollment files. Plans provide their benefit schedules through the HPMS platform. Medicare organizes this information and makes the files available publicly. In addition, this information is consolidated into various Plan Finder files, which store data on pharmacy networks, drug tiers, and drug pricing. In addition to these benefit structure files, we use the Medicare Database (MBD), which provides information on beneficiary enrollment and demographic characteristics. This analysis also relies on two crosswalks derived from commercial databases that allow us to link Service Provider IDs and NDCs, in order to assign pharmacy type and pharmacy status to each PDE claim. Table C- 1 presents the non-PDE Medicare data files used in the analysis.

Table C- 1 External Data Sources Used to Calculate Beneficiary Cost

Data File	Extracted Information
2007 HPMS Approved Plan Benefit Package	Information on copayment or coinsurance amounts for beneficiary cost sharing given combination of tier, pharmacy type and status, days of supply, and benefit phase. In the case of a phase with coinsurance amounts, beneficiary cost share is a percentage, e.g. 100 percent or 25 percent. If the phase has copayment amounts, the beneficiary cost share is a dollar amount, e.g. $5 or $10.
Plan Finder Formulary Files	Drug tier level and drug type (brand or generic) for given reference NDC. Reference NDCs represent all NDCs that have the same combination of active ingredient, strength, dosage, and form.
First Data Bank (FDB) Crosswalk	Maps NDC reported in PDE record to drug attributes that are subsequently used to identify reference NDC.
Plan Finder Pharmacy Files	Pharmacy type (mail order or retail) and preferred status for a given NCPDP.
NCPDP Crosswalk	Maps NPI to NCPDP. The PDE record may contain as the Service Provider ID either the National Provider Identifier (NPI) or the NCPDP. The Qualifier field on the PDE record indicates which of these Service Provider IDs is used. If the NPI is used, the NCPDP crosswalk allows us to identify pharmacy type information in the Plan Finder Pharmacy File.
MBD	Low Income Subsidy (LIS) status Part D Enrollment

Calculate Beneficiary Cost for Each PDE

For each beneficiary in the cohort, we extract all 2007 PDE records and order them according to date of service, inserting their Part B claims accordingly. This process is not always straightforward, as a beneficiary may have multiple drugs with the same date of service, and these drugs may fall into multiple benefit phases. While the PDE reports date of service, we do not observe the claims order within a date. When a group of same-date claims straddles benefit phases; we reconstruct the within-date claims sequence to reproduce the reported beneficiary costs on the PDEs. Our claims ordering algorithm is based on the starting and ending GDC amount for a group of claims within a date, the reported beneficiary costs share, and the catastrophic claim indicator in the PDE data. Using this procedure, we are able to recreate the order of claims for the vast majority of beneficiaries. However, if after applying these rules,

our total calculated beneficiary cost differs from the total reported beneficiary cost by more than 10 percent, we exclude this beneficiary from the simulation sample.

After ordering drugs for a given beneficiary, we calculate cost sharing amounts for the first drug by assigning it a benefit phase, drug tier, pharmacy type and status, and days supply. We then calculate cost sharing amounts of the consecutive drugs in sequential order based on the calculated beneficiary cost and GDC of all previous drugs.

Cost sharing amounts are calculated by first assigning the drug a benefit phase. This process requires: 1) the beneficiary's plan benefit structure reported in the HPMS Approved Plan Benefit Package data file and 2) the cumulative GDC *or* the cumulative calculated beneficiary cost. The cumulative calculated beneficiary cost for a given drug is the sum of the calculated beneficiary cost across all previous drugs. If this amount exceeds the legislated yearly threshold of $3,850, the claim is placed in the catastrophic coverage phase. If the PDE is not catastrophic, then the benefit phase is determined by the cumulative GDC.

