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ON

SUSTAINING THE MEDICARE PROGRAM THROUGH LOWER COSTS

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Hearing on Sustaining the Medicare Program through Lower Costs

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Chairman Kohl, Ranking Member Corker, and distinguished members of the Special Committee, thank you for the opportunity to discuss the Medicare Program with you, and more specifically, the laws guiding how Medicare pays for prescription medications. The Administration is committed to protecting and strengthening Medicare, and reducing health care costs in the Medicare program, which will provide care to approximately 50 million Americans in 2012. Paying appropriately for prescription drugs is an important part of that commitment.

The Affordable Care Act reforms the health care delivery system, reduces health care costs, and extended the solvency of Medicare. The Affordable Care Act also builds a stronger Medicare program by improving access and coverage of life-saving prescription drugs, through lower prescription drug costs for beneficiaries.

Medicare pays for prescription drugs in many ways: drugs provided as part of inpatient or outpatient hospital care are provided under Part A and Part B, respectively, physician-administered drugs are generally paid under Part B and other prescription drugs are paid under Part D.

Medicare Prescription Drug Benefit: Part D

The Medicare Part D pharmacy drug benefit program was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) P.L. 108-173. Part D is designed to provide beneficiaries with drug coverage through private prescription drug plans. Under Medicare Part D, private insurers contract directly with CMS to provide prescription drugs, certain vaccines, insulin and certain medical supplies associated with the injection of insulin. CMS pays plans per enrollee, and the plans compete for enrollees on the basis of premiums and coverage. Medicare subsidizes about 75 percent of the average cost for basic

coverage, with beneficiaries who choose to enroll in the voluntary Part D benefit paying the balance through monthly plan premiums. Beneficiaries also have the option to choose "enhanced plans" that have higher premiums and more generous coverage than basic plans.

Each plan year, beneficiaries decide whether they want to remain in their current plan or enroll in a different plan that best meets their unique health and specific prescription drug needs. The Administration values giving beneficiaries that choice, and in recent years, CMS has worked to simplify the plan selection process for beneficiaries so that the differences between health plan and prescription drug coverage choices are easily understandable to the Medicare population. Beginning in 2011, CMS adopted its meaningful differences policy whereby CMS will approve a bid submitted by a Medicare Advantage (MA) organization or Part D sponsor only if the plan's benefits or cost sharing are substantially different from those of other plans offered by the organization or sponsor in the area. In making this determination for Part D, CMS takes in to account key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. These policies are in place to ensure that CMS is providing a meaningful choice to beneficiaries.

The 2011 deductible is $310 and average monthly premiums for standard Part D basic coverage is $30.72, an increase of less than $2.00 from 2010. In addition, even with changes to simplify the plan selection process, there are at least 29 Part D plans available in each Region. For low-income beneficiaries, varying degrees of cost-sharing are available with co-payments ranging from $0 to $6.30 and low to no monthly premiums. Beneficiary premiums in the Part D program are stable even though the costs of prescription drugs have increased by 4.2 percent in the last year.[1] Part D plan sponsors have been able to manage benefit costs through the widespread use of generic drugs, refinements of drug formularies, and utilization management.

The average Part D premium for basic coverage in 2006 was $23.42 and is currently $30.72, an increase of less than $8.00 since the inception of the Part D program. For 2012, there will be about 32 million beneficiaries enrolled in Medicare Part D, including about 11 million low-

[1] Bureau of Labor Statistics, Consumer Price Index, Unadjusted % change June 2010 to June 2011 for prescription drugs: http://www.bls.gov/cpi/cpid1106.pdf

income subsidy beneficiaries. About 66 percent of those with Part D coverage are enrolled in stand-alone Part D prescription drug coverage and 34 percent are enrolled in a Medicare Advantage Prescription Drug Plan (Medicare Part C). Overall, approximately 87 percent of all Medicare beneficiaries receive prescription drug coverage through Medicare Part D, employer-sponsored retiree health plans, or other creditable coverage. Beginning in 2011, Part D premiums have been adjusted for beneficiaries whose modified adjusted gross income exceeds thresholds established for the Part B income-related premiums.

CMS pays Part D sponsors based on their bids to provide basic prescription drug coverage to beneficiaries. Part D plan sponsors are required to cover two drugs in every drug class and all drugs in six "protected" classes. These "protected" classes are: Antiretroviral; Anti-Cancer; Immunosuppressives; Antipsychotics, Antidepressants; and Anticonvulsants. In order to ensure that beneficiaries have access to a full array of medications to manage their health care conditions, each year CMS reviews Part D formularies for adequacy to ensure plans' pharmacy benefit packages are not being discriminatory. Further, a coverage determination can be requested by a beneficiary, by an appointed representative, or by the prescribing physician on behalf of the Medicare beneficiary. If a beneficiary does not agree with the initial coverage determination made by the Part D plan sponsor, there is a formal process through which the beneficiary has the right to appeal the coverage determination of a non-formulary drug, request an exception to a plan's tiered cost sharing structure, and request an exception to the application of a cost utilization management tool.

