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 the form of the drug. The overlapping coverage of drugs by Part B and Part D makes administration quite complex. Navigating the system to correctly dispense and bill these "overlap" drugs is burdensome for pharmacists, physicians, plans, and beneficiaries. Consolidating drugs under either Part B or Part D could eliminate these burdens. Drugs that are routinely administered in a physician's office would not be good candidates for consolidation. On the other hand, drugs for which coverage under Part B versus Part D depends on the specific diagnosis, treatment history, administration setting, or timing of prescription would be good candidates. In 2007, Acumen, LLC was contracted by the Centers for Medicare and Medicaid Services (CMS) to study the impacts of consolidating coverage of drugs under either Part B or Part D. In particular, the study uses a simulation to predict the impacts of consolidating six categories of drugs (hereafter referred to as the analysis drugs): oral anticancer and antiemetic drugs, vaccines, insulin, inhalants, immunosuppressant drugs, and parenteral nutrition. The analysis addresses three research questions:

1) How does the Part B versus Part D determination process work for each drug under study?
2) What are the benefits of the proposed consolidation?
3) What is the financial impact of the proposed consolidation on Medicare spending?

The next section reviews the pricing structure of the Part B and Part D programs. We then explain the current determination rules for covering the analysis drugs under Part B versus Part D and show the program under which each drug type would be consolidated under the proposed consolidation. Next, we describe the methods for conducting the simulation. We then present the current utilization of the analysis drugs, followed by the financial impact of the proposed consolidation. The final section discusses the behavioral response analysis, which describes how beneficiaries might respond to the proposed consolidation and how those behavioral changes affect simulation results of post-consolidation costs.

Comparison of Part B and Part D Benefit Structures

In the Part B fee-for-service (FFS) program, Medicare decides what services should be covered, as well as how much beneficiaries should pay and how much providers should be reimbursed for these services. Part B drugs are defined by Healthcare Common Procedure Coding System (HCPCS) codes. Prices are generally either 106 percent of the Average Sales

Price (ASP) or, for vaccines and DME-infused drugs (including insulin), 95 percent of the Average Wholesale Price (AWP). Medicare payments for parenteral nutrition are based on a fee schedule furnished by CMS, which is in turn based on the lesser of the 1995 or 2002 reasonable charge rates. ASP and AWP do 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. 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 coinsurance covered by Medicaid, as long as they see providers who accept Medicaid. Beneficiaries pay monthly premiums that vary by personal income. Overall, premiums cover 25 percent of Part B costs.

Part D benefits are administered by private health care organizations through stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription 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 negotiate prices for drugs, as defined by National Drug Codes (NDCs), with network 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 provide a standard benefit or one of three types of non-standard benefits. The standard plan has four benefit phases: deductible, initial coverage phase (ICP), gap, and catastrophic. Beneficiaries must meet a utilization threshold before moving to the next benefit phase. Beneficiaries pay 100 percent of drug costs in the deductible phase, 25 percent in the ICP, 100 percent in the coverage gap, and 5 percent in the catastrophic coverage phase. Once a beneficiary reaches the catastrophic phase, Medicare pays for 80 percent of the drug costs through the Reinsurance Subsidy. Beneficiaries pay plans monthly premiums to cover point-of-sale plan liabilities, which are zero percent of drug costs in the deductible and gap phases, and 15 percent of drug costs in both the ICP and catastrophic phases. For non-standard plans, the amount the beneficiary pays at the point-of-sale for a given drug depends not only on drug cost and benefit phase, but also on drug tier, pharmacy type and status, and days of supply. Beneficiaries who are eligible for Low-Income Cost Sharing (LICS) subsidies also have some or all of their point-of-sale costs covered by Medicare. Premiums are determined by plan bids, and they vary by beneficiary. Medicare covers premiums for low-income beneficiaries through the Low-Income Premium Subsidy (LIPS).

Part B versus Part D Determination

One of the main reasons for consolidating certain drugs under either the Part B or the Part D program is to avoid the administrative complexity of the B versus D determination process for

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

pharmacies and medical providers. Table ES- 1 summarizes the Part B and Part D coverage criteria for each analysis drug.

Table ES- 1: Coverage Criteria and Proposed Consolidation Program, by Drug Type

Analysis Drug	Part B Coverage Criteria	Part D Coverage Criteria
Anticancer/Antiemetic	Anticancer drugs used for cancer treatment and antiemetic drugs prescribed within 48 hours of cancer treatment as a replacement for intravenous antiemetic drugs	All other uses of anticancer or antiemetic drugs
Insulin	Pumped insulin	Injectable insulin
Inhalants	Nebulizer Inhalants	Metered Dose Inhalers (MDIs)
Immunosuppressants	Drugs used in immunosuppressive therapy to prevent rejection of a transplant covered under Part A of Medicare	All other uses of immunosuppressant drugs
Vaccines	Influenza, Pneumococcal, Hepatitis B (for medium to high-risk beneficiaries), other vaccines for beneficiaries who have been exposed to the disease	All other vaccines
Parenteral Nutrition	Parenteral nutrition for beneficiaries with a permanent dysfunction of the digestive tract	All other uses of parenteral nutrition

Consolidation Approach

Based on analysis of CMS documentation and interviews with pharmacists and medical providers, this study consolidates anticancer/antiemetic drugs, insulin, inhalants, and immunosuppressants under Part D and consolidates vaccines and parenteral nutrition under Part B as the basis for running the simulation models. In general, we simulate consolidating pills (i.e., anticancer/antiemetic drugs and immunosuppressants) under the Part D prescription drug benefit. According to our interviews, moving nebulizers to Part D, where they will be covered along with MDIs, facilitates step therapy, while moving pumped insulin to Part D facilitates pharmacy billing and eliminates the need to contact the prescribing physician to confirm the method of dispensing the drug. We simulate consolidating vaccines under Part B because the analysis of interviews and CMS documentation indicates that preventative vaccines have a higher adherence rate under Part B. Finally, we simulate consolidating parenteral nutrition under Part B since parenteral nutrition is an IV drug typically administered through a physician's office. Table ES-2 lists the six analysis drug types and the proposed Medicare program for consolidation (and for

the purposes of subsequent analysis in this study). The final column summarizes the benefits from consolidation.

Table ES- 2: Proposed Consolidation Program, by Drug Type

Analysis Drug	Consolidation Program	Benefits of Consolidation
Anticancer/Antiemetic	Part D	Facilitate pharmacy drug processing and billing; eliminate systems edits for Part D plans and Part B
Insulin	Part D	Eliminate the need to contact the prescribing physician for clarification on delivery method
Inhalants	Part D	Facilitate the use of step therapy and coordination of care, since nebulizers are often prescribed for patients who could not successfully treat their condition with MDIs.
Immunosuppressants	Part D	Facilitate pharmacy drug processing and billing; eliminate the necessity of maintaining systems edits
Vaccines	Part B	Improve access (particularly for herpes zoster); reduce billing burden
Parenteral Nutrition	Part B	Improve beneficiary access as Prior Authorization requirements on Part D are removed; lower administrative costs for Part B as consolidation eliminates the need to investigate the nature of the digestive problem

Simulation Model

We use a simulation model to assess the financial impact of consolidating the analysis drugs under either Part B or Part D. 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 input the utilization of the drug under 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.

Table ES- 3 presents the seven major steps of the simulation.

Table ES- 3: 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 for 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 is available, we use the per unit median price of NDCs that map to that active ingredient across all PDEs.
	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 the 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.	

Pre-Consolidation Utilization

In total, 1.6 million beneficiaries would be affected by the proposed consolidation because they consume anticancer/antiemetic drugs, pumped insulin, nebulizer inhalants, or immunosuppressants under Part B, or vaccines or parenteral nutrition under Part D; payments for these drugs are approximately $2 billion. The number of beneficiaries affected by consolidating the drugs considered in this analysis varies widely by drug type, ranging from only 3,500 beneficiaries taking parenteral nutrition under Part D to over 1.1 million beneficiaries taking nebulizer inhalants under Part B.

The Impact of the Proposed Consolidation

The key findings from the financial impact of the proposed consolidation on beneficiaries, Medicare, and Part D and B plans are summarized as follows:

Analysis drugs are priced differently under Part D and Part B, affecting the financial impact of the proposed consolidation.

The proposed consolidation results in a significant change in total costs for pumped insulin 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 since October 1, 2003. Nebulizers in Part D also cost substantially more than in Part B, with a 16 percent price difference. Therefore, by moving pumped insulin and nebulizer inhalants from Part B to Part D, holding coverage rules constant, total cost would rise considerably. Costs for anticancer/antiemetic drugs, immunosuppressants, vaccines, and parenteral nutrition are comparable across the two programs.

On average, for the proposed consolidation, beneficiary out-of-pocket costs increase due to B to D consolidation and consolidation of parenteral nutrition under Part B, and they decrease due to consolidation of vaccines under Part B.

As drugs move from Part B to Part D, total costs for Medicare and Medicaid per beneficiary fall for all beneficiary cohorts, while costs for beneficiaries rise (Table ES- 4). The increase in beneficiary out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication. Beneficiaries taking parenteral nutrition experience an increase in annual costs of approximately $160, while Medicare expenditures decrease by $140 and Medicaid expenditures increase by $820. Since 60 percent of beneficiaries taking parenteral nutrition under Part D end in the catastrophic phase where they pay approximately five percent of drug costs, out-of-pocket costs rise after moving parenteral nutrition to Part B, where beneficiaries pay 20 percent of drug costs after reaching the deductible. Beneficiaries receiving vaccines consolidated under Part B

experience a relatively small decrease in payments, while Medicaid experiences a slight increase and Medicare experiences an increase in payments of approximately $110. Overall, decreases of approximately $230 for Medicare and $100 for Medicaid are partially offset by an increase of $210 for beneficiaries.

Table ES- 4: Change in Point-of-Sale Costs for Beneficiaries, Medicare, and Medicaid, by Cohort, 2007

Beneficiary Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid
B to D Cohort				
Anticancer/Antiemetic	68,082	$391	-$814	-$113
Pumped Insulin	12,269	$426	-$351	-$40
Nebulizer Inhalant	1,101,622	$287*	-$239*	-$95*
Immunosuppressant	74,136	$418	-$700	-$708
D to B Cohort				
Vaccines	353,158	-$10*	$107*	$4*
Parenteral Nutrition	3,587	$161	-$137	$820
Combined Cohort	1,600,053	$207*	-$230*	-$99*

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 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, vaccines, and *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at a 95% confidence level.
The number of beneficiaries in the *combined* row is less than the sum of beneficiaries in the six cohorts because some beneficiaries take multiple analysis drugs.

The percent of beneficiaries reaching the Part D coverage gap increases with the proposed B to D consolidation and decreases with D to B consolidation.

Since moving drugs from Part B to Part D tends to increase Part D costs, the percent of beneficiaries reaching the coverage gap increases after consolidation for all four B to D beneficiary cohorts. When drugs move from Part D to Part B, beneficiary Part D payments decrease. Consolidation under Part B therefore results in a lower percentage of beneficiaries receiving vaccines or parenteral nutrition reaching the coverage gap.

The proposed consolidation results in a slight increase in Part D plan bids and a slight decrease in Part B plan bids.

We assume that changes in liability due to the proposed consolidation are fully passed on to Part D plan bids and Part B premiums. Under this assumption, the percent change in Part D plan 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 per beneficiary. As expected, Part D plan liability increases due to B to D consolidation but decreases due to D to B consolidation. In the combined simulation, the increase in Part D plan liability for B to D cohorts is only partially offset by decreases in liability for D to B cohorts. The overall increase in average Part D plan-covered costs per beneficiary is $180, or 0.9 percent of total plan costs. This results in an increase of $0.70 in the average plan bid. Similarly, Part B liability decreases as drugs move from Part B to Part D, but increases due to consolidation under Part B. Overall, Part B liability decreases by approximately $1.8 billion, resulting in a decrease of one dollar in the Part B premium.

Medicare experiences a slight net decrease in costs due to the proposed consolidation of the six analysis drugs.

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 phase. Because of that structure, consolidation under Part D tends to reduce Medicare's total payments at constant drug prices, unless a large share of beneficiary costs is accrued in the catastrophic phase. As expected, Table ES- 5 shows that consolidation under Part D does reduce Medicare's total payments for each B to D beneficiary cohort and for beneficiaries taking parenteral nutrition. In contrast, consolidation of vaccines under Part B increases total payments since most Part D payments for vaccines do not occur in the catastrophic phase. Overall, total payments for Medicare decrease by about $154 million.

Table ES- 5: Total Financial Impact of the Proposed Consolidation on Medicare, by Cohort, 2007

Beneficiary Cohort	Change in Medicare Payments (in Thousands)					
	Part B	Part D				Total
		LICS	Reinsurance Subsidy	Direct Subsidy	LIPS	
B to D						
Anticancer/Antiemetic	-$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
Immunosuppressant	-$413,995	$60,000	$302,065	$40,339	$4,689	-$6,902
D to B						
Vaccines	$44,339	-$3,719	-$2,779	-$24,041	$0	$13,800
Parenteral Nutrition	$14,630	-$2,286	-$12,457	-$1	-$331	-$445
Combined	-$1,475,499	$379,496	$758,351	$168,000	$16,052	-$153,600

LICS refers to the Low-Income Cost Sharing subsidy; LIPS refers to the Low-Income Premium Subsidies.
Cost statistics for nebulizer inhalants, vaccines, and the *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.

Impact of Beneficiary Plan Choice on Consolidation Costs

The proposed consolidation would change the relative attractiveness of different Part D plans. Upon consolidation, beneficiaries may enroll in plans that provide lower-cost coverage for cancer treatments and immunosuppressants. The study explores some of the ways in which beneficiaries could respond by enrolling in more generous plans and how such responses affect the simulation results.

We first examine the sensitivity of Medicare consolidation cost estimates with respect to benefit type. Among all Part D and Part B payment mechanisms, only changes in Reinsurance Subsidy payments depend on plan choice. First, LICS and LIPS apply exclusively to Low Income Subsidy (LIS) beneficiaries, who will be unlikely to change their benefit type upon consolidation because their out-of-pocket costs are very low, giving them little incentive to change plans. Second, while Direct Subsidies are determined by the enrollment-weighted average standard bid, significant enrollment shifts are required to generate non-negligible changes in Direct Subsidies. Finally, Part B premiums and point-of-sale costs do not depend on Part D enrollment. Therefore, the adjustment for plan choice is calculated by the difference in additional Reinsurance Subsidy payments resulting from differences in the number of beneficiaries by benefit type.

The adjusted estimate of additional Reinsurance Subsidy payments is about $3 million higher than the baseline estimate. This adjustment reduces savings for Medicare from $154 million to $151 million. Two factors explain the low level of adjustment. First, except for plans that provide gap coverage, the financial baseline impact for Medicare does not change significantly from one plan to the next. Second, the distribution of enrollment across benefit types is not very sensitive to the level of drug costs.

Limitations of the Analysis

This analysis has several limitations. First, it does not take into consideration the costs of enacting legislation to implement the proposed 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 to allow for consolidation under certain scenarios. Second, we do not address the administrative costs of any systems changes needed to implement the proposed consolidation, such as adding drugs to or removing drugs from payment calculation methods or disseminating information about changes to providers. Third, the cost projections presented in this study do not take into consideration costs incurred by providers in adopting new coverage rules. For example, consolidation of nebulizer inhalants under Part D could impact suppliers of nebulizer drugs, as typical chain and community retail pharmacies may not have the resources to accommodate a large and sudden increase in patients who require

nebulizer inhalants. Stocking, dispensing, and potentially delivering 30 to 90-day supplies of nebulizer drugs may require more space and resources than some pharmacies currently have at their disposal. Also, DME suppliers would lose a source of revenue if they were prevented from supplying drugs associated with pumps and nebulizers. This loss of revenue could impact the willingness of these entities to supply pumps and nebulizers, as well as the costs of the equipment. Finally, our pricing of Part D prescriptions for parenteral nutrition under Part B is imperfect. About 50 percent of Part D claims for parenteral nutrition are for compounded products. However, a PDE only reports the NDC for one of the active ingredients of the drug. We therefore cannot identify HCPCS equivalents for compound PDEs and apply our typical pricing strategy using the Part B fee schedule. In the analysis, projected Part B costs for compounded Part D products equal Gross Drug Costs (GDC) under Part D.

