Examining Reforms to Improve the Medicare Part B Drug Program for Seniors
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Chairman Pitts, Ranking Member Pallone, and distinguished Subcommittee Members, I am Cliff Binder, Health Financing Analyst with the Congressional Research Service. I appreciate the opportunity to be here today to provide an overview on Medicare Part B prescription drugs – what they are and how Medicare reimburses providers for these products. I also will provide context by discussing recently introduced legislation and the potential effect of sequestration on Medicare Part B drug payments. Part B drug reimbursement is complex, I am presenting the major points that I hope will be most useful in facilitating today's discussion.

BACKGROUND

Medicare is a federal program that pays for covered health care services of qualified beneficiaries. It was established in 1965 under Title XVIII of the Social Security Act to provide health insurance to individuals 65 and older, and has been expanded over the years to include permanently disabled individuals under 65.[1] The program is administered by the Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (DHHS). Medicare consists of four distinct parts:

- Part A covers inpatient hospital services, skilled nursing care, hospice care, and some home health services.
- Part B covers physician services, outpatient services, and some home health and preventive services.
- Part C (Medicare Advantage, or MA) is a private health plan option that covers all Parts A and B services, except hospice. Individuals who choose to enroll in Part C must also enroll in Part B.
- Part D covers outpatient prescription drug benefits.

The majority of beneficiaries, nearly 73%, receive benefits through Medicare's fee-for-service (FFS) program, known as "original" or "traditional" Medicare. The remaining beneficiaries, approximately 27%, chose to enroll in private health care plans under Medicare Part C, the Medicare Advantage (MA) program. Approximately 73% of Medicare beneficiaries chose to enroll in Part D.[2]

Medicare covers drugs and biologics under Part B when they are furnished "incident to physician services," but only if they usually are not self-administered – the drugs are not *usually* taken by the patient without professional assistance.[3] Generally, Part B drugs are infused or injected. Most drugs administered as pills are not covered under Part B because they are self-administered.[4] To be covered by Part B, drugs must meet the following incident to physician services requirements (some drugs furnished by other health care practitioners may meet these requirements):

- furnished by a physician and administered by the physician or by auxiliary personnel under the physician's personal supervision;

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[1] For more information, see CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis and Scott Talaga.
[2] Ibid.
[3] *2013 Medicare Explained*, Sec. 351, Commerce Clearing House, Inc., WoltersKluwer.
[4] Medicare contractors determine whether or not a drug is considered *usually* self-administered. Usually, in this sense, means more than 50% of the time for all Medicare beneficiaries. If a drug was self-administered by more than 50% of Medicare beneficiaries, it would not be covered by Medicare Part B.

- the charge for the drug must be included in the physician's bill and the cost must represent an expense to the physician;
- are reasonable and necessary to diagnose or treat an existing illness or condition; and
- are not considered less than effective by the Food and Drug Administration (FDA).

There are a number of exceptions to these requirements. Preventive vaccinations and inoculations are not covered under Medicare Part B because they are considered "immunizations," unless they are directly related to treatment of a disease.[5] Other exceptions that are covered under Part B include antigens, blood clotting factors, erythropoietin (EPO) for treating anemia in dialysis and cancer patients, immunosuppressive drugs, injected osteoporosis drugs, and oral anti-cancer and anti-nausea drugs.[6],[7] Most other outpatient drugs are covered under Medicare's Part D outpatient prescription drug benefit.

Providers, mostly physicians, but also hospital outpatient departments, clinics, and durable medical equipment suppliers, buy Part B drugs, then bill Medicare when they administer the drugs to patients. Physicians and other providers receive two payments from Medicare for Part B drugs (1) for administering the drug and (2) for purchasing and supplying the drug.[8]

In 2010, Medicare expenditures for most prescription drugs were approximately $81 billion.[9] Part B drug expenditures were about one-quarter of this spending, or about $19 billion, including the portion paid by beneficiaries.[10] Medicare beneficiaries generally pay 20% of Part B payments, although about 65% of Medicare beneficiaries have some form of supplemental health insurance coverage that pays most Part B coinsurance costs.[11] Even though a high percentage of Medicare beneficiaries have supplemental insurance, those without this coverage can face large Part B drug cost-sharing expenses, because many cancer and related drugs are expensive.