Part D: Actual Costs

According to the Medicare Trustees, total 2010 benefit costs ($61.7 billion) were almost identical to those projected last year, and were about 6 percent lower than the projection from the 2009 report. Further, overall net Medicare costs for the Part D program in 2011 are approximately 40 percent lower than what was initially projected upon enactment

Part D: Management Tools for Lowering Costs

Most Part D plans use drug formularies to assist in the overall management of drug costs. Plans negotiate rebates (price concessions) with brand-name drug manufacturers in exchange for preferential formulary or "tier placement" that reduces the copayment for the beneficiary.

Part D plans are able to manage drug costs using utilization management techniques such as prior-authorization; "step therapy," which encourages lower-cost therapeutic alternatives by requiring beneficiaries to try generics or lower-cost alternative drugs first; and quantity limits, with appropriate appeals process in place to protect beneficiaries. Plans also manage drug costs by encouraging beneficiaries to use in-network pharmacies and mail order programs.

Part D formularies include generic drugs. Part D plans promote generic drug use by placing them on the first or second tier that contains minimal or zero cost sharing. As a result, generic utilization in Part D far exceeds private insurers' generic utilization rates and has grown over time. In 2006, the first year of Part D, generic utilization was 60 percent, as a percentage of drug fills, and in 2009 generic utilization had risen to 72 percent.[2]

Part D: Affordable Care Act Improvements

As a result of new provisions in the Affordable Care Act, people with Medicare have already received relief from the cost of their prescription medications. For 2010, nearly 4 million eligible seniors and people with disabilities who reached the donut hole received help through a one-time, tax-free $250 rebate check to help reimburse them for out-of-pocket drug costs. And beginning this year (2011), applicable beneficiaries have been automatically receiving a 50 percent discount on covered brand name drugs in the Part D coverage gap, or "donut hole." Almost half a million individuals enrolled in Medicare's prescription drug benefit who have reached the donut hole have saved an average of $545 each, for total savings to beneficiaries of more than $260 million, so far this year. People with Medicare Part D will pay a smaller share of their prescription drug costs in the coverage gap every year from now until 2020, when the coverage gap will be closed.

[2] http://www.cms.gov/Dashboard/DBRD/list.asp#TopOfPage

Medicare Drug Benefit: Part B

Medicare Part B coverage is defined by statute and includes a limited number of prescription drugs under three basic categories:

- **Drugs that are administered by a physician or under physician supervision.** Most Part B drugs are paid under this "incident to" provision, where the physician buys the drug, administers it and then bills for it. These are typically injectable drugs that are administered in a physician's office, for example injectable prostate cancer drugs; drugs used to treat cancer and side effects of cancer medications; injectable drugs used to treat rheumatoid arthritis; and drugs used to treat age-related macular degeneration, the most common cause of blindness among older Americans. Part B also covers these types of drugs when furnished in a hospital outpatient setting.

- **Drugs administered through durable medical equipment (DME) such as nebulizers or IV pumps.** For example, inhalation drugs, such as albuterol sulfate and ipratropium bromide, are frequently administered through a nebulizer, when used in a home setting.

- **Specific drugs covered by statute.** The list of Part B drugs covered by statue includes a variety of items that are administered in specified settings, including: certain drugs used for the treatment of end-stage renal disease (ESRD) furnished by dialysis facilities; certain oral anticancer drugs; certain oral antiemetic drugs; drugs for beneficiaries with a Medicare covered organ transplant; influenza, pneumococcal, and hepatitis B vaccines; as well as intravenous immune globulin G (IVIG) used to treat primary immunodeficiency in the homecare setting.

Part B generally does not cover drugs that are self-administered.

Part B: Payment for Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) P.L.108-173, the statute that created Part D, substantially revised Medicare payments for Part B drugs. Prior to the MMA, payment for many Part B drugs was calculated from the Average

Wholesale Price (AWP). The MMA authorized the Average Sales Price (ASP) methodology which calculates payments from manufacturers' reported sales prices.

Numerous reports by the MedPAC, HHS Office of Inspector General (OIG) and the Government Accountability Office (GAO) indicated that Medicare's AWP based payment was significantly higher than physician acquisition costs for these drugs.[3] The difference between Medicare's payment and acquisition costs is referred to as "spread". We believe that physicians used this spread in order to cross subsidize other expenses.

The MMA revised the system, changing Medicare's payment both for Part B drugs and their administration. The MMA specifies that Medicare's payment for most Part B drugs be 106 percent of the volume weighted average of manufacturers' Average Sales Price (ASP). The ASP-based payment rates, commonly known as "ASP + 6," became effective January 1, 2005.