Table of Contents

LIST OF TABLES AND FIGURES

1 INTRODUCTION

Since its inception in 2006, all Medicare beneficiaries have been eligible for prescription drug coverage under the Part D prescription drug benefit authorized in the Medicare Modernization Act (MMA). While Part D represents a fundamental new benefit through Medicare, a limited number of outpatient prescription drugs were covered under Medicare Part B prior to the introduction of Part D. Part B generally covers drugs administered by physicians, which include drugs that are furnished "incident to a physician's service," drugs administered using durable medical equipment (DME), and drugs specifically covered by statute, such as oral anti-cancer drugs, anti-emetic drugs, and blood-clotting factors. When Part D was created, it specifically excluded these drugs from coverage under Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs). However, in some cases, the same drugs may be prescribed under circumstances that trigger Part B coverage as well as in other settings that do not qualify for Part B. In these cases, the same drug may be covered under both Part B and Part D.

Much of the impetus for consolidating coverage under either Part B or Part D arises from the administrative complexity caused by a subset of Part B drugs for which there is an overlap between Part B and Part D. Drugs that are routinely administered in a physician's office, for example, would not be good candidates for consolidation. On the other hand, for some drugs coverage under Part B versus Part D depends on the specific diagnosis, treatment history, administration setting, or timing of prescription. Navigating the system to correctly dispense and bill these "overlap" drugs is burdensome for pharmacists, physicians, plans, and beneficiaries. Some of these problems could be eliminated by consolidating coverage of these drugs under one Medicare program. Certain drugs would move to Part D, while others would move to Part B.

This report focus on the impacts of consolidating coverage for six categories of drugs (hereafter referred to as the analysis drugs): 1) certain oral drugs and antiemetic drugs used in cancer treatment, 2) nebulizer inhalants, 3) pumped insulin, 4) immunosuppressants, 5) vaccines, and 6) parenteral nutrition.[2] In particular, we will address the financial impact of the proposed consolidation on Medicare spending and beneficiary costs based on the proposed consolidation, accounting for the different plan structures and the potential impact on competitive pricing.

Our strategy for assessing the cost impacts of switching drugs from Part B to Part D coverage (or from Part D to Part B coverage) is both straightforward and comprehensive. We simulate what would have happened had a specific drug been dispensed under the alternative

[2] A previous report evaluating the impact of consolidating anticancer, inhalants, and insulin can be found at http://www.cms.gov/reports/downloads/Acumen_PartBtoDBase_Final_2010.pdf.

program. In conducting these simulations we account for behavioral responses by beneficiaries. These include beneficiary decisions to participate in the Part D program and the selection of their Part D plans. Output from our simulation directly estimates the changes in costs incurred by all parties, including beneficiaries, Part D plans, and Medicare.

The remainder of this report is organized as follows. Section 2 compares 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 six analysis drug categories. For each drug class in the study, the section discusses whether Part B or Part D is the best choice for consolidation. Section 4 describes the methods for conducting the simulation, including data sources, cohort selection, and total cost and cost-share calculation. The current utilization of these drugs under Part B and Part D is described in Section 5. Section 6 presents the financial impact of the proposed consolidation. Section 7 discusses the methodology and findings of the behavioral response analyses, describing how beneficiaries might respond to the proposed consolidation and how those behavioral changes affect simulation results of post-consolidation costs.[3]

[3] The 2010 report investigated whether beneficiaries would substitute drugs after consolidation, based on changes in relative price. Because the 2010 report found no evidence of substitution, the substitution analysis is omitted from this report.

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 substantial. In the Part B fee-for-service (FFS) program, Medicare decides what services should be covered, as well as how much beneficiaries should pay and how much 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 PDPs or MA-PDs. Part D plans are able to negotiate prices with network pharmacies based on manufacturer rebates and discounts. In addition, Part D plans 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. In CY 2011, the average Part D beneficiary can choose from 150 plans with varying premiums, copayments, drug coverage and pharmacy networks, meaning different beneficiaries would face different tradeoffs when Part B drugs are moved to Part D.[4] In this section, we describe in detail Part B and Part D price-setting mechanisms, premiums, and beneficiary cost-share structures.

2.1 Pricing

While the Part B program uses the Average Sales Price (ASP[5]) to set drug prices, individual Part D plans base prices on negotiations and contractual agreements with pharmacies and drug manufacturers. 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[6]). AWP is more similar to a "manufacturer's suggested list price" than to actual prices

[4] Source: HPMS Plan-Service Area enrollment files.

[5] The ASP is the weighted average of all non-federal sales to wholesalers, net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug (http://www.hrsa.gov/opa/glossary.htm). Drug manufacturers calculate ASP by national drug code (NDC), which indicates the manufacturer, product dosage form, and package size. Manufacturers submit this information to CMS in a quarterly report within 30 days of the close of the quarter. CMS then maps NDCs to Health Care Common Procedure Coding System (HCPCS) codes, which may contain multiple NDCs. CMS calculates ASPs for HCPCS codes by weighting ASPs at the NDC level by the amount of drug sold during the quarter. See "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs," http://oig.hhs.gov/oei/reports/oei-03-05-00310.pdf.

[6] The AWP is a national average of list prices charged by wholesalers to pharmacies. The AWP does not reflect the actual price that larger purchasers normally pay, as these purchasers may receive substantial discounts. See DHHS

paid to drug manufacturers.[7] 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 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, accounting for rebates and discounts.

Part B currently pays providers 106 percent of the ASP for most drugs. The specific Part B pricing rules for the six types of drugs in this analysis are reviewed below:[8]

- Oral anticancer and antiemetic drugs – Medicare pays 106 percent of ASP in addition to a pharmacy supply fee of $24 per prescription.[9]
- Pumped insulin (along with all other infusion drugs furnished through DME) – Medicare pays 95 percent of the AWP that was in effect since October 1, 2003.
- Nebulizer inhalants – Medicare pays 106 percent of the ASP, in addition to an initial dispensing fee of $57 per month. Thereafter, Medicare will pay a dispensing fee of $33 for each 30-day supply and $66 for each 90-day supply.
- Immunosuppressant drugs – Medicare pays 106 percent of ASP, in addition to a pharmacy supply fee of $50 per prescription for beneficiaries in the first month after a transplant and $24 per prescription for all other beneficiaries.
- Vaccines – Medicare pays 95 percent of AWP. When furnished in a hospital outpatient department, Rural Health Clinic, or Federally Qualified Health Center, payment for these vaccines is based on reasonable cost. The Part B deductible and coinsurance apply for hepatitis B vaccines, but these are waived for influenza and pneumococcal vaccines.[10]
- Parenteral nutrition – Medicare payments are based on a fee schedule furnished by the Centers for Medicare and Medicaid Services (CMS). The fee schedule was

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Health Resources and Services Administration Glossary of Pharmacy-Related Terms: http://www.hrsa.gov/opa/glossary.htm.

[7] 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.

[8] "Medicare Claims Processing Manual Chapter 17: Drugs and Biologicals," revised 10 December 2010, downloaded from https://www.cms.gov/Manuals/IOM/itemdetail.asp?itemID=CMS018912.

[9] When oral anticancer/antiemetic drugs or immunosuppressive drugs are prescribed multiple times in a 30-day period, Medicare will pay $24 for the first prescription and $16 for each subsequent prescription in that 30-day period.

[10] "Quick Reference Information: Medicare Immunization Billing," http://www.cms.gov/MLNProducts/downloads/qr_immun_bill.pdf.

implemented in 2002, and base year prices were set at the lesser of the 1995 reasonable charge, or the reasonable charge that would have been used for 2002. Since 2002, the fee schedule has been updated annually by the percentage increase in the consumer price index (CPI) over the 12 months ending in June of the preceding year.[11]

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. With the exception of parenteral nutrition and pumped insulin (which are billed under Part B using HCPCS codes), pharmacies typically submit 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's 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 independently decide 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.[12]

[11] "Medicare Program; Replacement of Reasonable Charge Methodology by Fee Schedules for Parenteral and Enteral Nutritents, Equipment, and Supplies." The Federal Register, August 28, 2001. Accessed April 4, 2011. http://www.federalregister.gov/articles/2001/08/28/01-21657/medicare-program-replacement-of-reasonable-charge-methodology-by-fee-schedules-for-parenteral-and.

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

On the pharmacy side, a plan may negotiate discounts on dispensing fees by agreeing to include the pharmacy in its network.[13]

2.2 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.

2.2.1 Part B Premiums

The law requires that funds collected during the year from monthly premiums be 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 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 were responsible for paying 1/3 of the adjustment amount in 2007, 2/3 in 2008 and the full amount in 2009.[14] Table 2-1 provides a breakdown of the fully implemented adjusted premium amounts by income level in 2010.

Table 2-1: Part B Premiums by Income Level, 2010

Annual Income		Total Monthly Premium
Individual Beneficiaries	**Married Beneficiaries**	
Not greater than $85,000	Not greater than $170,000	$110.50
Between $85,000 and $107,000	Between $170,000 and $214,000	$154.70
Between $107,000 and $160,000	Between $214,000 and $320,000	$221.00
Between $160,000 and $214,000	Between $320,000 and $428,000	$287.30
Greater than $214,000	Greater than $428,000	$353.60

Source: CMS Manual System Publication 100-01 Transmittal 56, http://www.cms.gov/Transmittals/downloads/R61GI.pdf.

[13] If enrollees fill their prescriptions at pharmacies outside their plan's network, their drugs may not be covered by the plan or beneficiaries may pay a higher copay amount.

[14] 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

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 who are enrolled in MA plans continue to pay the standard Part B premium they would pay under FFS Medicare (Part B).[15] 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 FFS costs and is 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.

2.2.2 Part D Premiums

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 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 higher premiums.[16] A risk adjustment factor is added to increase the subsidy provided for beneficiaries with greater

[15] For additional coverage, beneficiaries can pay a premium amount to the MA plan.
[16] 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 any low-income premium subsidy.

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).

2.3 Beneficiary Point-of-Sale Costs

In addition to monthly premiums, Part B and Part D beneficiaries 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.

2.3.1 Part B Beneficiary Point-of-Sale Costs

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 a beneficiary has met the deductible, Medicare covers 80 percent of Medicare-approved charges, and the beneficiary pays the remaining 20 percent.[17] Providers may not charge rates in excess of 115 percent of the Medicare-approved charge. 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.

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 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.

2.3.2 Part D Beneficiary Point-of-Sale Costs

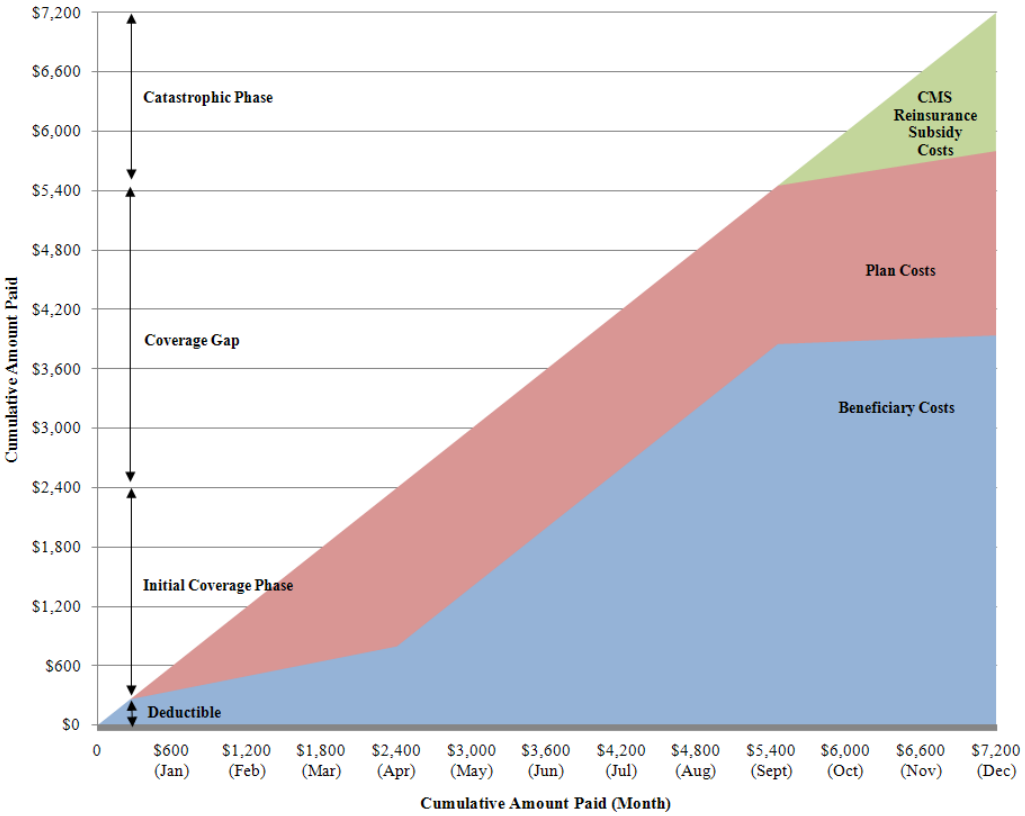
Part D point-of-sale costs are designed by the beneficiary's plan, which can be a standard plan or one of three types of non-standard plans: actuarially equivalent plans, basic alternative plans, or enhanced plans. For the standard plan, beneficiary cost for a given drug is strictly decided by the cost of the drug 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:

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

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 pays 75 percent.
3. *Coverage Gap:* A beneficiary passes into the coverage gap when Gross Drug Costs (GDC) 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 (2007). In the catastrophic coverage phase, the beneficiary pays either five 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 via a payment referred to as the Reinsurance Subsidy.

Figure 2-1 demonstrates how costs are shared between the beneficiary, plan, and CMS's Reinsurance Subsidy for a beneficiary in a standard plan with $600 of monthly drug costs.

Figure 2-1: Share of Costs for Beneficiary, Plan, and Medicare in a Standard Plan, 2007



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, increased 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 eligible for the Low-Income Subsidy (LIS) also have some or all of their point-of-sale costs covered by Medicare; this is referred to as Low-Income Cost-Sharing (LICS) Subsidy.

2.4 Summary Comparison of Part B and Part D Benefit Structures

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 Part D benefit phase.

3 PART B VERSUS PART D DETERMINATION

One of the main reasons for consolidating certain drugs under either the Part B or the Part D program is to avoid the administrative complexity of the B versus D determination process for pharmacies and medical providers. In this section, we describe the current process and how this would change as a result of the proposed consolidation for each of the analysis drugs. We have developed the following narrative based on CMS documentation and interviews with pharmacists and medical providers. This qualitative analysis included extensive review of the Medicare Coverage Manuals, the Prescription Drug Benefit Manual, and the CMS document entitled "Medicare Part B versus Part D Coverage Issues." We also interviewed several CMS staff members and other experts using a protocol designed to obtain information both on how the analysis drugs are prescribed and billed under the Part B and Part D programs as well as the Part B versus Part D determination process. CMS staff members interviewed for this analysis included members of the Office of Clinical Standards and Quality, members of the Center for Drug and Health Plan Choice, and a DME Medicare Administrative Contractor (DMAC) officer. Additional interviewees included pharmacists, physicians, and DMACs.

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 be approved by the Food and Drug Administration (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 used as a replacement for intravenous (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 off-label uses and all antiemetic drugs not for use within 48 hours of cancer treatment. [18]

Part D utilization in 2007 far surpassed utilization under Part B, while costs were split evenly between the two programs. In 2007, 68,000 beneficiaries took oral anticancer/antiemetic drugs under Part B; total costs for these drugs were $170 million. Approximately 1.6 million beneficiaries took these drugs under Part D; total costs were also approximately $170 million.[19]

[18] Examples of off-label uses of anticancer drugs include the treatment of severe rheumatoid conditions, progressive rheumatoid arthritis, and Crohn's disease.

[19] The sources for all 2007 utilization numbers presented in this chapter are the 2007 Standard Analytical Files: Carrier, DME, and OP, and PDE Data.

3.1.1 Current Determination Process

The anticancer/antiemetic 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 1990s, 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. However, the Part D plan's Pharmacy Benefit Manager (PBM) often rejects such claims via the use of extensive edits.

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 International Classification of Diseases (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 and antiemetic 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. An interview with a DMAC indicated a key factor preventing the development of effective edits is that the system needs to recognize that there is some lag between the time a physician administers an IV anticancer drug and the time the claim is filled. An edit in the DME system that rejects claims for oral antiemetic drugs if no claims for IV anticancer drugs are found within two days of the date of service would lead to a considerable amount of incorrect rejections. At the same time, DMACs seldom conduct audits to recover inappropriate payments because they are not a large enough share of total payment to warrant this time-intensive exercise.

The complications involved in the determination process can also impact 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.

3.1.2 Benefits of the Proposed Consolidation

Consolidating all anticancer and antiemetic 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 covers vaccinations for influenza and pneumonia for all beneficiaries and for Hepatitis B for medium and high-risk beneficiaries.[20] 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 rusty nail). The MMA requires Part D to provide coverage for many other vaccines.