After assigning a drug a benefit phase, we capture within-phase differences in cost sharing amounts, which are determined by drug tier, pharmacy type, and days supply. Because we do not have these values for Part B claims, we make several assumptions: drugs are dispensed at a preferred retail pharmacy and located in the drug tier with the highest beneficiary cost share. To determine cost sharing amount for PDE records, we map values within a PDE record to values in external data. The mapping for each of the variables is as follows:

- **Drug Tier**: We assign the NDC reported in the PDE record a drug tier. The NDC is found in the PDE record's Product Service ID field. This NDC is then mapped to a reference NDC in the Plan Finder Formulary file, which can then be mapped to drug tier level and drug type (brand or generic) within the beneficiary's PBP.
- **Pharmacy Type and Status**: As beneficiary cost also relies on delivery channel, we next assign pharmacy type and status to the PDE record. To do so, we map the Service Provider ID and the Service Provider Qualifier as reported in the PDE record to the NCPDP number found in the Plan Finder Pharmacy File. We then assess whether the given NCPCP is a mail or retail pharmacy, and if it is a retail pharmacy, we determine its status, preferred or non-preferred.
- **Days Supply:** Days supply is taken from the PDE record and mapped to one of the two amounts possible in the HPMS Approved Plan Benefit Package – 30 days or 90 days.

Once we determine the PDE record's benefit phase, drug tier, delivery channel, and days supply, we have all the elements necessary to calculate beneficiary cost. For example, assume a beneficiary is enrolled in an enhanced plan with no coverage gap or deductible. During the ICP,

the beneficiary's copayment structure is outlined inTable C- 2. If a PDE record falls within the ICP and corresponds to a tier 1 drug with a 90 days supply and the drug is dispensed at non-preferred retail pharmacy, the calculated beneficiary cost is a $20 copayment amount.

Table C- 2: Example Copayment Amounts for ICP

Tier	Delivery Channel		Days Supply	Copayment Amount
1	Mail	Preferred	30	$5
			90	$10
		Non Preferred	30	$10
			90	$15
	Retail	Preferred	30	$10
			90	$15
		Non Preferred	30	$15
			90	$20
2	Mail	Preferred	30	$15
			90	$20
		Non Preferred	30	$20
			90	$25
	Retail	Preferred	30	$20
			90	$25
		Non Preferred	30	$25
			90	$30
3	Mail	Preferred	30	$25
			90	$30
		Non Preferred	30	$30
			90	$35
	Retail	Preferred	30	$30
			90	$35
		Non Preferred	30	$35
			90	$40

If external data is missing or ambiguous, we impute values to create a match between reported and calculated beneficiary cost. Our decision rules for this imputation are described below.

A.2 Predicting Benefit Structure

Drug Tier

Out methods address two limitations in the Plan Finder Formulary File. First, by design, the Plan Finder Formulary file only reports a reference or proxy NDC to represent all NDCs that

have the same brand name, [22] active ingredient, strength, dosage, and route of administration. NDC uniquely defines a drug by active ingredient, strength, dosage, route of administration, manufacturer and package size. Medicare does not provide a crosswalk to determine how to map all NDCs into reference NDCs and plans can use any method to implement this mapping.

To map the NDC reported in the PDE record to a reference NDC in the Plan Finder Formulary file, we use the First Data Bank crosswalk from NDC to Generic Sequencing Number-Brand Name (GSN-BN), which is conceptually equivalent to the reference NDC. The Generic Sequence Number (GSN) contains multiple NDCs; NDCs within the same GSN code are pharmaceutically equivalent (i.e. equal in active ingredient, dose, and strength), but differ by packaging size. GSN-BN further distinguishes between brand and generic drugs. For example, if a drug is sold under two brand names and has generic equivalents, there are three GSN-BNs representing the drug: one for each brand drug and one for all generic drugs. Although reference NDCs and GSN-BNs are conceptually equivalent, the mapping is not always unique; two reference NDCs in the formulary file can be mapped to one GSN-BN. As a result, a GSN-BN can be mapped into two different tiers. A multisource drug, a drug with the same active ingredient, dose, strength and route of administration that is produced by multiple manufacturers, can be in different tiers depending on the source.