Medicare Part B covered about 600 outpatient drugs in 2010, although spending on these drugs was concentrated, with the top ten drugs accounting for nearly half of Part B drug expenditures.[12] Cancer

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[5] Medicare Part B covers influenza, pneumococcal, and hepatitis B vaccines regardless of setting, but physician supervision for the administration may not be necessary. Other vaccines, such as the shingles vaccine, are covered under Part D.

[6] Medicare began paying dialysis facilities a bundled rate January 1, 2011. EPO is included in the dialysis bundle although it also is covered under Part B when used in other situations.

[7] Oral dose drugs are covered by Part B when they have the same active ingredients and are used for the same indications as the drugs that are not self-administered and would have been administered incident to physician services. Oral anti-nausea drugs are covered under Part B when used as part of an anti-cancer chemotherapeutic regimen.

[8] Department of Health and Human Services, Office of Inspector General, *Medicare Part B Chemotherapy Administration Payment and Policy* (OEI-09-08-00109), June 2009.

[9] The Medicare Payment Advisory Commission (MedPAC), *Health Care Spending and the Medicare Program, A Data Book*, Section 10, Prescription Drugs, June 2012. This estimate includes Medicare payment, beneficiary cost sharing, and state expenditures for Parts B and D, including drugs supplied in physician offices, renal dialysis facilities, and hospital outpatient departments. These estimates exclude physician and other provider Part B drug administration payments.

[10] Ibid. Supplemental insurance coverage data is for non-institutionalized Medicare beneficiaries in 2009. In addition to the 65% of beneficiaries with supplemental coverage, another 27% of Medicare beneficiaries were enrolled in Medicare Advantage (MA) plans. MA plan beneficiaries might have coinsurance, but it would be lower than the 20% paid by fee-for-service beneficiaries.

[11] Ibid.

[12] MedPAC, *Health Care Spending and the Medicare Program, A Data Book*, Section 10, Prescription Drugs, June 2012.

treatment is the largest category of Part B drug expenditures – in 2010, seven of the top 10 drugs were for fighting cancer or relieving symptoms associated with chemotherapy.[13] The 2010 seven top-selling Part B drugs were biologic products.[14]

Medicare Part B Drug Reimbursement Methodology

The Balanced Budget Act of 1997 (BBA97, P.L. 105-33), set the payment amount for Medicare Part B drugs at 95% of the average wholesale price (AWP).[15] The BBA Part B drug changes were intended to help control Medicare's rising drug payments (Medicare did not cover outpatient drugs then, so the concern was with Part B drugs), but these drug payments continued to escalate rising nearly 25% per year from 1999-2003. AWP is a published list price, similar to the price sticker displayed on a new car's window. AWP and other list prices might be considered the price at which manufacturers would like to sell their product rather than a market price or acquisition cost. Since most buyers do not pay list price, AWP was limited as a benchmark. After BBA97, Medicare was paying substantially in excess of the physician/provider supplier drug acquisition cost, and Medicare's payments were higher than those paid by most other large payers. Providers argued that the reimbursement for Part B drugs was justified, because payments were too low to cover the cost of administering the drugs to beneficiaries.

The Medicare Prescription Drug Improvement and Modernization Act of 2003

In response to the Part B price escalation and with supporting analysis from the Medicare Payment Advisory Commission (MedPAC), Congress made changes to the Part B payment methodology in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108-173).[16] MMA made the following two changes to Part B drug reimbursement: (1) adjusted (increased) the physician fee schedule amount physicians would receive for administering Part B drugs; and (2) established a new payment methodology for Part B drugs, effectively decreasing physician payments for supplying these drugs. The policy changes embodied in MMA moved drug reimbursement closer to what physicians and other providers and suppliers actually paid for these products and increased the amount they were paid for administering the drugs.

Since passage of MMA, annual Medicare Part B drug expenditures have grown at a slower rate. **Table 1** displays Medicare Part B drug spending and the growth rate percentage from 1997 to 2010.

Table 1. Medicare Part B Drug Expenditures 1997-2010 (in $billions)

Calendar Year	Estimated Part B Drug Expenditures	% Annual Expenditure Change
1997	$2.8	
1998	$3.2	14.3%
1999	$4.1	28.1%

[13] Ibid
[14] Ibid. Drugs refer to both biologic and synthesized products. Biologics are manufactured from living sources, including humans, animals, and micro-organisms. Synthesized products are manufactured from chemicals.
[15] Balanced Budget Act of 1997 (BBA97, P.L. 105-33), Sec. 4556, Reimbursement for Drugs and Biologicals.
[16] Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108-173), Sec. 303, Payment Reform for Covered Outpatient Drugs and Biologicals.