Utilization and total costs for vaccines are significantly higher under Part D than Part B. In 2007, 12.7 million beneficiaries took vaccines covered under Part B at a cost of $172 million. Only 350,000 beneficiaries took vaccines covered under Part D, at a cost of about $54 million. 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 of vaccines for beneficiaries receiving them under Part D, where the majority of claims are for the herpes zoster vaccine, is $153, compared to just $14 in Part B, where most claims are for the relatively inexpensive influenza and pneumonia vaccines.

3.2.1 Current Determination Process

The vast majority of vaccines are dispensed at physician's offices, although it is increasingly common for pharmacies to offer vaccines, depending on state regulations and administration practices. Because physicians are more 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 under 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

[20] "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, and 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 CMS Adult Immunization Provider Resources: https://www.cms.gov/AdultImmunizations/02_Providerresources.asp.

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 not within Part D plan pharmacy networks, beneficiaries receiving a vaccine covered by Part D at a physician'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.[21] Physicians can prescribe the vaccine to the beneficiary, who then takes the prescription to and receives the vaccine from a pharmacist. In cases where state regulations or administrative complexities prohibit the pharmacist from injecting the vaccine, the pharmacy can mail (or the beneficiary can transport) the vaccine to the prescribing physician. However, 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 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 the Proposed Consolidation

Due to the obstacles physicians face in billing Part D and concerns regarding beneficiary access, the Medicare Payment Advisory Commission (MedPAC) recommended in 2007 that all

[21] 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.

vaccines and administration fees be paid under Part B.[22] Furthermore, 22 medical organizations including the American Medical Association (AMA) drafted a letter to members of the U.S. 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. Interviews with CMS staff indicated the transition would not place substantial burden on the Part B system, as any additional work would be easily absorbed into current Part B billing mechanisms.

3.3 Insulin

The Medicare program that covers insulin depends on the delivery method by which the drug is dispensed. Insulin 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 pump, Part B is the covering program.

Many more beneficiaries take insulin under Part D than under Part B. In 2007, 13,000 beneficiaries took insulin under Part B, with total costs of $10.9 million. Approximately 1.1 million beneficiaries took insulin under Part D, costing over $1 billion.

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 pharmacies. Additionally, as discussed above in reference to anticancer and antiemetic 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 the pump (covered by Part B). This analysis does not consider moving the syringe or

[22] "Report to the Congress: Promoting Greater Efficiency in Medicare." MedPAC. June 2007. http://www.medpac.gov/documents/jun07_entirereport.pdf.

pump to a separate Medicare program, and costs for the syringe and pump are not included in the findings.

3.3.2 Benefits of the Proposed Consolidation

Moving all insulin to Part D, regardless of dispensing form, 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, consolidation would remove the need for the Part B program or Part D plans to maintain systems edits. While moving insulin dispensed by pump to Part D would mean that insulin solution and pumps would be covered under different programs, beneficiaries receive pumps from a separate provider, not the pharmacy, so covering the two under separate programs should not create additional complexity.

Consolidating insulin under Part B poses two challenges. First, because pharmacies fill prescriptions for insulin vials, consolidation under Part B would not address the issues associated with pharmacies billing Part B. Second, the current payment limit for insulin in Part B is significantly lower than the median price for insulin in Part D. If insulin were consolidated under Part B and the payment limit remained unchanged, providers may be resistant to providing the drug at the lower rate. However, if insulin was consolidated under Part B and the payment limit increased to the median Part D price, Medicare costs for insulin coverage would increase.[23]

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 be 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. Part B covers nebulizers under the DME benefit for patients with certain respiratory problems or related illnesses. These conditions include chronic bronchitis, emphysema, asthma, and cystic fibrosis.[24] Medication dispensed in a nebulizer is covered under the same benefit as a supply for the effective use of the equipment.

[23] The previous analysis examined the effects of consolidating insulin under Part B. 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 were used.
[24] "Nebulizers." http://www.medicare.com/equipment-and-supplies/nebulizers.html.

Inhalants are more commonly used under Part D than Part B. In 2007, 1.1 million beneficiaries took inhalants covered under Part B, costing $1.2 billion. Both utilization and costs were significantly higher under Part D, with 3.7 million beneficiaries taking inhalants at a cost of $2.5 billion.

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 provided through DME, 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 less familiar to pharmacies than the Part D process.

3.4.2 Benefits of the Proposed Consolidation

Nebulizer inhalants have historically been covered under Part B as DME. Subsequent to the creation of the Part D benefit, these inhalants would more naturally be covered under Part D as prescription drugs. Consolidating nebulizer inhalants under Part D could facilitate the use of step therapy and coordination of care, since nebulizers are often prescribed for patients who could not successfully treat their condition with MDIs. Consolidation would also mean that pharmacies would switch from billing Part B to Part D, which is a more familiar billing process. Although the nebulizer solution and equipment would be covered under different programs after consolidation, beneficiaries already receive equipment from a separate DME provider, not the pharmacy, so covering each component separately should not create additional complexity for beneficiaries. For nebulizer inhalants, there are no gains from consolidation for the Part B and Part D processing systems. MDIs and nebulizer inhalants are easily distinguishable by NDC codes, and no edits are required under the current system to reject a given code under some situations and accept it under others.

3.5 Parenteral Nutrition

Patients suffering from digestive system dysfunction who cannot consume food orally or through the gastrointestinal (GI) tract may receive food intravenously via parenteral nutrition. Parenteral nutrition drugs may be administered in hospitals, skilled nursing facilities, or in a patient's home on a long-term or short-term basis. Long-term use is usually due to the extended consequences of an accident, surgery, or digestive disorder, which prevent the consumption of nutrients via normal feeding methods. A short-term need for parenteral nutrition may result from

conditions requiring complete bowel rest, including some stages of Crohn's disease or ulcerative colitis, along with bowel obstruction, short bowel syndrome, and various other GI diseases.

Parenteral nutrition is covered under Part B if the patient has a permanent dysfunction of the digestive tract. In cases where the dysfunction is not permanent, parenteral nutrition is covered under Part D.

Utilization of parenteral nutrition is split across Part B and Part D, but average costs are higher in Part B since those beneficiaries have permanent dysfunctions that cause them to utilize more of the drug each year than their Part D counterparts. In 2007, 5,000 beneficiaries took parenteral nutrition under Part B, with total costs exceeding $150 million. Approximately 4,000 beneficiaries took parenteral nutrition under Part D, at a cost of $18 million.

3.5.1 Current Determination Process

In cases where the digestive tract dysfunction is permanent, parenteral nutrition is covered under the prosthetic device provision of Medicare Part B. In all other cases, it is covered under Part D, although Part D does not pay for the equipment, supplies, and professional services associated with the provision of parenteral nutrition. Individuals who are not medical professionals, such as family members, may receive training to administer parenteral nutrition in a non-medical setting. However, Medicare does not reimburse these individuals for their services. To avoid disrupting beneficiary care, CMS discourages Part D plans from requiring that a claim be rejected by Part B prior to Part D approval.[25]

The process for obtaining Part B coverage places considerable burden on both physicians and the Part B program. To receive coverage under Part B, the beneficiary's claim must contain a physician's written order or prescription and sufficient medical documentation to show that parenteral nutrition therapy is medically necessary (i.e., the beneficiary cannot absorb the nutrients needed to maintain weight and strength via other feeding methods) and that the patient's gastrointestinal dysfunction will last indefinitely. As such, requests for Part B coverage are approved by the carrier's medical consultant or trained staff on a case-by-case basis. Approval is required when the patient begins receiving parenteral nutrition, and afterwards at intervals of three months or less. The process of providing the relevant medical documentation places a burden on the prescribing physician. The burden on Part B program integrity activities is also extensive, as carriers must pay experts to review each case.

[25] "Medicare Part B versus Part D coverage issues." http://www.cms.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf.

3.5.2 Benefits of the Proposed Consolidation

As with vaccines, consolidation under Part B would improve access to care because more Medicare beneficiaries receive benefits under Part B. Consolidation would also reduce billing burden as pharmacies would no longer bill Part B or D on a case-by-case basis. Plans would not have to require prior authorization nor maintain other systems' edits to avoid inappropriate coverage. Finally, the Part B program would no longer have to investigate and approve beneficiaries for coverage, a process that involves determining the duration of the parenteral nutrition treatment. Consolidation would also reduce the burden for physicians, as they would no longer have to provide documentation that beneficiaries covered under Part B have permanent digestive tract dysfunctions.

3.6 Immunosuppressant Drugs

Immunosuppressant drugs are covered under Part B provided they are used in immunosuppressive therapy by a beneficiary who received a transplant covered under Medicare Part A. In all other situations, these drugs are covered under Part D.

Part B currently has no time limits for coverage of immunosuppressive drugs for beneficiaries age 65 or older. For End Stage Renal Disease (ESRD) beneficiaries under 65 years of age, Part B covers immunosuppressive drugs up to 36 months after discharge from the hospital for a kidney transplant. Medicare Part B only provides coverage for immunosuppressive drugs that have been labeled as such and approved for marketing by the FDA. No exceptions are made for individual cases where the use of non-approved drugs is found to be reasonable and necessary. Part B contractors are expected to keep informed of any changes to the FDA list and to maintain system edits to reject non-covered drugs. Coverage of immunosuppressant drugs is guaranteed under Part D since immunosuppressants are one of the six protected drug classes that all Part D plans must cover.[26]

Utilization for immunosuppressant drugs is split across Part B and Part D, but costs under Part B are higher. In 2007, 74,000 beneficiaries took immunosuppressants under Part B, costing $517 million. Over 80,000 beneficiaries took immunosuppressants under Part D, at a cost of $181 million.

[26] The six protected drug classes are antipsychotics, antidepressants, anticonvulsants, immunosuppressants (for prophylaxis of organ transplant rejection), antiretrovirals, and antineoplastics https://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

3.6.1 Determination Process

The determination process for immunosuppressants places burden on both pharmacies and Part D plans as Part D plans must maintain systems edits to prevent inappropriate billing, while pharmacists must often override these edits to bill Part D. Under CMS policy, pharmacies may bill Part B or Part D depending on information they receive from individual beneficiaries and from the PDP plan. However, interviews indicate that pharmacies do not typically ask for documentation from the beneficiary. Instead, they bill the Part D plan, which may have edits in place to prevent payment for drugs that should be covered under Part B. To prevent the disruption of beneficiaries' immunosuppressive therapy, CMS discourages Part D plans from requiring a Part B claim rejection prior to accepting a claim for immunosuppressant drugs. Plans may instead require prior authorization for these drugs, leading to edits that the pharmacy must override before the Part D plan will accept the claim.[27]

3.6.2 Benefits of the Proposed Consolidation

Consolidating all immunosuppressive 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. Furthermore, since immunosuppressants are one of the six drug classes protected under Part D, CMS does not need to make revisions to the Part D program to ensure coverage of all FDA-approved immunosuppressants.

3.7 Consolidation Approach

Based on the information presented above, this analysis explores consolidating four categories of drugs under Part D: oral anticancer/antiemetic drugs, insulin, inhalants, and immunosuppressants. In general, we simulate consolidating pills (i.e., anticancer/antiemetic drugs and immunosuppressants) under the Part D prescription drug benefit because medical assistance is not required to administer these medications, and they are similar in form to other prescription drugs dispensed under Part D. To accomplish this, oral anticancer drugs prescribed for cancer treatment and oral antiemetic drugs prescribed within 48 hours of cancer treatment are moved from Part B to Part D, as are immunosuppressants taken by beneficiaries who received an organ transplant covered under Medicare Part A. According to our interviews, moving nebulizers to Part D, where they will be covered along with MDIs, facilitates step therapy, while moving pumped insulin to Part D facilitates pharmacy billing and eliminates the need to contact the prescribing physician to confirm the method of dispensing the drug.

[27] "Medicare Part B versus Part D coverage issues." http://www.cms.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf.

Additionally, this analysis explores consolidating two categories of drugs under Part B: vaccines and parenteral nutrition. We simulate consolidating vaccines under Part B because the analysis of interviews and CMS documentation indicates that preventative vaccines have a higher adherence rate under Part B. For this analysis, vaccines for diseases other than influenza, pneumonia, and Hepatitis B are moved from Part D to Part B. Finally, parenteral nutrition is an IV drug typically administered through a physician's office; therefore, we move parenteral nutrition for beneficiaries who do not have a permanent dysfunction of the digestive system to Part B.

Table 3-1 summarizes the Part B and Part D coverage criteria for each analysis drug and the proposed Medicare program for consolidation, chosen based on CMS documentation and analysis of interviews with pharmacists and medical providers.

Table 3-1: Coverage Criteria and Proposed Consolidation Program, by Drug Type

Analysis Drug	Current Part B Coverage Criteria	Current Part D Coverage Criteria	Proposed Consolidation Program
Anticancer/Antiemetic	Anticancer drugs used for cancer treatment and antiemetic drugs prescribed within 48 hours of cancer treatment as a replacement for IV antiemetic drugs	All other uses of anticancer or antiemetic drugs	Part D
Insulin	Pumped insulin	Injectable insulin	Part D
Inhalants	Nebulizer Inhalants	MDIs	Part D
Immunosuppressants	Drugs used in immunosuppressive therapy to prevent rejection of a transplant covered under Part A of Medicare	All other uses of immunosuppressant drugs	Part D
Vaccines	Influenza, Pneumococcal, Hepatitis B (for medium to high-risk beneficiaries), other vaccines for beneficiaries who have been exposed to the disease	All other vaccines	Part B
Parenteral Nutrition	Parenteral nutrition for beneficiaries with a permanent dysfunction of the digestive tract	All other uses of parenteral nutrition	Part B

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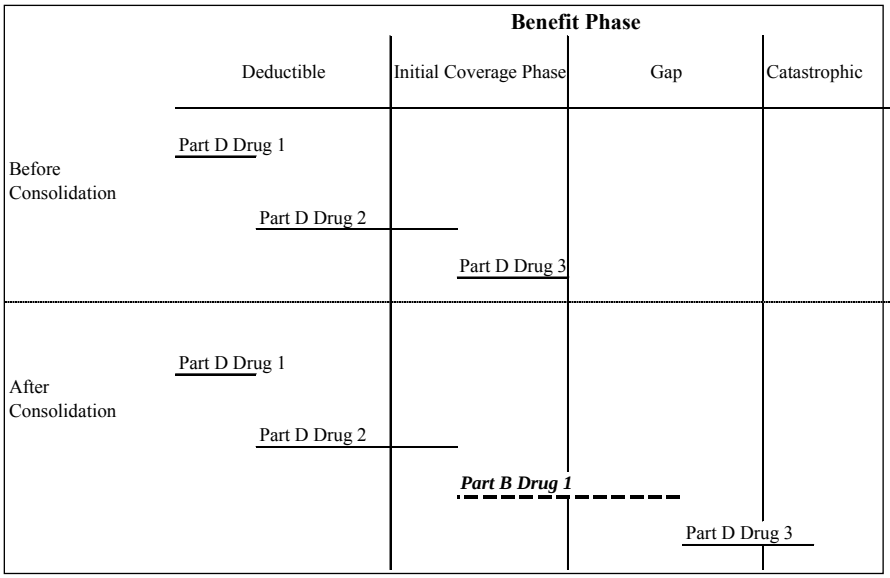
4 SIMULATION FRAMEWORK

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 4-1 illustrates the simulation methodology for calculating 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), 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 into 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 4-1: 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 (HPMS), 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 the proposed 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 4-1 presents the seven major steps of the simulation. The following subsections discuss each step in more detail.

Table 4-1: 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 for 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 is available, we use the per unit median price of NDCs that map to that active ingredient across all PDEs.
	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 the 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.	

4.1 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 identify the HCPCS codes associated with B to D drugs (i.e., anticancer/antiemetic, pumped insulin, nebulizer inhalants, and immunosuppressants) and extract all associated claims from the 2007 DME, Carrier or Outpatient (OP) claims files.[28] We use information in Medispan and First DataBank (FDB) to identify NDCs related to D to B drugs (i.e., vaccines and parenteral nutrition). For vaccines, we first identify the NDCs that correspond to the relevant therapeutic classes.[29] We then exclude any Part D claims for influenza, pneumonia, and hepatitis B vaccines because they should be covered under Part B. For parenteral nutrition, we identify relevant NDCs administered through an IV and classified as nutrients or mineral electrolytes, and then we remove NDCs lacking a caloric component from the minerals and electrolytes category.[30] Appendix A lists the HCPCS codes that correspond to each drug cohort.[31] 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 under its original Medicare program in 2007 (see Table 5-1). Therefore, a beneficiary taking multiple drugs could appear in more than one drug-specific cohort. For the simulation, we restrict the cohort size to a maximum of 120,000 individuals obtained by randomly sampling the population taking a particular drug. This restriction applies to beneficiaries using vaccines and nebulizer inhalants, and the *Combined* cohort consisting of all beneficiaries taking analysis drugs.