As an example, take the case of lithium citrate. For this drug, the same GSN-BN maps into two different reference NDCs and, as a result, into two different tiers. In this case, we cannot know how the plan mapped the NDCs into these two tiers. We calculate beneficiary cost for the PDE record with both tier options. The calculated beneficiary cost most similar to the reported beneficiary cost is used in the reinsurance and LICS payments determination.

Table C- 3: Example of a GSN-BN that Maps to Two Tiers for a Given PDP

Reference NDC	Tier	GSN-BN
00054352763	1	004006
00054852904	3	004006

Second, there is a potential two-week lag from the date a plan implements a negative formulary change to the date the change appears in the Plan Finder Formulary File. For example, once a generic drug becomes available, its brand equivalent is often moved to a higher tier. The Plan Finder Formulary file only picks up these changes every two weeks. Because we cannot know the exact timing of the change, we assume a PDE is correct if the tier assignment in the PDE is consistent with any of the Plan Finder Formulary File submissions corresponding to

[22] Brand name is the name under which the drug is sold; it can apply to both brand and generic drugs.

two weeks before and two weeks after DOS. This assumption may lead to slightly lower payment errors.

Pharmacy Types and Status

The Service Provider ID in the PDE may map to a NCPDP that is both mail and retail in the pharmacy file; the PDE will not indicate which type of pharmacy actually dispensed the drug. We calculate beneficiary cost for the PDE record with both pharmacy type options, and once again, we use the calculated beneficiary cost most similar to the reported beneficiary cost to calculate reinsurance and LICS payments.

Days Supply

The days supply value on the claim may not exactly map to 30 or 90 days. In these cases, days supply is inferred by finding a days supply consistent with the beneficiary cost on the PDE record. For example, suppose a drug has a days supply of seven days. Some plans may charge a copayment equal to the 30 days supply copayment, while others may prorate the copayment, e.g. charge ¼ of the 30 days supply copayment. Both of these scenarios are acceptable under Medicare regulations and should not lead to an error. By reviewing the copayment and days supply on the given PDE, we can determine the plan's payment strategy for drugs with copayments other than 30 or 90 days and apply that to the beneficiary cost calculation.

APPENDIX D: ACRONYM REFERENCES

Table D-1: Description of Commonly Used Acronyms

Acronym	Description
ASP	Average Sales Price
AWP	Average Wholesale Price
CMS	Center for Medicare and Medicaid Services
DME (MAC)	Durable Medical Equipment (Medicare Administrative Contractor)
ESRD	End Stage Renal Disease
FFS	Fee for Service
GCN-SEQNO	Generic Sequence Numbers
GDC	Gross Drug Cost
HCPCS	Healthcare Common Procedures Coding System
HHA	Home Health Agency
HPMS	Health Plan Management System
ICP	Initial Coverage Period
IP	Inpatient
LICS	Low Income Cost Share Subsidy
LIS	Low Income Subsidy
MA PDP	Medicare Advantage Prescription Drug Planner
MAC	Medicare Administrative Contractor
MBD	Medicare Database
MSP	Medicare Savings Program
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NOC	Not Otherwise Classified
NPI	National Provider Identifier
OP	Outpatient
Carrier	Physician / Supplier
PBM	Pharmacy Benefit Manager
PDE	Prescription Drug Event

Acronym	Description
PDP	Prescription Drug Planner
PLRO	Patient Liability Reduction Due to Other Payer Amount
RxHCC	Prescription Drug Hierarchical Condition Categories
SAF	Standard Analytical File
SNF	Skilled Nursing Facility
TrOOP	True Out-of-pocket costs
VIPS	Viable Information Processing System