2000	$5.0	24.4%
2001	$6.4	25.5%
2002	$8.5	32.8%
2003	$10.3	21.2%
2004	$10.9	5.8%
2005	$10.1	-7.3%
2006	$10.6	5.0%
2007	$11.0	3.8%
2008	$10.7	-2.7%
2009	$11.1	3.7%
2010	$11.5	3.6%

Source: Medicare Payment Advisory Commission (MedPAC), A Data Book: Health Care Spending and the Medicare Program, Section 10, June 2012.

Notes: Data include Part B covered drugs administered in physician offices or furnished by suppliers (e.g., durable medical equipment). Data do not include Part B drugs furnished in hospital outpatient departments or dialysis facilities.

MMA passed on December 8, 2003. The Part B drug payment changes were phased-in, so 2004 was a transition year during which time providers were paid for most Part B drugs based on 85% of the product's AWP.[17] Beginning in 2005, Medicare began paying for the majority of Part B drugs based on 106% of a drug's Average Sales Price (ASP).[18] ASP is defined as a manufacturer's quarterly sales of a drug to all U.S. purchasers; divided by the drug's total units sold for the same quarter.

However, MMA allowed for exceptions to this methodology depending on the site where a drug was administered. For example, vaccines, infusion drugs furnished through Durable Medical Equipment (DME), and blood products are paid at 95% of AWP.[19] Since sales data might not be available, new drug reimbursement may be based on the product's list price or invoice price. In addition, even though Medicare reimbursement for Part B drugs administered in hospital outpatient departments is based on ASP, there can be year to year variation. In 2013, hospitals receive 106% of ASP, but in some situations when the cost of the drugs exceed a certain threshold, Medicare makes additional (pass through) payments under the outpatient prospective payment system for certain drugs (some cancer drugs, new drugs, and orphan drugs).[20]

Drug manufacturers are required to report certain types of price information to the DHHS Secretary (the Secretary), including ASP and Average Manufacturer Price (AMP). CMS collects and maintains these confidential data. Drug manufacturers submit ASP and AMP data to CMS quarterly using National Drug Codes (NDCs), a standard 11-digit code that identifies the manufacturer, dosage form, and the product package size. Using a CMS-supplied template, manufacturers submit the number of units sold and the

[17] AWP has some limitations as a drug price benchmark including that is not necessarily based on actual sales transactions; it is not defined in law or regulation so it varies across manufacturers; and it fails to account for prompt pay or other discounts, rebates, and price concessions.
[18] Social Security Act Sec. 1847A(b)(1).
[19] CMS sets payment rates for blood products and vaccines based on current AWPs, but infusion drugs used with DME reimbursement is based on AWPs in effect October 1, 2003.
[20] In FY2012 the threshold was $75. Orphan drugs are those approved by the Food and Drug Administration to treat rare diseases. Drug manufacturers generally are given a seven-year market exclusivity period and other financial incentives for these drugs.

ASP for those units. CMS aggregates all drug manufacturers' ASP data and groups it by Medicare billing codes, so that ASP is the weighted average of all manufacturers' sales prices for each product classified under a Medicare billing code.[21] CMS calculates Part B ASPs for each billing code using an equation that includes the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS.[22]

Generally, there is one billing code for sole source products, but there can be many multiple-source products under a single billing code. Each billing code has a volume-weighted ASP.

ASP includes most price concessions – volume, prompt-pay, and cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates except Medicaid rebates.[23] Price concessions have the effect of lowering a drug's ASP.[24] Manufacturers' ASP data exclude nominal price sales and "best price" sales. To calculate ASP a manufacturer uses the amount that a buyer paid for a product, after deducting the amount or value of price concessions. The following examples help illustrate how price concessions affect ASPs.

- If a hospital bought 400 units of a drug for $2.50 per unit and was offered a 3% prompt pay discount, the manufacturer would consider the ASP for this transaction to be $2.425 per unit.
- If a drug wholesaler bought 400,000 units of the same drug and received a 3% prompt pay discount as well as a 5% rebate for a higher volume purchase, the ASP would be $2.304 for this product.
- If a manufacturer sold a state Medicaid program 1,000 units of the same drug for 2.50 per unit, then paid the state and the federal Medicaid program a combined 23.1% rebate, this entire transaction would be excluded from the manufacturer's ASP reporting for the quarter.