4.2 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

[28] We use the CMS Claims Processing Manual (https://www.cms.gov/manuals/downloads/clm104c17.pdf) to identify HCPCS associated with anticancer/antiemetic drugs, pumped insulin, and nebulizer inhalants. Since the manual does not contain a list of HCPCs for immunosuppressant drugs, we use commercial databases to identify NDCs classified as immunosuppressant drugs, map these NDCs to HCPCS codes using the CMS NDC-HCPCS crosswalk, and restrict to oral drugs.

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

[30] NDCs with 10% Dextrose or less are excluded as lacking a caloric component.

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

consolidated under D, and 2) Part D drugs to be consolidated under B. The discussion below describes in detail the calculation of pre-consolidation Part B and Part D costs.

4.2.1 Pre-Consolidation Part B Costs

For each Part B drug to be consolidated under Part D (anticancer/antiemetic, pumped insulin, nebulizer inhalants, and immunosuppressants), we extract all simulation drug claims found in the DME, Carrier, and OP files of the 2007 Standard Analytical Files (SAFs). The DME and Carrier files provide claim-level information on drug quantity, which we multiply by ingredient cost per unit found in the 2007 ASP Drug Pricing files, to establish the total ingredient cost of each claim.[32] OP claims, which make up approximately 38 percent of total Part B anticancer/antiemetic drug claims, three percent of pumped insulin claims, and 0.2 percent of nebulizer inhalant claims, do not contain drug quantity. 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. Since the ASP files are 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 any applicable pharmacy supply fees (anticancer/antiemetic drugs[33]) and administration fees (vaccines[34]).

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.

4.2.2 Pre-Consolidation Part D Costs

Pre-consolidation Part D costs are calculated from the financial information reported in the PDE data. For each PDE, costs are calculated for three parties: the beneficiary, Medicare, and the Part D plan.

[32] 2007 ASP Drug Pricing Files: https://www.cms.gov/McrPartBDrugAvgSalesPrice/01b_2007aspfiles.asp.
[33] 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.
[34] $19.93 for 2007.

We calculate beneficiary costs for each PDE as the sum of "patient pay amount" and "other True Out-of-Pocket (TrOOP) amount," both of which appear on the PDE claim. The beneficiary cost share varies considerably depending on the beneficiary's LIS status (since Medicare subsidizes the costs of LIS beneficiaries) and the benefit phase. For example, a beneficiary in a standard plan pays 100 percent of drug costs in the coverage gap but only five percent in the catastrophic phase.

Medicare payments can be decomposed into LICS payments and the Reinsurance Subsidy, with the LICS subsidy applying only to claims for LIS beneficiaries. LICS payments are calculated by adding LICS amounts that are reported in the claim. Reinsurance Subsidy payments are calculated using all PDE claims in the catastrophic benefit phase. These claims are identified by selecting all claims with a positive Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA).[35] Reinsurance Subsidy payments are calculated by taking 80 percent of the total GDCA reported in the catastrophic claims.[36]

Finally, Part D plan costs for non-catastrophic claims are equal to the difference between the GDC and the sum of the beneficiary costs and the patient liability reduction due to other payer (PLRO) amount. In the catastrophic phase, plan costs are equal to 15 percent of the GDC, less any beneficiary payments in excess of five percent of the GDC.

4.3 Projecting Post-Consolidation Prices

We simulate the amount that beneficiaries would have paid if the drugs had been covered under a different program. The subsections below explain how we infer Part D prices for drugs moving from Part B to Part D, and Part B prices for drugs moving from Part D to Part B. These prices enable us to calculate post-consolidation drug costs, presented in Section 6, and to allocate these costs across beneficiaries, Medicare, Medicaid, and Part D plans.

4.3.1 Pricing Part B Drugs under Part D Coverage

To determine drug prices (i.e., ingredient costs) under Part D for each B to D drug, we use pricing information from 2007 PDE data. Because PDE data reports drugs by NDC, we first identify all NDCs corresponding to the active ingredient and strength information listed in the HCPCS description. We also match HCPCS to NDCs based on dosage form (e.g., powder, liquid) for nebulizer inhalants, and based on route of administration (e.g., oral) for vaccines.

[35] A PDE record's total drug costs in the PDE claim can also be broken into GDCB (Gross Drug Cost Below Out-Of-Pocket Threshold) and GDCA (Gross Drug Cost Above Out-Of-Pocket Threshold). GDCB are drug costs incurred in pre-catastrophic phases, while GDCA are costs incurred in the catastrophic phase.

[36] For the calculation of Reinsurance Subsidy payments, CMS calculates plans' total GDCA net of direct and indirect remunerations from drug manufactures to plans (e.g., rebates and volume discounts). The remunerations are consolidated in the direct and indirect remunerations (DIR) data, which was not available for this study.

NDC codes are more specific than HCPCS codes in certain dimensions (e.g., NDCs are specific to brand/generic status, manufacturer, and package size), so one HCPCS code can map to multiple NDCs. Therefore, we map each HCPCS to a group of NDCs that share the same active ingredient, route of administration, and dosage form, and extract all 2007 PDEs corresponding to the list of NDCs. We then exclude compound PDE claims; we require that the active ingredient in the HCPCS description be the only active ingredient.

Based on this mapping and quantity information found in the Part B claims, we assign a GDC to each Part B claim moving 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 – and the dispensing fee. This amount is then multiplied by one plus the sales tax rate.

$$GDC = (quantity_b * strength_b * p_j^D + df) * (1+tax)$$

Where

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

4.3.2 Pricing Part D Drugs under Part B Coverage

We construct post-consolidation prices of vaccines under Part B by using the published Part B Payment Allowance Limit for the HCPCS code that corresponds to the Part D claim

NDC, whenever the HCPCS code is reported in the ASP Pricing File.[37] Most vaccines are priced in this fashion. In cases where the HCPCS code 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.

For parenteral nutrition, we first separate claims into compound and non-compound claims. For compound claims and for claims corresponding to NDCs that had fewer than 300 claims in 2007, we use the Part D price on the claim as the simulated price under Part B. This applies to 74 percent of parenteral nutrition claims. For non-compound claims, we use the Part B price for any claim with an NDC that could be mapped to a billing unit in the DME pricing file. Prices for 21 percent of claims are assigned this way. For the remaining claims (five percent of claims for parenteral nutrition), we use the median observed Part D price for the NDC.

4.4 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 the beneficiary's 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 sharing for each of the following three groups: 1) Part D enrollees, 2) beneficiaries not enrolled in Part D, with creditable coverage, and 3) beneficiaries not enrolled in Part D, without creditable coverage. We describe each method in detail below.

4.4.1 Part D Enrollees

For the beneficiaries enrolled in Part D, the calculation of post-consolidation financial impact 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.

[37] 2007 ASP Drug Pricing Files: https://www.cms.gov/McrPartBDrugAvgSalesPrice/01b_2007aspfiles.asp.

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

4.4.2 Beneficiaries with Creditable Coverage

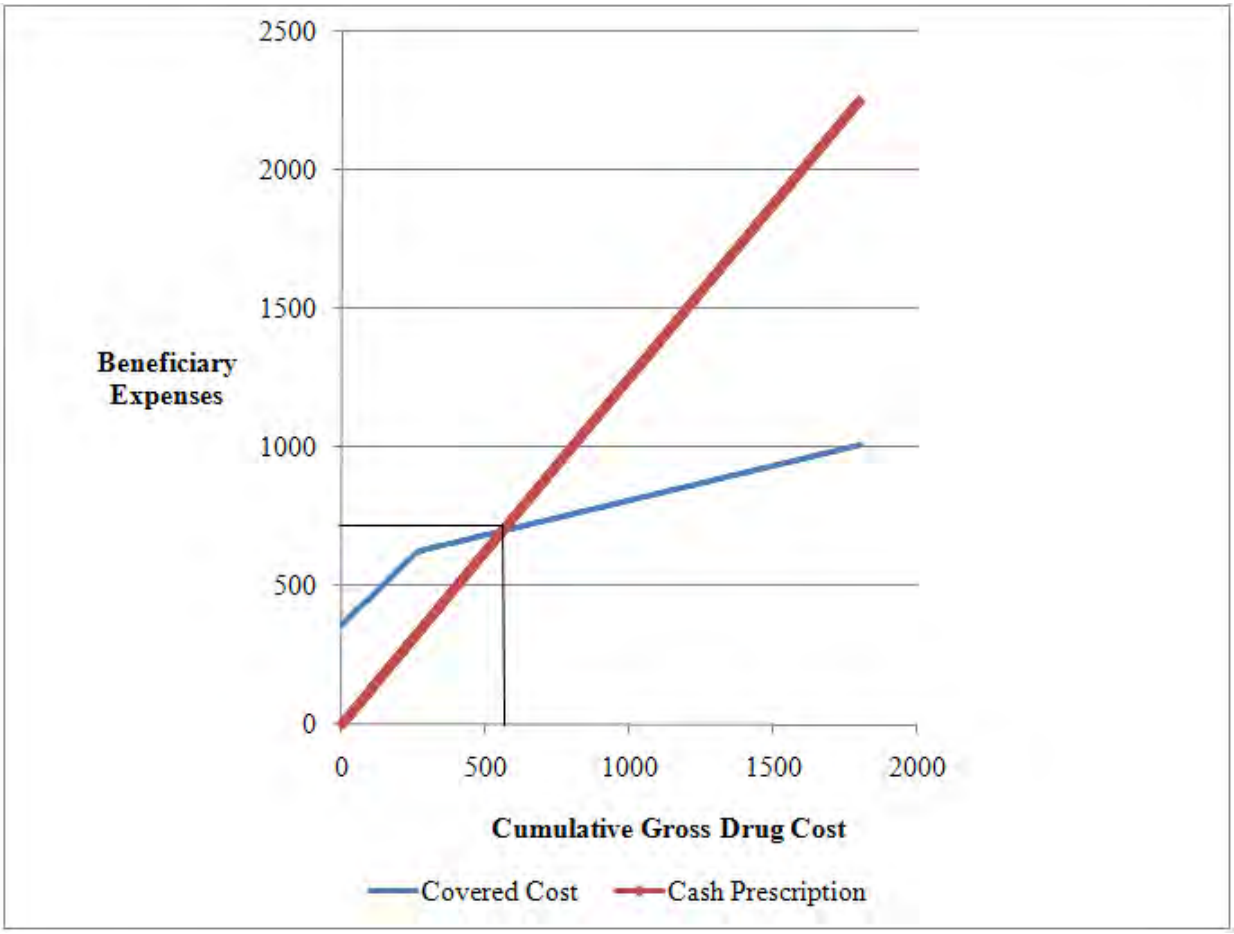
For beneficiaries with creditable coverage, we resolve the problem of unobserved annual drug costs by extrapolating results from an OLS regression on a sample of Part D beneficiaries who were not eligible for LIS in 2007. Specifically, we regress the natural logarithm of annual beneficiary GDC on demographic characteristics (e.g., gender, age brackets) and diagnostic data (Prescription Drug Hierarchical Condition Categories [RxHCC] indicator variables, which are included in Medicare's Part D risk adjustment model). We run separate regressions for each cohort. We then predict annual GDC for the creditable coverage beneficiaries. This serves as the base for pre-consolidation calculations for this group of beneficiaries. Since creditable coverage plans must be at least actuarially equivalent to the standard Part D plan, we use the standard benefit structure to approximate cost sharing 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 the proposed B to D consolidation.

4.4.3 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 4-2 illustrates 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 out-of-pocket costs with no insurance, accounting for the fact that the GDC of a prescription is higher for individuals who do not have prescription drug insurance. Using the commercial database Verispan, we found that in 2007, pharmacy prices of drugs were on average 25 percent higher for purchasers without 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. For each beneficiary without creditable coverage, we predict GDC from the OLS regression described above, rescaling so that the distribution is bounded in the range

(0,559). This approach ensures that imputed prescription costs are higher for beneficiaries with higher risk scores. We then assess whether out-of-pocket costs are lower if the beneficiary enrolls in Part D rather than remaining without coverage when Part B drugs are added to Part D. 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 4-2: Relationship between GDC and Beneficiary Expenses



4.5 Calculating the Financial Impact on Beneficiaries

For each beneficiary in the simulation sample, we calculate beneficiary-level post-consolidation costs for each payer 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.

4.6 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 cannot directly estimate the rise in total cost for each plan; thus, we assume that the increase in the Part D bid for each plan is proportional to the increase in plan liability after the proposed 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 liability. Analogously, in D to B simulations, Part B premiums increase and Part D plan bids fall due to the changes in coverage.

4.7 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 Subsidy 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 the proposed consolidation.

4.8 Limitations

This analysis has several limitations. First, it does not take into consideration the administrative costs of enacting legislation to implement the proposed 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 to allow for consolidation under certain scenarios. Second, we do not address the administrative costs of any systems changes needed to implement the proposed 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. For example, consolidation of nebulizer inhalants under Part D could impact suppliers of nebulizer drugs, as typical chain and community retail pharmacies may not have the resources to accommodate a large and sudden increase in patients who require nebulizer inhalants. Stocking, dispensing, and potentially delivering 30 to 90-day supplies of nebulizer drugs may require more space and resources than some pharmacies currently have at their disposal. Also, DME suppliers would lose a source of revenue if they are prevented from supplying drugs associated with pumps and nebulizers. This loss of revenue could impact the

willingness of these entities to supply pumps and nebulizers, as well as the costs of the equipment. Finally, our pricing of Part D prescriptions for parenteral nutrition under Part B is imperfect. About 50 percent of Part D claims for parenteral nutrition are for compound products. However, a PDE only reports the NDC for one of the active ingredients of the drug. We therefore cannot identify HCPCS equivalents for compound PDEs and apply our typical pricing strategy using the Part B fee schedule. In the analysis, projected Part B costs for compounded Part D products equal the GDC under Part D.

5 PRE-CONSOLIDATION UTILIZATION PATTERNS

In this chapter, we review pre-consolidation utilization and costs. Section 5.1 provides an overview of pre-consolidation utilization in each of the six drug cohorts. Section 5.2 focuses on drugs moving from Part B to Part D, presenting average annual costs and average costs per drug fill; the division of costs between beneficiaries, Medicare, and Medicaid; and the distribution of Part B beneficiary costs. This section also examines Part D coverage of Part B drugs and the pricing of B to D drugs under Part B and Part D. Section 5.3 focuses on drugs moving from Part D to Part B and presents average costs for these drugs; the division of costs between beneficiaries, Medicare, and Part D plans; and pricing of D to B drugs under Part B and Part D.

5.1 Overview of Pre-Consolidation Utilization and Costs

The number of beneficiaries affected by consolidating the drugs considered in this analysis varies widely by drug type, ranging from only 3,500 beneficiaries taking parenteral nutrition under Part D to over 1.1 million beneficiaries taking nebulizer inhalants under Part B (Table 5-1). Since a small share of affected beneficiaries take multiple analysis drugs, the total number of beneficiaries in the "combined" row (1.6 million) is less than the sum of beneficiaries in each of the six beneficiary cohorts. Overall, 1.2 million beneficiaries would be affected by moving the proposed drugs from Part B to Part D. Of these, 900,000 currently have coverage under Part D and 100,000 have creditable coverage, meaning the remaining 200,000 beneficiaries would likely lose access to a drug due to the proposed consolidation if they do not enroll in Part D. Since almost all beneficiaries enrolled in Part D are also enrolled in Part B, very few beneficiaries would lose coverage after the proposed consolidation under Part B.

The proposed consolidation would affect approximately $2 billion in drug payments across both Part B and Part D. The most expensive cohort is beneficiaries taking nebulizer inhalants, whose total Part B costs exceed $1.2 billion. Beneficiaries taking pumped insulin have the lowest amount of payments potentially affected, at $10.8 million.

Table 5-1: Number of Beneficiaries and Total Payments Potentially Affected by the Proposed Consolidation

Beneficiary Cohort	Number of Beneficiaries Potentially Affected	Total Payments Potentially Affected
B to D Cohort		
Anticancer/Antiemetic	68,082	$169,253,702
Pumped Insulin	12,269	$10,864,039
Nebulizer Inhalants	1,101,622	$1,227,000,468
Immunosuppressant	74,136	$517,493,645
D to B Cohort		
Vaccines	353,158	$54,205,827
Parenteral Nutrition	3,587	$18,603,545
Combined Cohort	1,600,053	$1,997,421,227

Source: 2007 Standard Analytical Files: DME, Carrier, and OP, Prescription Drug Event Data
The number of beneficiaries in the *combined* row is less than the sum of beneficiaries in the six cohorts because some beneficiaries take multiple analysis drugs.