APPENDIX E: PATTERNS OF UTILIZATION OF NEBULIZER INHALANTS/MDIS

Table E- 1: Patterns of Utilization of Nebulizer Inhalants (NI) and MDIs by Non-LIS Beneficiaries Who Used the Drug in All Benefit Phases

Active Ingredient	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Total Beneficiaries
Acetylcysteine	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	79
Albuterol	22.1%	66.2%	11.7%	22.7%	61.8%	15.5%	23.1%	62.4%	14.5%	9,981
Albuterol and Ipratropium	29.1%	61.9%	9.0%	29.0%	60.3%	10.7%	29.1%	61.9%	9.0%	7,578
Beclomethasone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	464
Budesonide	63.8%	35.0%	1.1%	63.4%	35.3%	1.3%	63.6%	35.6%	0.8%	1,926
Budesonide and Formoterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	1
Cromolyn	27.8%	70.4%	1.9%	27.8%	69.8%	2.5%	27.2%	71.6%	1.2%	162
Dornase	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	7
Flunisolide	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	232
Fluticasone and Propionate	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	2,700
Fluticasone and Salmeterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	21,608
Formoterol	0.0%	100.0%	0.0%	0.1%	99.9%	0.0%	0.0%	100.0%	0.0%	1,534
Iloprost	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	58
Insulin	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	36
Ipratropium	58.6%	38.5%	2.9%	58.3%	38.5%	3.2%	58.4%	39.1%	2.6%	2,379
Levalbuterol	33.1%	54.3%	12.5%	27.8%	60.1%	12.1%	19.9%	78.2%	1.9%	694
Metaproterenol	20.6%	79.4%	0.0%	20.6%	79.4%	0.0%	20.6%	79.4%	0.0%	34
Mometasone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	877
Nedocromil	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	30

Active Ingredient	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Patient Using NI Only	Patient Using MDI Only	Patient Using NI and MDI	Total Beneficiaries
Pentamidine Isethionate	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	1
Pirbuterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	116
Salmeterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	1,646
Tiotropium	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	14,876
Tobramycin	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	10
Triamcinolone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	602

Table E- 2: Patterns of Utilization of Nebulizer/MDI Drugs by LIS Beneficiaries with Medicaid Status Who Used Drug in All Benefit Phases

Active Ingredient	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Total Beneficiaries
Acetylcysteine	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	247
Albuterol	14.5%	70.7%	14.8%	14.5%	67.8%	17.7%	15.2%	66.2%	18.6%	94,159
Albuterol and Ipratropium	26.1%	64.4%	9.5%	25.9%	63.2%	10.9%	26.2%	63.4%	10.4%	51,747
Beclomethasone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	2,463
Budesonide	86.2%	12.9%	0.9%	86.0%	12.9%	1.1%	85.8%	12.9%	1.2%	9,597
Budesonide and Formoterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	6
Cromolyn	39.6%	58.1%	2.2%	39.0%	57.9%	3.0%	38.8%	57.5%	3.7%	492
Dornase	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100
Flunisolide	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	593

Active Ingredient	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Patient Using Nebulizers Only	Patient Using MDI Only	Patient Using Nebulizers and MDIs	Total Beneficiaries
Fluticasone and Propionate	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	14,934
Fluticasone and Salmeterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	100,846
Formoterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	3,412
Iloprost	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	57
Insulin	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	99
Ipratropium	51.2%	44.0%	4.7%	51.0%	43.7%	5.3%	51.3%	44.0%	4.8%	17,067
Levalbuterol	43.9%	47.3%	8.8%	40.6%	50.2%	9.3%	35.0%	61.6%	3.4%	5,976
Metaproterenol	15.2%	82.4%	2.4%	15.7%	80.5%	3.8%	15.7%	81.0%	3.3%	210
Mometasone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	3,111
Nedocromil	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	39
Pentamidine Isethionate	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	21
Pirbuterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	398
Salmeterol	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	4,497
Tiotropium	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	52,139
Tobramycin	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	57
Triamcinolone	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	3,004