CMS sets the Part B drug ASPs for each quarter based on sales data submitted by drug manufacturers from two previous quarters. For example, ASP data submitted for sales from January-March (Quarter 1) is used to set Part B drug payment rates for the third quarter (October-December). If drug manufacturers raise prices in the two quarters after they submit their ASP data, it may be more difficult for providers to purchase products below the Medicare payment rate. However, when prices decline after manufacturers submit their ASP data, providers often are able to purchase these drugs for prices significantly below Medicare's payment rate. Part B drug prices decline when generic, multiple-source products are introduced that compete with sole source products or when other therapeutic equivalent sole-source products are introduced.

MMA also required the DHHS Office of Inspector General (OIG) to conduct drug price monitoring studies to determine if widely available market prices (WAMP) for Part B drugs varied by a specified percentage above AMP. MMA set the threshold at 5% for 2005, but the Secretary was to determine the

[21] Manufacturers report ASP data by NDC code, but Part B drug prices are set by billing codes (called J-codes), so CMS "crosswalks" NDC codes to J-codes. J-codes are Level II Healthcare Common Procedure Coding System Codes.
[22] Social Security Act Sec. 1847A(b)(6).
[23] Manufacturers negotiate discounted prices with some purchasers who buy through wholesalers. Wholesalers can deliver the drugs at discounted prices, inform the manufacturers, and then request reimbursement from the manufacturers. These discounts, handled through wholesalers, are generally known as charge-backs.
[24] Social Security Act Sec. 1847A(c)(3), Net of Discounts, identifies the price concessions that manufacturers are to subtract from ASP.

threshold after 2005. The Secretary set the threshold at 5% in 2006, and it has remained at that level.[25] If the Medicare Part B drug payment rate for specific drugs exceeds WAMP or ASP by 5% or more, the Secretary has authority to substitute the lesser of either WAMP or 103% of a drug's AMP for ASP in setting Part B drug reimbursement. Generally, AMP is lower than ASP, so that Medicare would reduce provider reimbursement for most Part B drugs, under AMP. The OIG has consistently found that there was at least a 5% difference between WAMP or AMP and ASP for some portion of Part B drugs.[26] In November 2012, CMS published a final rule that will implement a Part B drug price substitution policy beginning on January 1, 2014.[27]

Selected Issues

A number of Medicare Part B drug payment issues have been discussed for some time. In spite of considerable analysis, there is concern that Part B drug reimbursement may be inadequate for some providers in some situations. Some providers are concerned that discounts provided by manufacturers to drug wholesalers have the effect of reducing ASP, making it difficult for these providers to cover their costs when purchasing some Medicare Part B drugs.[28] In addition, some in Congress and some stakeholders have questioned whether drug shortages have been complicated by the Part B drug pricing methodology changes in MMA and whether these, along with manufacturers' production problems, speculation, industry consolidation, and other factors, have contributed to drug shortages, particularly for sterile injectable drugs, a Part B drug category.[29] [30]
Moreover, concerns have been raised that the two-quarter lag between the time when manufacturers report ASP and AMP and the time when CMS releases Medicare Part B drug prices make it difficult for some providers to purchase drugs at competitive prices.[31] The OIG also has reported that the two-quarter lag between ASP reporting and setting new prices causes the federal government to overpay for Part B drugs, particularly when new generic drugs are released.[32] Most recently, some providers have raised concerns that the effect of applying the mandatory Budget Control Act of 2011 (BCA, P.L. 112-25)