5.2 Drugs Consolidated Under Part D

This section examines pre-consolidation Part B utilization for the four beneficiary cohorts taking drugs moving from Part B to Part D under the proposed consolidation. It then reviews current Part D coverage of proposed drugs being moved from Part B to Part D. Finally, this section examines pricing of proposed B to D drugs under both Part B and Part D.

5.2.1 Pre-Consolidation Part B Costs and Utilization

Table 5-2 summarizes the utilization of each type of drug currently covered in Part B, including the number of beneficiaries with claims, the average number of claims per beneficiary, and the average cost per beneficiary. The first three rows of the table separate beneficiaries into cohorts based on consumption of each individual drug.[38]

As the conditions treated by anticancer/antiemetic drugs, insulin, inhalants, and immunosuppressants tend to be chronic, beneficiaries taking these drugs average multiple claims during the year. Beneficiaries taking immunosuppressants, who incur the highest annual cost, will likely enter the coverage gap under Part D if immunosuppressants are moved to Part D. Entering the gap could be more problematic for beneficiaries taking anticancer/antiemetic drugs since the average cost per claim for these drugs is $620. The average cost per claim in the coverage gap drops to $496 under the new Coverage Gap Discount Program (CGDP) instituted as part of the Patient Protection and Affordable Care Act of 2010. The CGDP makes manufacturer discounts available to Medicare beneficiaries receiving applicable Part D drugs in

[38] 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 analysis drug.

the coverage gap.[39] Overall, beneficiaries taking B to D drugs had an average annual cost of $1,500.

Table 5-2: Part B Utilization, 2007

Beneficiary Cohort	Number of Beneficiaries Taking the Drug	Average Cost per Fill	Average Annual Cost per Beneficiary
Anticancer/Antiemetic	68,082	$622	$2,486
Pumped Insulin	12,269	$177	$885
Nebulizer Inhalant	1,101,622	$159	$1,114
Immunosuppressant	74,136	$499	$6,980
All B to D Cohorts	1,249,085	$220	$1,541

Source: 2007 Standard Analytical Files: Carrier, DME, and OP
The number of beneficiaries in the *All B to D* row is less than the sum of beneficiaries in the four cohorts because some beneficiaries take multiple analysis drugs.

Part B costs are split between beneficiaries, Medicare, and, for beneficiaries who are dual-eligible, Medicaid. Table 5-3 describes how Part B average drug costs for beneficiaries taking drugs currently covered by Part B are divided among those stakeholders. Average beneficiary costs are highest for beneficiaries taking immunosuppressant drugs. Consistent with Part B 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 5-3: Part B Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicaid and Medicare, by Cohort, 2007

Drug Class	Number of Beneficiaries	Part B Costs		
		Beneficiary	Medicaid	Medicare
Anticancer/Antiemetic	68,082	$385	$113	$1,989
Pumped Insulin	12,269	$137	$40	$708
Nebulizer Inhalant	1,101,622	$126*	$95*	$886*
Immunosuppressant	74,136	$688	$708	$5,584
All B to D Cohorts	1,249,085	$172*	$130*	$1,210*

Source: 2007 Standard Analytical Files
Cost statistics for the nebulizer inhalant and *All B to D* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
*Statistically significant at the 95% CI level.
Medicaid payments are averaged across all beneficiaries, but the program makes payments for dual-eligible beneficiaries only.
The number of beneficiaries in the *All B to D* row is less than the sum of beneficiaries in the four cohorts because some beneficiaries take multiple analysis drugs.

[39] http://www.amcp.org/data/jmcp/367-368.pdf.

The distribution of total pre-consolidation Part B costs across beneficiaries is presented in Table 5-4. Total costs for beneficiaries taking anticancer/antiemetic drugs or nebulizer inhalants are considerably more positively skewed (i.e., the mean exceeds the 50th percentile value) than costs for beneficiaries taking pumped insulin or immunosuppressants. The distribution of combined Part B costs is also positively skewed, which implies that the effect of the proposed consolidation will vary considerably across beneficiaries.

Table 5-4: The Distribution of Part B Pre-Consolidation Point-of-Sale Costs for Beneficiaries with B to D Drugs, by Cohort, 2007

Cohort	Number of Beneficiaries	Cost at 25th Percentile	Cost at 50th Percentile	Cost at 75th Percentile	Mean
Anticancer/Antiemetic	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*
Immunosuppressant	74,136	$2,484	$6,027	$10,101	$6,980
All B to D Cohorts	1,249,085	$187*	$594*	$1,507*	$1,513*

Source: 2007 Standard Analytical Files
Cost statistics for the nebulizer inhalant and *All B to D* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
*Statistically significant at the 95% CI level.
The number of beneficiaries in the *All B to D* row is less than the sum of beneficiaries in the four cohorts because some beneficiaries take multiple analysis drugs.

5.2.2 Part D Coverage of B to D Drugs

This section examines whether Part D plans currently provide coverage of drugs moving from Part B to Part D. Unlike with Part B, Part D plans have considerable flexibility in designing their own formularies, although CMS does provide some regulation. First, Part D plans must offer coverage of six protected classes of drugs (antipsychotic agents, antidepressants, anticonvulsants, immunosuppressants [for prophylaxis of transplant rejection], antiretroviral drugs, and antineoplastic drugs). Second, formularies may not discourage enrollment by beneficiaries with certain disease states. To that end, formularies must include drug categories and classes that cover all disease states; regardless of the classification system utilized by the plan, plans must include at least two drugs in each category (unless only one drug is available or one drug is clinically superior to the other).[40] If Part B drugs are consolidated under Part D, CMS may need new regulations to ensure that beneficiaries retain coverage under Part D.

To illustrate how Part D formularies would need to expand if the proposed Part B drugs were moved to Part D, Table 5-5 presents the average percentage of reference NDCs covered by

[40] Medicare Prescription Drug Benefit Manual, Chapter 6. https://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

Part D sponsors for each drug class. With the exception of nebulizer inhalants, the drug classes have coverage rates above 70 percent. As expected, enhanced plans have higher rates of coverage across drugs.

Table 5-5: Average Percentage of Reference NDCs in Formulary by Plan Type, 2007

Drug Type	Standard	Actuarial Equivalent	Basic Alternative	Enhanced
Anticancer/Antiemetic	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%
Immunosuppressant	73.8%	79.9%	76.87%	79.5%

Source: Approved 2007 Part D Formulary Files

5.2.3 Pricing of B to D Drugs under Part B and Part D

The difference in relative prices between Part B and Part D plays a key role in determining the financial impact of moving drugs from Part B to Part D. To assess the implications of the price differential on total drug costs, Table 5-6 compares total drug costs under Part B and Part D for beneficiaries taking B to D drugs. Total Part B costs reflect costs observed on Part B claims, while total Part D costs are the median unit price paid under Part D. The last column shows the ratio of Part D to Part B costs. For example, anticancer drugs cost three percent more under Part D compared to Part B. Part D prices for anticancer/antiemetic drugs and for immunosuppressant drugs are slightly higher than Part B rates. Pumped insulin has the largest price differential because Part B rates for all infusion drugs provided through DME, including insulin, are set by statue at the AWP that was in effect since October 1, 2003.

Table 5-6: Total Costs of B to D Drugs under Part B Compared to Simulated Costs under Part D, by Cohort, 2007

Beneficiary Cohort	Total Costs in Part B	Total Costs under Part D Prices	Ratio of Part D to Part B Costs
Anticancer/Antiemetic	$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
Immunosuppressant	$517,493,645	$549,251,719	1.06

Source: Part B claims data, Part D unit prices.
Part D prices are calculated as the median unit cost observed in the 2007 PDE data.

5.3 Drugs Consolidated under Part B

This section examines pre-consolidation Part D utilization for the two beneficiary cohorts taking drugs moving from Part D to Part B. It then examines pricing of D to B drugs under both Part B and Part D.

5.3.1 Pre-Consolidation Part D Costs and Utilization

As shown in Table 5-7, beneficiaries taking parenteral nutrition average higher costs than beneficiaries receiving vaccines. Because beneficiaries taking parenteral nutrition spend on average over $5,000 a year, moving these drugs to Part B will likely decrease the number of beneficiaries who enter the Part D coverage gap. In contrast, because average annual cost for beneficiaries receiving vaccines is only about $150, moving vaccines to Part B will have limited impact on beneficiaries' Part D ending coverage phases. Since the cohort of beneficiaries receiving vaccines is approximately 100 times larger than the cohort of beneficiaries taking parenteral nutrition, the overall average more closely reflects vaccine utilization than parenteral nutrition utilization. Overall, beneficiaries receiving vaccines and parenteral nutrition average one claim per year in Part D, at a cost of $200.

Table 5-7: Part D Utilization, 2007

Beneficiary Cohort	Number of Beneficiaries Taking the Drug	Average Cost per Fill	Average Annual Cost per Beneficiary
Vaccines[41]	353,158	$153	$153
Parenteral Nutrition	3,587	$576	$5,186
All D to B Cohorts	356,707	$204	$204

Source: Prescription Drug Event Data
Cost statistics for vaccines and *All D to B* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.

Part D costs for vaccines and parenteral nutrition are shared between beneficiaries, Medicare, and Part D plan sponsors. The first two rows of Table 5-8 report the pre-consolidation average Part D cost of analysis drugs for beneficiaries in each cohort. Beneficiary cost is lower for vaccines ($36) than for parenteral nutrition ($176). Total Medicare costs at point-of-sale, derived by summing the Medicare: LICS and Medicare: Reinsurance Subsidy amounts in Table 5-8, are significantly higher for beneficiaries taking parenteral nutrition than for beneficiaries receiving vaccines, $3,900 compared to just $14. Part D plans pay 67 percent of costs for beneficiaries receiving vaccines, but only 21 percent of costs for beneficiaries taking parenteral nutrition.

[41] Over 95 percent of Part D vaccine claims were for the zoster vaccine.

The final row of the table presents the average pre-consolidation costs for all beneficiaries receiving vaccines or parenteral nutrition. Medicare pays about 28 percent of the average cost for all beneficiaries potentially affected by the proposed consolidation. Part D plan payments are about 54 percent of average costs in the combined simulation.

Table 5-8: Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries, Medicare, and Plans, by Cohort, 2007

Beneficiary Cohort	Number of Beneficiaries	Total Cost Per Beneficiary Pre-Consolidation	PRE-Consolidation Costs			
			Beneficiary	Medicare: LICS	Medicare: Reinsurance	Plan
Vaccines	353,158	$154*	$36*	$11*	$3*	$103*
Parenteral Nutrition	3,587	$5,186	$176	$914	$2,993	$1,103
All D to B Cohorts	356,707	$213*	$38*	$20*	$39*	$116*

Source: 2007 Standard Analytical Files
Cost statistics for vaccines and *All D to B* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
*Statistically significant at the 95% CI level.
The number of beneficiaries in the combined row is less than the sum of beneficiaries in the two cohorts because some beneficiaries take multiple analysis drugs.

Table 5-9 presents the distribution of pre-consolidation Part D costs across beneficiaries receiving vaccines or parenteral nutrition. The distribution for beneficiaries receiving vaccines is negatively skewed, with the mean falling between the 25th and 50th percentile values. The distribution for beneficiaries taking parenteral nutrition is positively skewed; the mean of $5,000 is more than six times larger than the 50th percentile value of $850. Since many more beneficiaries take vaccines compared to parenteral nutrition, the distribution for *All D to B* cohorts closely resembles the distribution for vaccines.

Table 5-9: The Distribution of Part D Pre-Consolidation Point-of-Sale Costs for Beneficiaries with D to B Drugs, by Cohort, 2007

Beneficiary Cohort	Number of Beneficiaries	Cost at 25th Percentile	Cost at 50th Percentile	Cost at 75th Percentile	Mean
Vaccines	353,158	$156	$162	$166	$154
Parenteral Nutrition	3,587	$10	$851	$6,163	$5,186
All D to B Cohorts	356,707	$156	$162	$166	$213

Source: 2007 Standard Analytical Files
Cost statistics for vaccines and *All D to B* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
*Statistically significant at the 95% CI level.
The number of beneficiaries in the *All D to B* row is less than the sum of beneficiaries in the two cohorts because some beneficiaries take multiple analysis drugs.

5.3.2 Pricing of D to B Drugs under Part B and Part D

Table 5-10 compares total costs for D to B drugs under Part B and Part D. As in Table 5-6, Part D costs are based on observed costs on Part D claims, and Part B costs are computed using simulation prices. Total costs under both programs are roughly comparable for vaccines and parenteral nutrition, with vaccines costing slightly more under Part B compared to Part D.

Table 5-10: Total Costs of D to B Drugs under Part D Compared to Simulated Costs under Part B, by Cohort, 2007

Beneficiary Cohort	Total Costs under Simulated Part B Prices	Total Costs under Part D	Ratio of Part B to Part D Costs
Vaccines	$56,769,278	$54,205,827	1.05
Parenteral Nutrition	$18,287,944	$18,603,545	0.98

6 THE FINANCIAL IMPACT OF THE PROPOSED CONSOLIDATION

In this section, we describe our findings from the simulations consolidating drugs under Part B or Part D. In each simulation, the financial impact on Medicare payments is computed in three stages. First, we use the constructed consolidated sequence of drug events and associated prices to compute the new beneficiary, Part D plan, and Medicare point-of-sale costs implied for the new sequence. At this stage, changes in Medicare cost-sharing payments at point-of-sale are calculated for Part B and Part D. For Part D, the change in point-of-sale costs equals the Reinsurance Subsidy and LICS payments associated with the consolidated basket of drugs after removing D to B drugs and adding B to D drugs, minus pre-consolidation Reinsurance Subsidy and LICS payments.[42] For Part B, the change in point-of-sale cost for Medicare is 20 percent of the costs of D to B drugs minus 20 percent of the costs of B to D drugs. In the second stage, we calculate the impact on Part D plan bids and Part B premiums. To calculate the impact on Part D plan bids, we use the calculated changes in Part D plan liabilities; by assumption, the percent change in Part D bids is equal to the percent change in Part D plan liabilities. These amounts are then used in the third stage to recalculate Medicare Part D payments for the Direct Subsidy and LIPS. Finally, net changes in Part B costs are used to calculate the impact on Part B premiums.

The remainder of this section is organized as follows. Section 6.1 presents the impact of the proposed consolidation on point-of-sale costs for the beneficiary, Medicaid, and Medicare Reinsurance Subsidy and LICS. Section 6.2 shows the implications for Part D and Part B premiums. Finally, the total financial impact on Medicare is discussed in Section 6.3.

6.1 Change in Point-of-Sale Costs for Beneficiaries and Medicare

The share of total costs attributed to beneficiaries and Medicare changes after inserting Part B drug claims into each beneficiary's Part D drug sequence. This section presents the change in point-of-sale costs for beneficiaries, Medicare, and Medicaid, and shows how the proposed consolidation affects the share of beneficiaries reaching the coverage gap.

As drugs move from Part B to Part D, total point-of-sale costs per beneficiary for Medicare and Medicaid fall for all beneficiary cohorts, while costs for beneficiaries rise (Table 6-1). Higher beneficiary point-of-sale costs finance about 48 percent of the decline in Medicare's share of point-of-sale costs for beneficiaries taking anticancer drugs and compensate for 60 percent of the decline in Medicare costs among beneficiaries taking immunosuppressants. For beneficiaries taking pumped insulin and nebulizer inhalants, increases in beneficiary payments more than offset the decrease in Medicare's costs.

[42] RS pays for 80 percent of all drug expenditures in the catastrophic coverage phase, net of any other plan remuneration. LICS represent cost-sharing subsidies to qualifying low-income (LI) individuals in all benefit phases.

The increase in beneficiary out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication. Beneficiaries taking pumped insulin experience the largest increase in out-of-pocket costs ($426), followed by beneficiaries taking immunosuppressants ($418) and anticancer/antiemetic drugs ($391). While beneficiaries taking nebulizer inhalants experience a relatively smaller increase in costs ($287), the change would affect over one million beneficiaries.

Beneficiaries currently receiving vaccines under Part D experience a relatively small decrease in payments after the proposed consolidation, while Medicaid payments increase slightly and Medicare payments increase by approximately $100. Beneficiaries taking parenteral nutrition experience an increase in costs of approximately $160, while Medicare expenditures decrease by $140 and Medicaid expenditures increase by $820.