APPENDIX F: CHANGE OF COST TABLES

Table F- 1: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for Pumped Insulin by Part D characteristics

Beneficiary Characteristics Related to Part D (Pre)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan
All	12,269	$426	-$351	-$40	$448
Part D enrollment Status					
Enrolled in Part D	8,346	$335	-$198	-$58	$381
Not Enrolled in Part D, No Creditable Coverage; Not Enrolling after Reform	693	$257	-$121	$0	$0
Not Enrolled in Part D, No Creditable Coverage; Enrolling after Reform	2,030	$608	-$795	$0	$1,048
Not Enrolled in Part D, Creditable Coverage	1,200	$793	-$698	$0	$0
Part D Utilization					
Ended in Deductible (Low)	262	$163	-$494	-$42	$777
Ended in ICP (Low)	3,105	$357	-$516	-$37	$656
Ended in Gap (Medium)	3,241	$526	-$191	-$47	$179
Ended in Catastrophic (High)	1,738	-$32	$400	-$120	$208
Part D Benefit Type					
Standard	1,441	$320	-$83	-$79	$313
Alternative Basic	3,323	$291	-$143	-$67	$368
Actuarially Equivalent	1,024	$70	$188	-$126	$296
Enhanced	2,298	$510	-$488	-$9	$475
800 Series Plans	190	$545	-$524	$0	$405
Unknown Type	70	$304	-$454	-$18	$543
LIS Eligibility Status					
Not Eligible	4,721	$586	-$562	$0	$460
Eligible	3,625	$9	$275	-$135	$278

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.

Table F- 2: Change in Point-of-Sale Costs (Post – Pre) for Beneficiaries, Medicare, and Plans for Nebulizer Inhalants by Part D characteristics

Beneficiary Characteristics Related to Part D (Pre)	Number of Beneficiaries	Beneficiary	Medicare	Medicaid	Plan
All	110,020	$287*	-$239*	-$95*	$223*
Part D enrollment Status					
Enrolled in Part D	81,559	$207*	-$81*	-$128*	$164*
Not Enrolled in Part D, No Creditable Coverage; Not Enrolling after Reform	7,205	$105*	-$179*	$0	$0
Not Enrolled in Part D, No Creditable Coverage; Enrolling after Reform	12,073	$760*	-$989*	$0	$1,007*
Not Enrolled in Part D, Creditable Coverage	9,183	$589*	-$788*	$0	$0
Part D Utilization					
Ended in Deductible (Low)	2,482	$219*	-$356*	-$87*	$416*
Ended in ICP (Low)	28,149	$308*	-$323*	-$84*	$282*
Ended in Gap (Medium)	30,664	$268*	-$56*	-$112*	$41*
Ended in Catastrophic (High)	20,264	-$27*	$251*	-$220*	$155*
Part D Benefit Type					
Standard	13,011	$169*	-$21*	-$146*	$171*
Alternative Basic	36,920	$184*	-$28*	-$116*	$110*
Actuarially Equivalent	14,045	$16*	$175*	-$274*	$221*
Enhanced	15,261	$461*	-$443*	-$26*	$219*
800 Series Plans	1,777	$254*	-$371*	-$4*	$209*
Unknown Type	545	$344*	-$597*	-$50*	$438*
LIS Eligibility Status					
Not Eligible	31,668	$553*	-$576*	$0	$223*
Eligible	49,891	-$13*	$234*	-$210*	$126*

Medicaid's cost is an overestimation because we assume that the program covers all costs. In actuality, the program pays the less of the 20 percent coinsurance amount or the state's reimbursement rate. Reported Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
Additional costs imposed on Part D plans would in turn impact Medicare's and beneficiaries' overall costs because they would be passed on through higher premiums.
Cost statistics for all cohorts are based on samples.
* Statistically significant at a 95% confidence level.