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[25] See 77 *Federal Register* 68891, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013," November 16, 2012.
[26] Department of Health and Human Services Office of Inspector General, Memorandum Report: *Comparison of First-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for the Third Quarter 2012*, OEI-03-12-00730, December 2012. This report was the 26th report on Medicare ASPs prepared by OIG.
[27] See 77 *Federal Register* 68891, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013," November 16, 2012.
[28] See letter to U.S. House of Representatives from the American Society of Clinical Oncology and other cancer organizations, April 1, 2013 at https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/40a929e3-7abc-4ab8-ba26-8f1127438934.pdf.
[29] House Committee on Oversight and Government Reform, *FDA's Contribution to the Drug Shortage Crisis*, Staff Report, June 15, 2012 at http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-Report-FDAs-Contribution-to-the-Drug-Shortage-Crisis.pdf.
[30] *Shining Light on the "Gray Market," An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*, Staff Report, July 25, 2013. at http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=afa98935-2ff5-4004-88dc-be70d1c22b5d.
[31] Department of Health and Human Services, Office of Inspector General, *Average Sales Prices: Manufacturer Reporting and CMS Oversight* (OEI-03-08-00480), February 2010.
[32] Department of Health and Human Services, Office of Inspector General, *Medicare Payments for Newly Available Generic Drugs* (OEI-03-09-00510), January 2011.

reductions to Medicare Part B drug reimbursement will further reduce payments to providers, potentially reducing beneficiaries' access to services.[33]

The Effect of Sequestration on Medicare Part B Drug Reimbursement

"Sequestration" is a process of automatic, largely across-the-board spending reductions to meet or enforce certain budget policy goals.[34] It was first established by the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA, Title II of P.L. 99-177, 2 U.S.C. 900-922) to enforce deficit reduction targets.

Most recently under BCA, sequestration was tied to enforcement of new statutory limits on discretionary spending and achievement of the budget goal established for the Joint Select Committee on Deficit Reduction. A sequestration was triggered by the Joint Committee's failure to achieve its goal and was originally scheduled to occur on January 2, 2013, to affect spending for FY2013. Congress enacted legislation that delayed the effective date of this sequester until March 1, 2013 (American Taxpayer Relief Act of 2012, P.L. 112-240).[35]

In general, sequestration entails permanent cancellation of budgetary resources by a uniform percentage.[36] The uniform percentage reduction is applied to all "programs, projects, and activities" (PPAs) within a budget account, but certain programs and activities are exempt from sequestration, and special rules may be applied to other programs, such as Medicare.[37]

Specifically, Section 256(d) of BBEDCA contains special rules for the Medicare program in case of a sequestration. However, while BBEDCA ordinarily limits reduction of Medicare spending on program benefits to 4% under a sequestration order (which would apply in the case of a Statutory PAYGO sequestration), BCA limits the size of this reduction to 2%. Thus, beginning April 1, 2013, Medicare payments for covered services, including physician services and Part B drug payments, are subject to 2% reductions.

According to CMS guidance, provider payment adjustments are to be made to claims after determining coinsurance, any applicable deductible, and Medicare Secondary Payer adjustments.[38] In other words, the 2% reduction applicable to Medicare only applies to Medicare's provider payments; the beneficiary cost-sharing amounts and amounts paid by other health insurance are not reduced.

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[33] Healthcare Distribution Management Association, Medicare Average Sales Price Policy, at http://www.hdma.net/gov_affairs/pdf_positions/MedicareAverageSalesPrice.pdf.

[34] For more information on sequestration and its historical application, see (1) CRS Report RL31137, *Sequestration Procedures Under the 1985 Balanced Budget Act*, by Robert Keith; (2) CRS Report RS20398, *Budget Sequesters: A Brief Review*, by Robert Keith; and (3) CRS Report R41901, *Statutory Budget Controls in Effect Between 1985 and 2002*, by Megan S. Lynch.

[35] President Obama issued the sequestration order on March 1, 2013. See http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-06.pdf.

[36] "Budgetary resources" include new budget authority, unobligated balances, direct spending authority, and obligation limitations, as defined in Section 250(c)(6) of BBEDCA, as amended.

[37] For accounts included in appropriations acts, "programs, projects, and activities" (PPAs) within each budget account are delineated in those acts or accompanying reports; for accounts not included in appropriations acts, they are delineated in the most recently submitted President's budget. See Section 256(k) of BBEDCA, as amended.

[38] CMS, Medicare FFS Provider e-News, March 8, 2013, *Monthly Payment Reductions in the Medicare Fee-for-Service (FFS) Program –"Sequestration,"* http://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf.