The combined row reflects changes in payments for all beneficiaries taking drugs affected by the proposed consolidation. Since beneficiary expenditures increase for all beneficiaries taking either B to D drugs or parenteral nutrition but decrease for beneficiaries in the vaccines cohort, beneficiary expenditures increase in the combined simulation. Similarly, since Medicare and Medicaid point-of-sale costs decrease for all beneficiaries taking B to D drugs or parenteral nutrition but increase for vaccines, expenditures for both programs decrease in the combined simulation. Overall, decreases of approximately $230 for Medicare and $100 for Medicaid are partially offset by an increase of $200 for beneficiaries.[43]

[43] Beneficiary additional point-of-sale costs do not completely offset reductions in Medicare and Medicaid point-of-sale costs because price differentials between Part B and Part D will cause changes in total costs across all payers. Additionally, Part D plan liability at point-of-sale also changes with consolidation. The impact of changes in Part D plan liability on Medicare spending is captured through its impact on Part D plan bids.

Table 6-1: Change in Point-of-Sale Costs for Beneficiaries, Medicare, and Medicaid, by Cohort, 2007

Beneficiary Cohort	Number of Beneficiaries	Beneficiary	Medicare	Medicaid
B to D Cohort				
Anticancer/Antiemetic	68,082	$391	-$814	-$113
Pumped Insulin	12,269	$426	-$351	-$40
Nebulizer Inhalant	1,101,622	$287*	-$239*	-$95*
Immunosuppressant	74,136	$418	-$700	-$708
D to B Cohort				
Vaccines	353,158	-$10*	$107*	$4*
Parenteral Nutrition	3,587	$161	-$137	$820
Combined Cohort	1,600,053	$207*	-$230*	-$99*

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 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, vaccines, and *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at a 95% confidence level.
The number of beneficiaries in the *combined* row is less than the sum of beneficiaries in the six cohorts because some beneficiaries take multiple analysis drugs.

Changes in payments are affected by two factors: the price effect and the coverage effect. The price effect refers to payment changes resulting from the different drug prices for simulation drugs under Part D and Part B, which are caused by the different pricing structures used by the two programs (see Section 2). The coverage effect describes payment changes resulting from the different cost sharing structures under Part B and Part D. For example, a beneficiary in the catastrophic phase who has a claim for a vaccine under Part D that costs $50.00 would pay $2.50 in out-of-pocket cost, which is five percent of the total cost. Assuming the price of this vaccine under Part B is $60.00, the beneficiary would pay $12.00 (20 percent of $60.00) after the proposed consolidation. The total change in out-of-pocket payments for this beneficiary is $9.50. The coverage effect is the difference between paying 20 percent versus five percent of $50.00, which is equal to $10.00 - $2.50 = $7.50. The price effect, which is the difference between the total change in payments and the coverage effect, is $9.50 – $7.50 = $2.00.

To illustrate the effects of differences in price and cost-share structure under Part B and Part D, we decompose the total payment changes for beneficiaries and Medicare into price and coverage effects. To obtain the coverage effects, we simulate consolidation changes, keeping prices unchanged. We identify the price effect as the difference between the total effect and the coverage effect. Table 6-2 presents these findings for each beneficiary cohort and for the combined simulation.

For B to D beneficiary cohorts, the price and coverage effects tend to increase beneficiary payments, while Medicare payments increase because of the price effect but decrease because of the coverage effect. For beneficiaries taking anticancer/antiemetic drugs, nebulizer inhalants, and immunosuppressants, almost all of the change in cost is explained by the change in coverage. For beneficiaries taking pumped insulin, the increase in price under Part D explains about 40 percent of the total change in cost, while the coverage effect explains 60 percent. Medicare payments increase because of the price effect but decrease because of the coverage effect. Since Medicare's coverage effect exceeds the price effect for all cohorts, total Medicare expenditures decrease. Price and coverage effects impact stakeholders differently, although distinct patterns emerge across B to D cohorts. For beneficiaries in the four B to D cohorts, both the price and coverage effects tend to increase beneficiary spending, except for beneficiaries who originally end in the coverage gap or the catastrophic phase, or who are LIS eligible (data not shown).

The price and coverage effects impact beneficiary and Medicare spending differently for beneficiaries receiving vaccines and parenteral nutrition because a large share (approximately 60 percent) of beneficiaries taking parenteral nutrition under Part D end in the catastrophic phase. For beneficiaries receiving vaccines, the overall decrease in costs comes entirely from the coverage effect. Beneficiaries taking parenteral nutrition experience a $160 increase in cost, 85 percent of which comes from the coverage effect. Since most beneficiaries taking parenteral nutrition under Part D end in the catastrophic phase where they pay approximately five percent of drug costs, out-of-pocket costs rise after moving parenteral nutrition to Part B, in which beneficiaries pay 20 percent of drug costs after reaching the deductible. Both the price and coverage effect increase Medicare's payments on behalf of beneficiaries receiving vaccines but decrease Medicare's payments on behalf of beneficiaries taking parenteral nutrition. For beneficiaries in D to B cohorts, the price effect increases 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 (data not shown).

The final row of Table 6-2 shows the disaggregated price and coverage effects for the combined simulation. Overall, beneficiaries would experience an increase in costs of about $200, approximately 86 percent of which is due to the coverage effect. In general, the price effect increases Medicare spending on B to D drugs and vaccines but decreases spending on parenteral nutrition. Conversely, the coverage effect decreases spending on B to D drugs and parenteral nutrition but increases spending on vaccines. This means that in the combined simulation, Medicare costs increase because of the price effect but decrease because of the

coverage effect. Since the coverage effect is larger, total Medicare costs per beneficiary would decrease by $230.

Table 6-2: Disaggregated Price and Coverage Effects for All Beneficiary Cohorts, by Cohort, 2007

Beneficiary Cohort	Beneficiary			Medicare		
	Total Change	Price Effect	Coverage Effect	Total Change	Price Effect	Coverage Effect
B to D Cohort						
Anticancer/Antiemetic	$391	-$1	$392	-$814	$64	-$879
Pumped Insulin	$426	$175	$251	-$351	$136	-$487
Nebulizers Inhalants	$287*	$52*	$235*	-$239*	$104*	-$342*
Immunosuppressant	$418	$25	$393	-$700	$325	-$1,026
D to B Cohort						
Vaccines	-$10*	$2*	-$12*	$107*	$5*	$102*
Parenteral Nutrition	$161	$24	$137	-$137	-$91	-$46
Combined Cohort	$207*	$30*	$178*	-$230*	$81*	-$311*

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, vaccines, and *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at a 95% confidence level.
The number of beneficiaries in the *combined* row is less than the sum of beneficiaries in the six cohorts because some beneficiaries take multiple analysis drugs.

Figure 6-1 shows the percentage of beneficiaries taking B to D drugs that reach the Part D coverage gap before and after the proposed consolidation. Since moving drugs from Part B to Part D increases Part D costs, the percentage of beneficiaries reaching the coverage gap increases after consolidation for all four beneficiary cohorts.

Figure 6-1: The Percentage of Beneficiaries Taking B to D Drugs Who Reach the Part D Coverage Gap, by Cohort, 2007

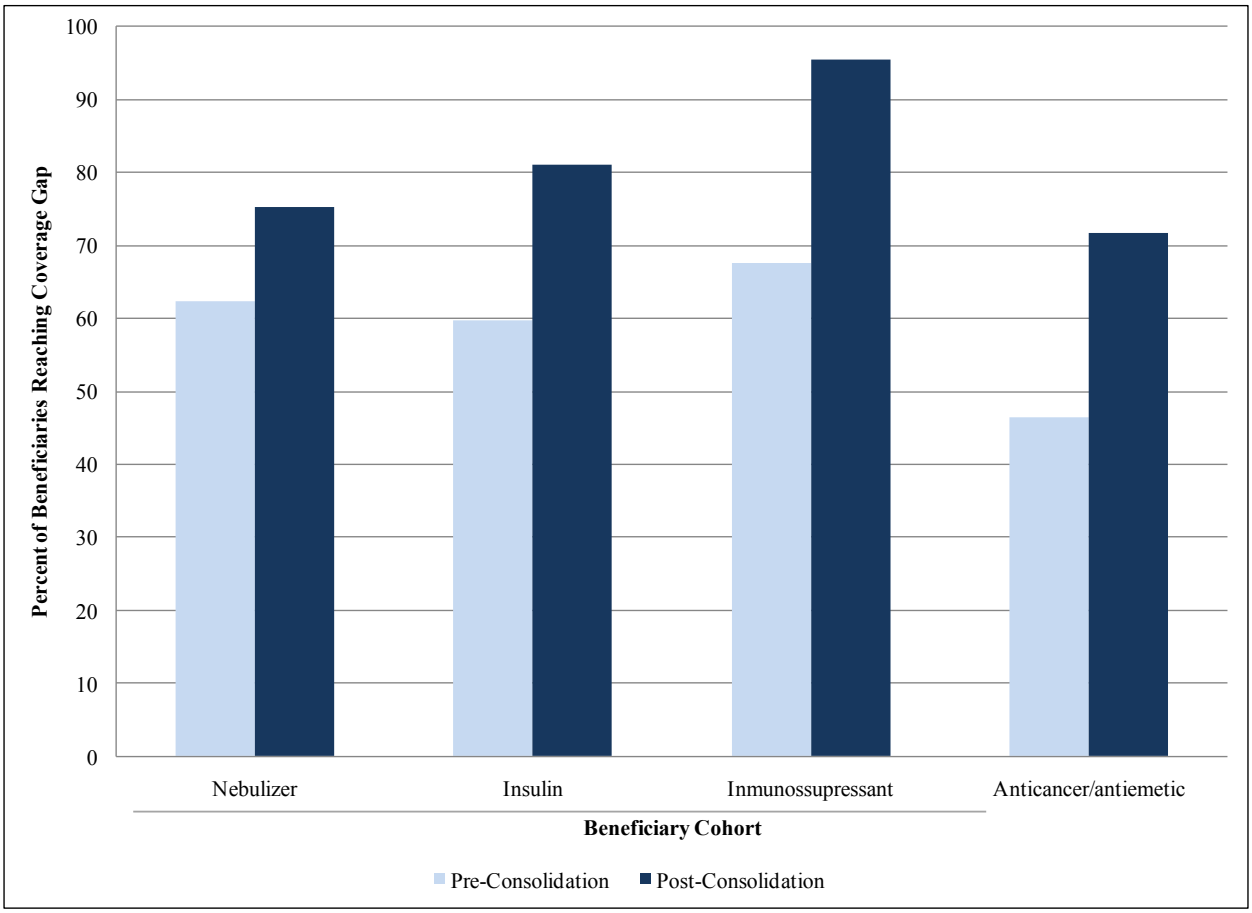
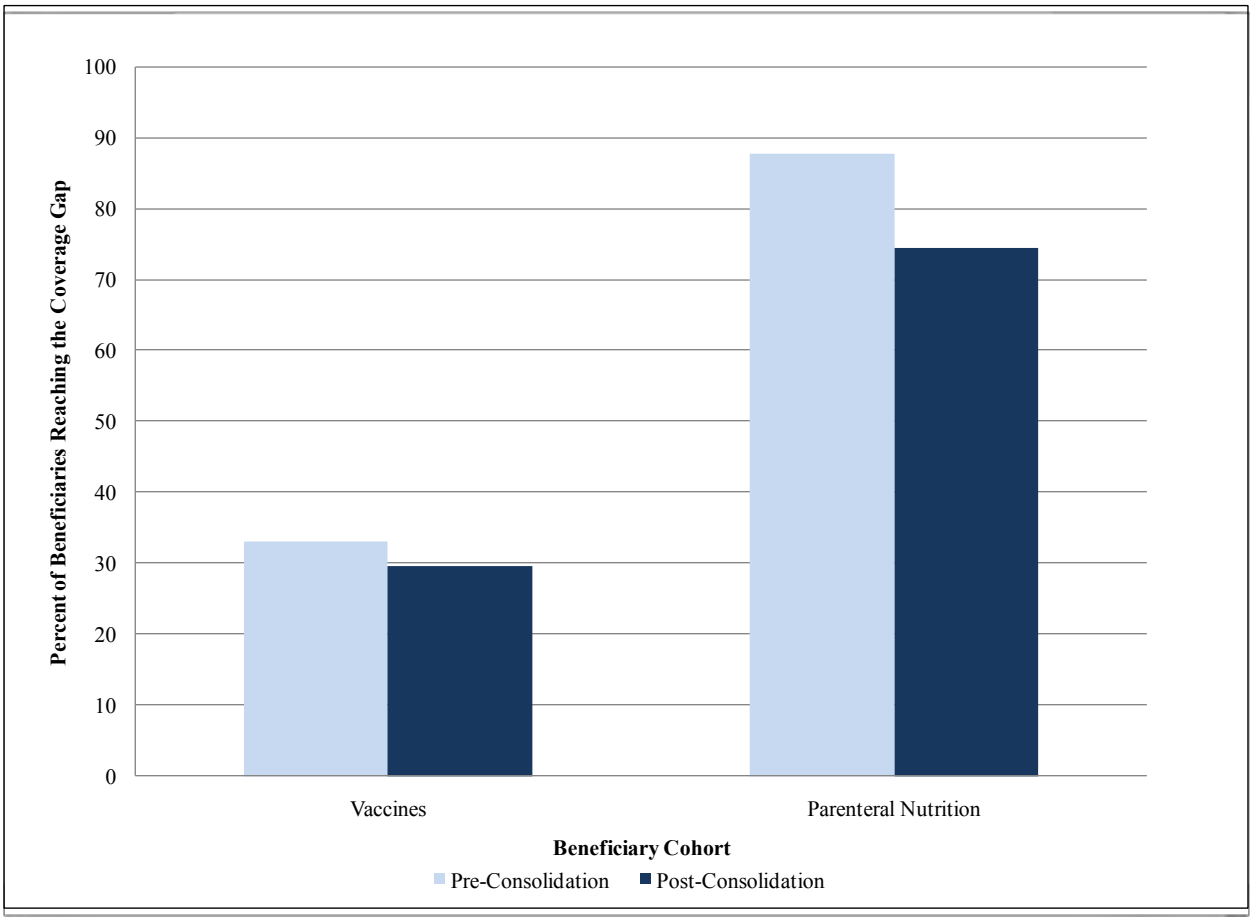


Figure 6-2 shows the percentage of beneficiaries taking D to B drugs who reach the Part D coverage gap before and after the proposed consolidation. When drugs move from Part D to Part B, beneficiary Part D payments decrease. Consolidation under Part B therefore results in a lower percentage of beneficiaries reaching the coverage gap for both beneficiary cohorts.

Figure 6-2: Percentage of Beneficiaries Taking D to B Drugs Who Reach the Part D Coverage Gap, by Cohort, 2007



6.2 Changes in Part D Plan Liability and Bids, Part B Liability and Premiums

We assume that changes in plan liabilities due to the proposed 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 per beneficiary, presented in Table 6-3.

As expected, average Part D plan costs increase for all B to D cohorts, with costs for beneficiaries taking immunosuppressant drugs increasing the most (by about $1,200) and costs for beneficiaries taking pumped insulin increasing the least (by about $160). The beneficiaries potentially affected by the proposed consolidation represent a small share of all Part D participants — less than one percent for anticancer drugs, pumped insulin, and immunosuppressants, and about three percent for nebulizer inhalants. Plan liability for the average beneficiary therefore changes relatively little, by less than one percent in all four cases. Accordingly, average national bids are mostly unchanged.

Part D plan liability decreases for beneficiaries receiving vaccines and parenteral nutrition as drugs move out of Part D. The decrease in plan liability per beneficiary is relatively small for beneficiaries receiving vaccines ($94) and substantially larger for beneficiaries taking parenteral nutrition ($930). However, the percent change in liability is quite small, less than one percent for both cohorts. The average plan bid decreases by $0.10 for beneficiaries receiving vaccines and does not change for beneficiaries taking parenteral nutrition. The effect is larger for beneficiaries receiving vaccines because the size of the vaccine cohort means that total costs for vaccines exceed total costs for parenteral nutrition, but the effect is small in both cases because costs for both drugs ultimately make up a small share of total Part D costs.

In the combined simulation, the increase in Part D plan liability for B to D cohorts is only partially offset by decreases in liability for D to B cohorts. The overall increase in average Part D plan-covered costs per beneficiary is $180, or 0.9 percent of total plan costs. This results in an increase of $0.70 in the average plan bid.

Table 6-3: Part D Plan Bid Changes per Beneficiary for the Proposed Consolidation, by Cohort, 2007

Beneficiary Cohort	Average Plan Cost for Beneficiaries Pre-Consolidation	Average Plan Cost for Beneficiaries Post-Consolidation	Post-Pre Average Costs	Percent Change in Total Plan Costs	Post-Consolidation Average Bid	Change in Average Bid
B to D Cohort						
Anticancer/Antiemetic	$1,567	$2,106	$539	0.10%	$75.66	$0.09
Pumped Insulin	$1,571	$1,735	$164	0.00%	$75.57	$0.00
Nebulizer Inhalant	$1,703*	$1,981*	$278*	0.90%*	$76.23*	$0.66*
Immunosuppressant	$1,854	$3,038	$1,184	0.23%	$75.74	0.17
D to B Cohort						
Vaccines	$1,207*	$1,113*	-$94*	-0.10%*	$75.47*	-$0.10*
Parenteral Nutrition	$2,858	$1,926	-$932	-0.01%	$75.57	$0.00
Combined Cohort	$1,497*	$1,678*	$181*	0.94%*	$76.28*	$0.71*

Cost statistics for the nebulizer inhalant, vaccines, and *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at a 95% confidence level.