Table 2 illustrates how budget cuts might affect Medicare Part B drug payments for physicians and patients.[39] As shown in line #2 in **Table 2**, for a Part B drug with an ASP of $943.40, the Part B drug

Table 2. Example Sequestration Effects on Medicare Part B Drug Payments

Line #	Medicare Part B Drug Payment Calculation	Medicare Payment Amount
1	ASP	$943.40
2	106% ASP	$1,000.00
3	Beneficiary Coinsurance	$200.00
4	Pre-sequestration Medicare Payment Portion	$800.00
5	Medicare Payment Portion after 2% Sequester	$784.00
	Physician Payment Before Sequester	
6	Medicare	$800.00
7	Beneficiary	$200.00
8	Total	$1,000.00
	Physician Payment After Sequester	
9	Medicare	$784.00
10	Beneficiary	$200.00
11	Total	$984.00

Source: Centers for Medicare & Medicaid Services (CMS).

Notes: This example assumes that the beneficiary has met the deductible. This example also assumes that the provider participates in Medicare and accepts assignment, so the beneficiary may not be billed for higher copayments to make up for reduced provider reimbursement.

reimbursement would be $1,000 based on the normal Medicare payment methodology. Line 3 displays the beneficiary's coinsurance, which is 20% of what Medicare pays – in this case $200. Line 4 displays what the physician would have received in payment from Medicare for the Part B drug, prior to sequestration (106% of ASP [$1000] – beneficiary coinsurance $200, i.e. $200. Line 5 shows the reduced payment the physician receives under sequestration, where the 2% reduction was applied only to the portion of the reimbursement paid by Medicare [($800* 2% = $16) and ($800-$16 = $784)]. As shown in lines 9-11, under sequestration physicians would receive a total payment of $984 for this Part B drug, which represents approximately a 1.6% payment reduction from the $1,000 that they would have been paid before sequestration. The sequestration cuts would reduce Medicare Part B drug payments in this example to approximately 104.3% of ASP.

Some providers and other stakeholders assert that the BCA budget cuts potentially could force providers to stop seeing Medicare patients who need particular drugs that these providers cannot purchase at competitive prices.[40]

[39] Letter to Representative Sessions (R-TX) from Marilyn Tavenner, Administrator, Centers for Medicare & Medicaid Services, June 3, 2013.

[40] See April 1, 2013 letter to United States House of Representatives from American Society of Clinical Oncology, Community Oncology Alliance, International Oncology Network/AmerisourceBergin, and the US Oncology

Proposed Legislation

H.R. 800, introduced by Representative Whitfield on February 15, 2013, would amend the Social Security Act to exclude customary prompt pay discounts extended by manufacturers to wholesalers from the Medicare Part B ASP calculation.[41] This exclusion would increase manufacturers' ASPs.[42] Supporters of the legislation assert that higher ASPs would increase reimbursement for physicians who are administering Medicare Part B drugs. This higher reimbursement might be more important and more beneficial for smaller, community-based oncology practices that are unable to purchase drugs in sufficient volume to get the most competitive market prices.

Excluding customary wholesale prompt pay discounts from ASP calculations would not change other price concessions that are subtracted from ASP. Pharmaceutical pricing can be very dynamic, so that price concession currently provided to wholesalers as prompt payment discounts might re-emerge in another form or be passed on through other existing mechanisms such as chargebacks, rebates, or in bundled prices. In addition, H.R. 800 also might increase coinsurance payments for Medicare beneficiaries, since they pay 20% of Medicare Part B drug costs.

H.R. 1428, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2013, was introduced by Representative Burgess on April 9, 2013. Under current law, individuals with End Stage Renal Disease (ESRD), who meet certain requirements, are eligible for Medicare. If an ESRD patient receives a kidney transplant, Medicare eligibility expires three years after the successful kidney transplant. Generally, kidney transplant recipients must take immunosuppressive drugs the rest of their lives to suppress their body's immune system reaction to the transplanted organ. Medicare covers immunosuppressive drugs under Part B for an unlimited period of time, but kidney transplant patients lose their Medicare eligibility three years after they received their successful transplant. H.R. 1428 would, among other things, amend the Social Security Act to provide Medicare coverage of immunosuppressive drugs beyond the three-year period.

H.R. 1416, the Cancer Patient Protection Act of 2013, was introduced by Representative Ellmers (R-NC) on April 12, 2013. H.R. 1416 would exempt Medicare Part B drug payments from the BCA mandatory budget cuts. H.R. 1416 would be effective for payments made beginning April 1, 2013, and would not be applicable to any other Medicare program or law.

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[41] Senator Roberts introduced S. 806, a parallel bill, April 24, 2013.

[42] Similar legislation was introduced in the 111th and 112th Congresses.