The methodology described above can also be applied to calculate post-consolidation Part B premiums, assuming that the change in premiums is proportional to the change in liability. As demonstrated in Table 6-4, the estimated changes in total Part B premiums are minimal.

With over $176 billion spent on Part B overall in 2007,[44] the impact of changing the coverage status of these six drug classes is small. As expected, Part B liability decreases when drugs move from Part B to Part D and increases when drugs move from Part D to Part B. Overall, Part B liability would decrease by approximately $1.8 billion under the proposed consolidation, resulting in an average premium decrease of one dollar.

Table 6-4: Total Part B Premium Changes for the Proposed Consolidation, by Cohort, 2007

Beneficiary Cohort	Total Change in Part B Costs	Percent Change in Costs	Post-Consolidation Part B Premium	Change in Post-Consolidation Part B Premium
B to D Cohort				
Anticancer/Antiemetic	-$169,253,702	-0.1%	$93.41	-$0.09
Pumped Insulin	-$10,864,039	0.0%	$93.49	-$0.01
Nebulizer Inhalant	-$1,227,000,468*	-0.7%*	$92.85*	-$0.65*
Immunosuppressant	-$517,493,645	-0.3%	$93.23	-$0.27
D to B Cohort				
Vaccines	$56,769,278*	0.0%*	$93.53*	$0.03*
Parenteral Nutrition	$18,287,944	0.0%	$93.51	$0.01
Combined Cohort	-$1,849,554,633*	-1.1%*	$92.52*	-$0.98*

Cost statistics for the nebulizer inhalant, vaccines, and *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at a 95% confidence level.

6.3 Total Financial Impact for Medicare

The total financial impact on Medicare is derived from changes in point-of-sale costs and capitated payments. For Part D, point-of-sale costs are divided into LICS and Reinsurance Subsidy payments; capitated payments are composed of Direct Subsidies and LIPS payments. The effect of the proposed 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 phase. Because of that structure, consolidation under Part D tends to reduce Medicare's total payments at given drug prices, unless a large share of beneficiary costs is accrued in the catastrophic phase. As expected, we find that consolidation

[44] 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.

under Part D does reduce Medicare's total payments for each B to D beneficiary cohort and for beneficiaries taking parenteral nutrition (Table 6-5). In contrast, consolidation of vaccines under Part B increases total payments since most Part D payments for vaccines do not occur in the catastrophic phase. Overall, total payments for Medicare decrease by about $154 million.

The decrease in Medicare payments is due to a large decrease in Part B payments ($1.5 billion), which is mostly offset by Part D payment increases for LICS, the Reinsurance Subsidy, Direct Subsidies, and LIPS. The majority (nearly 60 percent) of the increase in Part D costs comes from an increase in Reinsurance Subsidy payments for beneficiaries in the catastrophic phase; substantial increases also come from LICS payments for low-income beneficiaries and the Direct Subsidy. Increases in LIPS payments account for just one percent of the increase in Part D payments.

Table 6-5: Total Financial Impact of the Proposed Consolidation on Medicare, by Cohort, 2007

Beneficiary Cohort	Change in Medicare Payments (in Thousands)					
	Part B	Part D				Total
		LICS	Reinsurance Subsidy	Direct Subsidy	LIPS	
B to D Cohort						
Anticancer/Antiemetic	-$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*
Immunosuppressant	-$413,995	$60,000	$302,065	$40,339	$4,689	-$6,902
D to B Cohort						
Vaccines	$44,339*	-$3,719*	-$2,779*	-$24,041*	$0	$13,800*
Parenteral Nutrition	$14,630	-$2,286	-$12,457	-$1	-$331	-$445
Combined Cohort	-$1,475,499*	$379,496*	$758,351*	$168,000*	$16,052*	-$153,600*

LICS refers to the Low-Income Cost Sharing subsidy; LIPS refers to the Low-Income Premium Subsidies.
Cost statistics for nebulizer inhalants, vaccines, and the *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at the 95% CI level.

7 IMPACT OF BENEFICIARY PLAN CHOICE ON CONSOLIDATION COSTS

Because B to D simulation drugs are considerably more expensive than drugs moved from Part D to Part B, consolidation makes Part D participation more attractive for beneficiaries. The proposed consolidation also changes the relative attractiveness of different Part D plans. Upon consolidation, beneficiaries may prefer to enroll in plans that provide lower-cost coverage for cancer treatments and immunosuppressants. While our simulation framework and the results presented so far account for induced Part D participation in response to more extensive coverage, no adjustments have been made to capture changes in Part D plan choice in response to higher expected Part D costs.[45] This section explores some of the ways in which beneficiaries could respond to consolidation by enrolling in more generous plans and how such responses affect the results of the simulation.[46]

7.1 Overview of Approach

Our approach to incorporating beneficiary plan choice in our simulations exploits enrollment patterns observed in the data to infer a reasonable scenario for reallocating beneficiaries across benefit types after the proposed consolidation. At the same time, it assesses how the financial costs for Medicare depend on beneficiary plan choice. The change in Medicare's costs for a given benefit type can be calculated by multiplying the number of beneficiaries in a given benefit type by the average increase in Medicare Reinsurance Subsidy payments per beneficiary for beneficiaries enrolled in that benefit type. We then obtain Medicare's total change in financial costs by taking the sum across all benefit types. Using this decomposition, we calculate an alternative estimate of the financial impact by changing the allocation of beneficiaries across benefit types in a way that is consistent with the relationship between Part D costs and plan enrollment observed in the data. Note that because most LIS beneficiaries are auto-enrolled in qualifying plans, our analysis excludes this group. We also exclude beneficiaries enrolled in employer plans since they are presumably unlikely to switch plans.

[45] Our simulation framework predicts that about two out of three beneficiaries without coverage will enroll in Part D in response to increased benefits. See section 4.4.3 for a description of the methods used to project Part D take up.
[46] In a previous report, Acumen explored whether beneficiaries with Part B and Part D coverage respond to changes in relative out-of-pocket costs by comparing insulin and inhalants utilization across Part D benefit phases between two groups of beneficiaries. The first group consists of non-LIS eligible beneficiaries who reached the catastrophic benefit phase. The second group is Medicaid eligibles, whose out-of-pocket costs do not change as they move through Part D benefit phases. We found no evidence of drug-use shifts between the Part B and Part D medications across benefit phases. http://www.cms.gov/reports/downloads/Acumen_PartBtoDBase_Final_2010.pdf.

Several inputs are required to conduct this calculation. First, Part D plans are classified into benefit types according to the level of coverage with respect to out-of-pocket costs at point-of-sale. The level of coverage is determined by the deductible and initial coverage level amounts, along with the level of gap coverage. Part D plans also differentiate by offering a standard cost share or a tiered copayment structure during the ICP. Second, beneficiaries are grouped by their level of drug utilization. Using pre-consolidation data, the empirical relationship between drug utilization level and plan choice is established. This relationship is represented by the distribution of beneficiaries across benefit types, conditional on the level of Part D costs. Next, the average consolidation cost per beneficiary is calculated for each plan type and beneficiary group. Upon consolidation, the addition of expensive B to D drugs shifts the distribution of beneficiary groups towards the highest levels of utilization. The conditional distribution of plan type enrollment given the level of Part D costs is applied to reallocate beneficiaries across benefit types. Finally, the new enrollment allocation is used to weight the average consolidation costs by beneficiary group and plan type.

7.2 Financial Cost of the Proposed Consolidation by Benefit Type

We first group Part D plans into broad categories according to specific features of their benefit structure. While a plan's benefit type (e.g., Defined Standard, Enhanced Alternative) is a general description of its benefit, other characteristics such as the level of its Initial Coverage Limit and whether it offers supplemental coverage in the gap directly impact the out-of-pocket costs of its enrollees. Part D plans are grouped according to the following plan characteristics: (1) Deductible level and Initial Coverage Limit (ICL), (2) Type of cost-share in the Initial Coverage Phase, and (3) Offering supplemental coverage in the Gap. The details of the characteristics are described below:

1. **Deductible and ICL:** Plans are grouped according to the deductible level and ICL they offer. The deductible and ICL information is obtained from the HPMS PBP Extract. In 2007, the standard benefit required payments of $265 in the deductible phase, and the ICL was $2,400. Plans, however, may offer more generous coverage by lowering the deductible or increasing the ICL. Thus, we group plans by using various combinations of the two limits.
2. **Type of Cost-Share in the Initial Coverage Phase:** Plans may have either a standard or tiered cost-share in the ICP. A plan is defined as offering standard cost-share if it administers a 25 percent beneficiary coinsurance in the ICP across all combinations of drug tier, pharmacy type, pharmacy preferred status, and days of supply. Otherwise, the plan is defined as having a tiered cost-share.
3. **Supplemental Coverage in the Gap:** Under the standard benefit, beneficiaries pay 100 percent of their drug costs in the coverage gap. Some plans, however, provide supplemental coverage in the gap, covering specific subsets of drugs. We differentiate

between plans with and without supplemental coverage in the gap as the final aspect of our benefit type classification.

Part D plans are grouped into four broad categories based on plan characteristics described above. Their attributes and the distribution of non-LIS beneficiaries across these benefit types are shown in Table 7-1.

Table 7-1: Beneficiary Enrollment across Part D Benefit Types

Benefit Type	Type of Cost-Share in Initial Coverage Phase	Deductible	Initial Coverage Limit	Gap Coverage	Non-LIS Enrollment
Standard Tiered	Tiered Cost-share	Standard	Standard	No	30,765
Reduced Deductible	Tiered Cost-share	< Standard	Standard	No	319,919
Gap Coverage	Tiered Cost-share	$0	Standard or > Standard	Yes	97,250
Basic Standard	Standard	Standard	Standard	No	67,296
Other	Other Combinations				29,082

Source: HPMS Prescription Benefit Package Extract, 2007

We examine the sensitivity of the impact of proposed consolidation on Medicare costs with respect to benefit type. This analysis includes only changes in Reinsurance Subsidy payments; no other Part D or Part B mechanisms are considered. First, LICS and LIPS apply exclusively to LIS beneficiaries, who will be unlikely to change benefit type upon consolidation. Second, while Direct Subsidies are determined by the enrollment-weighted average standard bid, significant enrollment shifts are required to generate non-negligible changes in Direct Subsidies. Finally, Part B premiums and point-of-sale costs do not depend on Part D enrollment.

Table 7-2 presents the consolidation costs for Non-LIS beneficiaries from added Reinsurance Subsidy payments. As expected, consolidation costs in the form of added point-of-sale costs are higher among beneficiaries with the highest level of drug expenditures, as a larger share of their spending applies to the catastrophic benefit phase where Medicare Part D co-payments are 80 percent compared to the flat rate of 20 percent copayment under Part B. The effect of benefit type on point-of-sale consolidation costs is assessed by comparing costs within a beneficiary group. Standard tiered plans have the highest costs for most beneficiary groups. For beneficiaries with drug expenditures below $6,000, the Gap Coverage benefit type results in the lowest cost increases for Medicare.

Table 7-2: Average Medicare Reinsurance Subsidy Cost Changes for Non-LIS Beneficiaries, By Benefit Type and Part D Cost Bracket

Total Part D Cost Bracket	Standard Tiered	Reduced Deductible	Gap Coverage	Basic Standard	Other
0-$1,000	$901	$271	$136	$445	$181
$1,000-$2,000	$917	$373	$272	$563	$ 244
$2,000-$3,000	$1,266	$586	$288	$799	$213
$3,000-$4,000	$1,382	$864	$487	$1,158	$621
$4,000-$5,000	$1,282	$1,020	$791	$1,429	$563
$5,000-$6,000	$1,528	$1,201	$691	$1,390	$383
$6,000-$7,000	$1,710	$1,111	$1,057	$1,361	$366
$7,000-$8,000	$1,705	$1,229	$767	$1,568	$298
$8,000+	$1,809	$1,230	$2,130	$1,603	$850

7.3 Adjusted Financial Impact to Medicare

The adjustment to the financial impact simulated under the baseline scenario is derived from changes in Reinsurance Subsidy payments due to the reallocation of beneficiaries across benefit types. Table 7-3 shows enrollment before reallocation, while Table 7-4 shows enrollment after reallocation. Note that the total enrollment by Part D cost bracket is the same in both scenarios. In both cases, total Part D drug costs are determined by the simulated consolidated sequences of drugs under Part D. However, the allocation of beneficiaries across benefit types within a cost bracket changes to reflect the empirical relationship between beneficiary drug costs and plan choice. Table 7-3 shows how non-LIS beneficiaries are enrolled across plan types, assuming beneficiaries remain enrolled in their pre-consolidation plan. In contrast, Table 7-4 depicts enrollment under the assumption that beneficiaries in a given Part D cost bracket are distributed across benefit types with the proportions observed in the data before consolidation.

Table 7-3: Allocation of Non-LIS Beneficiaries across Benefit Types, Baseline Enrollment

Total Part D Cost Bracket	Standard Tiered	Reduced Deductible	Gap Coverage	Basic Standard	Other	Total
0-$1,000	5,461	79,339	14,956	16,781	3,984	120,522
$1,000-$2,000	5,398	66,272	14,580	15,016	4,379	105,645
$2,000-$3,000	5,361	56,983	15,314	12,693	4,257	94,607
$3,000-$4,000	3,691	35,813	13,690	6,372	3,181	62,747
$4,000-$5,000	2,796	23,293	9,844	5,034	3,561	44,529
$5,000-$6,000	2,200	15,255	7,823	3,030	2,241	30,549
$6,000-$7,000	1,347	10,812	5,426	2,199	1,854	21,638
$7,000-$8,000	1,207	8,695	3,223	1,115	1,725	15,965
$8,000+	3,305	23,456	12,393	5,056	3,901	48,111

Table 7-4: Allocation of Non-LIS Beneficiaries across Benefit Types, Adjusted Enrollment

GDC Bracket	Standard Tiered	Reduced Deductible	Gap Coverage	Basic Standard	Other	Total
0-$1,000	6,513	78,945	13,963	17,453	3,649	120,522
$1,000-$2,000	5,626	66,739	14,366	14,516	4,397	105,645
$2,000-$3,000	4,922	56,371	17,369	11,754	4,192	94,607
$3,000-$4,000	4,118	32,724	15,844	6,176	3,885	62,747
$4,000-$5,000	2,645	21,180	11,619	4,308	4,776	44,529
$5,000-$6,000	1,755	12,253	10,266	2,512	3,764	30,549
$6,000-$7,000	1,635	9,608	6,463	1,451	2,482	21,638
$7,000-$8,000	1,060	7,109	4,402	609	2,784	15,965
$8,000+	3,611	21,684	13,389	4,831	4,596	48,111

Table 7-5 shows the impact of the enrollment adjustment on the total change in Medicare payments caused by the proposed consolidation. The adjustment for plan choice is calculated by the difference in additional Reinsurance Subsidy payments resulting from differences in the number of beneficiaries by benefit type in Table 7-4 compared to Table 7-3. The adjusted estimate of additional Reinsurance Subsidy payments is about $3 million higher than the baseline estimate. This adjustment reduces savings for Medicare from $154 million to $151 million. Two factors explain the low level of adjustment. First, except for plans that provide gap coverage, the financial baseline impact for Medicare does not change significantly from one plan to the next. Second, the distribution of enrollment across benefit types is not very sensitive to the level of drug costs.

Table 7-5: Adjusted Total Financial Impact of the Proposed Consolidation on Medicare

Simulation	Change in Medicare Payments (in thousands)					
	Part B	Part D				Total
		LICS	Reinsurance Subsidy	Direct Subsidy	LIPS	
Baseline	-$1,475,499*	$379,496*	$758,351*	$168,000*	$16,052*	-$153,600*
Adjustment for Plan Choice	-	-	$3,087*	-	-	-
Final	-$1,475,499*	$379,496*	$761,438*	$168,000*	$16,052*	-$150,513*

LICS refers to the Low-Income Cost Sharing subsidy; LIPS refers to the Low-Income Premium Subsidies.
Cost statistics for nebulizer inhalants, vaccines, and the *combined* cohorts are based on random samples of 100,000 beneficiaries rather than the full population.
* Statistically significant at the 95% level.

8 SUMMARY OF FINDINGS

This study models the financial impact of consolidating six analysis drug types under either Part B or Part D on beneficiaries, Medicare, Medicaid, and plans. The key findings are as follows:

Consolidation Approach

Based on analysis of CMS documentation and interviews with pharmacists and medical providers, this study simulates consolidating anticancer/antiemetic drugs, insulin, inhalants, and immunosuppressants under Part D and consolidating vaccines and parenteral nutrition under Part B. In general, we simulate consolidating pills (i.e., anticancer/antiemetic drugs and immunosuppressants) under the Part D prescription drug benefit. Accordingly to our interviews, moving nebulizers to Part D, where they will be covered along with MDIs, facilitates step therapy, while moving pumped insulin to Part D facilitates pharmacy billing and eliminates the need to contact the prescribing physician to confirm the method of dispensing the drug. We simulate consolidating vaccines under Part B because the analysis of interviews and CMS documentation indicates that preventative vaccines have a higher adherence rate under Part B. Finally, we simulate consolidating parenteral nutrition under Part B since parenteral nutrition is an IV drug typically administered through a physician's office.

Analysis drugs are priced differently under Part D and Part B, affecting the financial impact of the proposed consolidation.

The proposed consolidation results in a significant change in total costs for pumped insulin 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 since October 1, 2003. Nebulizers in Part D also cost substantially more than in Part B, with a 16 percent price difference. Therefore, by moving pumped insulin and nebulizer inhalants from Part B to Part D, holding coverage rules constant, total cost would rise considerably. Costs for anticancer/antiemetic drugs, immunosuppressants, vaccines, and parenteral nutrition are comparable across the two programs.

On average, for the proposed consolidation, beneficiary out-of-pocket costs increase due to B to D consolidation and consolidation of parenteral nutrition under Part B, and decrease due to consolidation of vaccines under Part B.

As drugs move from Part B to Part D, total costs per beneficiary for Medicare and Medicaid fall for all beneficiary cohorts, while costs for beneficiaries rise. The increase in beneficiary out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication. Beneficiaries taking

parenteral nutrition experience an increase in annual costs of approximately $160, while Medicare expenditures decrease by $140 and Medicaid expenditures increase by $820. Since 60 percent of beneficiaries taking parenteral nutrition under Part D end in the catastrophic phase where they pay approximately 5 percent of drug costs, out-of-pocket costs rise after moving parenteral nutrition to Part B, in which beneficiaries pay 20 percent of drug costs after reaching the deductible. Out-of-pocket costs for beneficiaries receiving vaccines consolidated under Part B decrease by a small amount, while Medicaid costs rise slightly and Medicare costs increase by approximately $100. Overall, decreases of approximately $230 for Medicare and $100 for Medicaid are partially offset by an increase of $200 in out-of-pocket costs for beneficiaries.

The percentage of beneficiaries reaching the Part D coverage gap increases with the proposed B to D consolidation and decreases with D to B consolidation.

Since moving drugs from Part B to Part D tends to increase Part D costs, the percent of beneficiaries reaching the coverage gap increases after consolidation for all four B to D beneficiary cohorts. When drugs move from Part D to Part B, beneficiary Part D payments decrease. Consolidation under Part B therefore results in a lower percentage of beneficiaries receiving vaccines or parenteral nutrition reaching the coverage gap.

The proposed consolidation results in a slight increase in Part D plan bids and a slight decrease in Part B premiums.

We assume that changes in liability due to the proposed consolidation are fully passed on to Part D plan bids and Part B premiums. Under this assumption, the percent change in Part D plan 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 per beneficiary. As expected, Part D plan liability increases due to B to D consolidation but decreases due to D to B consolidation. In the combined simulation, the increase in Part D plan liability for B to D cohorts is only partially offset by decreases in liability for D to B cohorts. The overall increase in average Part D plan-covered costs per beneficiary is $180, or 0.9 percent of total plan costs. This results in an increase of $0.70 in the average plan bid. Similarly, Part B liability decreases as drugs move from Part B to Part D but increases due to consolidation under Part B. Overall, Part B liability decreases by approximately $1.8 billion, resulting in a decrease of one dollar in the Part B premium.

Medicare experiences a slight net decrease in costs due to the proposed consolidation of the six analysis drugs.

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 phase. Because of that structure, consolidation under Part D

tends to reduce Medicare's total payments at given drug prices, unless a large share of beneficiary cost is accrued in the catastrophic phase. As expected, we find that consolidation under Part D does reduce Medicare's total payments for each B to D beneficiary cohort and for beneficiaries taking parenteral nutrition. In contrast, consolidation of vaccines under Part B increases total payments since most Part D payments for vaccines do not occur in the catastrophic phase. Overall, total payments for Medicare decrease by about $154 million.

Adjusting for beneficiary behavioral response to the proposed consolidation reduces savings due to consolidation by about $3 million.

The adjusted estimate of additional Reinsurance Subsidy payment, which allows beneficiaries to enroll into different plan types based on post-consolidation GDC, is about $3 million higher than the baseline estimate. This adjustment reduces savings for Medicare from $154 million to $151 million. Two factors explain the low level of adjustment. First, except for plans that provide gap coverage, the financial baseline impact for Medicare does not change significantly from one plan to the next. Second, the distribution of enrollment across benefit types is not very sensitive to the level of drug costs.

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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 Insulin

HCPCS	Description
J1817	Insulin Pump, 50 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

Table A- 5: HCPCS Codes for Immunosuppressants

HCPCS	Description
J7500	J7500, AZATHIOPRINE, ORAL, 50 MG
J7502	J7502, CYCLOSPORINE, ORAL, 100 MG
J7507	J7507, TACROLIMUS, ORAL, PER 1 MG
J7515	J7515, CYCLOSPORINE, ORAL, 25 MG
J7517	J7517, MYCOPHENOLATE MOFETIL, ORAL, 250 MG
J7518	J7518, MYCOPHENOLIC ACID, ORAL, 180 MG
J7520	J7520, SIROLIMUS, ORAL, 1 MG

Table A- 6: HCPCS Codes for Parenteral Nutrition

HCPCS	Description	Has Billing Information?
B4164	B4164, PARENTERAL NUTRITION SOLUTION: CARBOHYDRATES (DEXTROSE), 50% OR LESS (500 ML = 1 UNIT) - HOMEMIX	Yes
B4168	B4168, PARENTERAL NUTRITION SOLUTION; AMINO ACID, 3.5%, (500 ML = 1 UNIT) - HOMEMIX	Yes
B4172	B4172, PARENTERAL NUTRITION SOLUTION; AMINO ACID, 5.5% THROUGH 7%, (500 ML = 1 UNIT) - HOMEMIX	Yes
B4176	B4176, PARENTERAL NUTRITION SOLUTION; AMINO ACID, 7% THROUGH 8.5%, (500 ML = 1 UNIT) - HOMEMIX	Yes
B4178	B4178, PARENTERAL NUTRITION SOLUTION: AMINO ACID, GREATER THAN 8.5% (500 ML = 1 UNIT) - HOMEMIX	Yes
B4180	B4180, PARENTERAL NUTRITION SOLUTION; CARBOHYDRATES (DEXTROSE), GREATER THAN 50% (500 ML=1 UNIT) - HOMEMIX	Yes
B4216	B4216, PARENTERAL NUTRITION; ADDITIVES (VITAMINS, TRACE ELEMENTS, HEPARIN, ELECTROLYTES) HOMEMIX PER DAY	No
B5200	B5200, PARENTERAL NUTRITION SOLUTION: COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, STRESS - BRANCH CHAIN AMINO ACIDS -	No

APPENDIX B: ACTIVE INGREDIENTS

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
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
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 Immunosuppressants

Active Ingredients	Description
AZATHIOPRINE	AZATHIOPRINE POWDER
AZATHIOPRINE	AZATHIOPRINE SODIUM FOR INJ 100 MG
AZATHIOPRINE	AZATHIOPRINE TAB 100 MG
AZATHIOPRINE	AZATHIOPRINE TAB 50 MG
AZATHIOPRINE	AZATHIOPRINE TAB 75 MG
BASILIXIMAB	BASILIXIMAB FOR IV SOLN 10 MG
BASILIXIMAB	BASILIXIMAB FOR IV SOLN 20 MG
CYCLOSPORINE	CYCLOSPORINE (BULK) POWDER
CYCLOSPORINE	CYCLOSPORINE (OPHTH) EMULSION 0.05%
CYCLOSPORINE	CYCLOSPORINE CAP 100 MG
CYCLOSPORINE	CYCLOSPORINE CAP 25 MG
CYCLOSPORINE	CYCLOSPORINE IV SOLN 50 MG/ML
CYCLOSPORINE	CYCLOSPORINE MODIFIED CAP 100 MG
CYCLOSPORINE	CYCLOSPORINE MODIFIED CAP 25 MG
CYCLOSPORINE	CYCLOSPORINE MODIFIED CAP 50 MG
CYCLOSPORINE	CYCLOSPORINE MODIFIED ORAL SOLN 100 MG/ML
CYCLOSPORINE	CYCLOSPORINE ORAL SOLN 100 MG/ML
DACLIZUMAB	DACLIZUMAB FOR IV INJ CONC 25 MG/5ML
EVEROLIMUS	EVEROLIMUS TAB 0.25 MG
EVEROLIMUS	EVEROLIMUS TAB 0.5 MG
EVEROLIMUS	EVEROLIMUS TAB 0.75 MG
EVEROLIMUS	EVEROLIMUS TAB 10 MG
EVEROLIMUS	EVEROLIMUS TAB 2.5 MG
EVEROLIMUS	EVEROLIMUS TAB 5 MG
MUROMONAB	MUROMONAB CD3 INJ 1 MG/ML
MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL CAP 250 MG
MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL FOR ORAL SUSP 200 MG/ML
MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL HCL FOR IV SOLN 500 MG (BASE EQUIV)
MYCOPHENOLATE MOFETIL	MYCOPHENOLATE MOFETIL TAB 500 MG
MYCOPHENOLATE SODIUM	MYCOPHENOLATE SODIUM TAB DR 180 MG (MYCOPHENOLIC ACID EQUIV)
MYCOPHENOLATE SODIUM	MYCOPHENOLATE SODIUM TAB DR 360 MG (MYCOPHENOLIC ACID EQUIV)
PIMECROLIMUS	PIMECROLIMUS CREAM 1%
SIROLIMUS	SIROLIMUS ORAL SOLN 1 MG/ML
SIROLIMUS	SIROLIMUS TAB 0.5 MG
SIROLIMUS	SIROLIMUS TAB 1 MG
SIROLIMUS	SIROLIMUS TAB 2 MG
TACROLIMUS	TACROLIMUS (BULK) POWDER
TACROLIMUS	TACROLIMUS CAP 0.5 MG
TACROLIMUS	TACROLIMUS CAP 1 MG
TACROLIMUS	TACROLIMUS CAP 5 MG
TACROLIMUS	TACROLIMUS INJ 5 MG/ML
TACROLIMUS	TACROLIMUS OINT 0.03%
TACROLIMUS	TACROLIMUS OINT 0.1%
TOCILIZUMAB	TOCILIZUMAB IV INJ 20 MG/ML
USTEKINUMAB	USTEKINUMAB INJ 45 MG/0.5ML (90 MG/ML)

Table B- 5: Active Ingredients for Parenteral Nutrition

Active Ingredients	Description
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 2.75% in D10W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 2.75% in D5W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 3%***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 3.5% in D5W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 3.5%***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 4.25% in D10W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 4.25% in D25W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 4.25% in D5W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 5% in D25W***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 5.5%***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 7%***
Amino Acid, Electrolytes	*Amino Acid Electrolyte Infusion 8.5%***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 2.75% in D10W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 2.75% in D5W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 3.5% in D25W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 4.25% in D10W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 4.25% in D20W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 4.25% in D25W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 4.25% in D5W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 5% in D15W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 5% in D20W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 5% in D25W***
Amino Acid, Electrolytes, Calories	*Amino Acid Electrolyte w/Cal Infusion 5% in D35W***
Amino Acid	*Amino Acid Infusion 10%***
Amino Acid	*Amino Acid Infusion 15%***
Amino Acid	*Amino Acid Infusion 2.75%***
Amino Acid	*Amino Acid Infusion 20%***
Amino Acid	*Amino Acid Infusion 3.5% in D25W***
Amino Acid	*Amino Acid Infusion 3.5% in D5W***
Amino Acid	*Amino Acid Infusion 3.5%***
Amino Acid	*Amino Acid Infusion 4%***
Amino Acid	*Amino Acid Infusion 4.25% in D10W***
Amino Acid	*Amino Acid Infusion 4.25% in D20W***

Active Ingredients	Description
Amino Acid	*Amino Acid Infusion 4.25% in D25W***
Amino Acid	*Amino Acid Infusion 4.25% in D5W***
Amino Acid	*Amino Acid Infusion 5% in D15W***
Amino Acid	*Amino Acid Infusion 5% in D20W***
Amino Acid	*Amino Acid Infusion 5% in D25W***
Amino Acid	*Amino Acid Infusion 5%***
Amino Acid	*Amino Acid Infusion 5.2%***
Amino Acid	*Amino Acid Infusion 5.4%***
Amino Acid	*Amino Acid Infusion 5.5% in D10W***
Amino Acid	*Amino Acid Infusion 5.5% in D20W***
Amino Acid	*Amino Acid Infusion 5.5%***
Amino Acid	*Amino Acid Infusion 6%***
Amino Acid	*Amino Acid Infusion 6.5%***
Amino Acid	*Amino Acid Infusion 6.9%***
Amino Acid	*Amino Acid Infusion 7%***
Amino Acid	*Amino Acid Infusion 8%***
Amino Acid	*Amino Acid Infusion 8.5% in D10W***
Amino Acid	*Amino Acid Infusion 8.5% in D20W***
Amino Acid	*Amino Acid Infusion 8.5% in D50W***
Amino Acid	*Amino Acid Infusion 8.5%***
Electrolyte	*Parenteral Electrolyte Conc***
Electrolyte	*Parenteral Electrolyte Soln***
Dextrose	Dextrose Inj 10%
Dextrose	Dextrose Inj 20%
Dextrose	Dextrose Inj 25%
Dextrose	Dextrose Inj 30%
Dextrose	Dextrose Inj 40%
Dextrose	Dextrose Inj 5%
Dextrose	Dextrose Inj 50%
Dextrose	Dextrose Inj 60%
Dextrose	Dextrose Inj 70%
Fat Emulsion	Fat Emulsion IV Soln 10%
Fat Emulsion	Fat Emulsion IV Soln 20%
Fat Emulsion	Fat Emulsion IV Soln 30%

APPENDIX C: ASSIGNING COST SHARE AND PREDICTING BENEFIT STRUCTURE

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 (MDB), 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 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 a 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 a 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 the 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

Calculating 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 cost 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 to 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 to 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 in Table C- 2. If a PDE record falls within the ICP and corresponds to a tier 1 drug with a 90 day 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.

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, active ingredient, strength, dosage, and route of administration. [47]

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

The 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 fewer than 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.

An example case is lithium citrate. For this drug, the same GSN-BN maps to two different reference NDCs and, as a result, to 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 Subsidy 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 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 Subsidy 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 Acronyms

Acronym	Description
AMA	American Medical Association
ASP	Average Sales Price
AWP	Average Wholesale Price
CGDP	Coverage Gap Discount Program
CMS	Center for Medicare and Medicaid Services
CPI	Consumer Price Index
DME	Durable Medical Equipment
EDB	Enrollment Database
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
FDB	First DataBank
FFS	Fee-for-Service
GDC	Gross Drug Cost
GI	Gastrointestinal
HCPCS	Healthcare Common Procedure Coding System
HHA	Home Health Agency
HPMS	Health Plan Management System
ICD	International Classification of Diseases
ICP	Initial Coverage Phase
IP	Inpatient
IV	Intravenous
LIPS	Low Income Premium Subsidy
LICS	Low Income Cost-Sharing
LIS	Low Income Subsidy
MA	Medicare Advantage
MA PDP	Medicare Advantage Prescription Drug (Plan)
MBD	Medicare Database
MDI	Metered Dose Inhaler
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Modernization Act
MSP	Medicare Savings Program
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NPI	National Provider Identifier
OIG	Office of the Inspector General
OP	Outpatient
Carrier	Physician / Supplier
PBM	Pharmacy Benefit Manager

Acronym	Description
PDE	Prescription Drug Event
PDP	Prescription Drug Plan
PLRO	Patient Liability Reduction Due to Other Payer Amount
RxHCC	Prescription Drug Hierarchical Condition Categories
SAF	Standard Analytical File
TrOOP	True Out-of-Pocket (costs)