Part B: Payments through ASP

The ASP is the average of each manufacturer's sales price, net of most discounts, rebates and other price concessions. The ASP accounts for all sales from a manufacturer to all entities within the nation who purchase the drug from the manufacturer. Certain low price sales are not included in the manufacturers' ASP. Manufacturers report their ASPs to CMS on a quarterly basis. CMS takes each manufacturer's reported ASP for each National Drug Code (NDC) that is assigned to a billing code and weights it by the volume of sales of all NDCs assigned to the billing code and then determines the ASP-based payment rate for each billing code.

The statute requires that the Medicare payment amounts are updated each quarter based on the most recent data available, which is data from the second previous quarter. For example, Medicare ASP payments for the quarter beginning July 1 are based on sales of the drugs from January through March. Sales data must be reported to CMS no later than 30 days after the end of the quarter. After CMS receives manufacturers' submissions, CMS compiles the data and within a few weeks, calculates the rates, checks potentially erroneous data submissions with manufacturers, makes corrections, publishes the rates, and makes them available to the Medicare

[3] http://www.medpac.gov/publications%5Ccongressional_reports%5CJune03_Ch9.pdf

claims processing contractors' systems. Unlike most Medicare price files which are updated on an annual basis, the ASP files are updated quarterly. This allows the Medicare payment rate for Part B drugs to more accurately reflect the most current market conditions.

Part B: Drug Coverage

In accordance with Section 1862(a)(1)(A) of the Social Security Act, CMS makes coverage decisions based upon whether a treatment is "reasonable and necessary ." We do not consider cost as part of this decision. Payment for reasonable and necessary uses of drugs can include both FDA approved uses, as well as uses that are supported by evidence but not evaluated and approved by the FDA.

Part B: Spending

For 2010, the preliminary estimate of Medicare allowed charges for the approximately 800 drugs paid for by Medicare Part B contractors that are administered incident to a physician's service or in conjunction with DME was $12.5 billion. Most of the current spending for these Part B drugs is concentrated in less than 10 percent of the approximately 800 covered drugs. For example, of the $12.5 billion spent in 2010, 13 drugs accounted for 50 percent of spending, 34 drugs accounted for 75 percent of spending, and 70 drugs accounted for 90 percent of spending. From 2005 to 2010, spending on Part B drugs increased approximately 24 percent.

In 2010, the top two drugs, ranibizumab (Lucentis) and rituximab (Rituxan), accounted for an estimated 16 percent of spending for these Part B drugs.

Most of the highly utilized Part B drugs do not have generic equivalents. When generic equivalents become available, payment amounts can and often do drop significantly (see Generic Impact table). A number of recent biological approvals and drugs in the pipeline for approval will affect Part B spending in the near future. High cost items, such as Provenge and Jevtana (products used to treat advanced prostate cancer), and Benlysta (a biological used to treat lupus), are expected to add to Part B spending.

Lucentis and Avastin

According to the National Eye Institute (NEI), a component of the National Institutes for Health (NIH), Age-Related Macular Degeneration (AMD) is the leading cause of severe vision loss in people aged 60 and older. "Wet" AMD occurs when new, but abnormal, leaky blood vessels form under the central part of the retina, the macula. Leakage of blood and fluid raises the macula and destroys central vision.[4] Nearly 2 million American have a visual impairment as a result of this disease, and more than 7 million are at increased risk for vision loss.[5]

Lucentis was approved by the Food and Drug Administration (FDA) in 2006. The clinical trials, upon which FDA based its approval, showed that Lucentis stabilizes and in some cases improves vision for people with "wet" AMD.[6] Previous treatments for "wet" AMD, including the drug Macugen and an expensive laser procedure, did not improve a patient's vision.

Lucentis' manufacturer, Genentech Inc., also produces Avastin, a drug approved by the FDA in 2004 for the treatment of advanced colorectal cancer. Avastin is closely related to Lucentis and is used off-label to treat AMD. Similar to Lucentis, Avastin works by blocking formation of abnormal blood vessels.[7] Off-label prescribing of FDA-approved drugs is a common practice among physicians, and once FDA has approved a drug for one use, physicians can choose to prescribe the drug for another (unapproved) use for his or her patients. Lucentis and Avastin are injected directly into the vitreous (the gel-like filling inside the eye) in a physician's office, but there is a significant price differential as Lucentis costs up to $2,000 per injection and Avastin can be less than $50 per dose, depending upon how it is billed by the physician. A two year course of therapy with Lucentis may cost as much as $48,000.

While Avastin is not FDA approved for ophthalmic use, the recent, one-year published results of the NEI-sponsored randomized clinical trial comparing Lucentis and Avastin in over 1,100 patients, did not detect a statistically significant difference in the effectiveness of these two drugs

[4] http://www.nei.nih.gov/health/maculardegen/armd_facts.asp#more
[5] http://www.nei.nih.gov/news/pressreleases/022208.asp
[6] ibid
[7] ibid

in the treatment of AMD.[8] Medicare will cover Lucentis injections as in-office procedures, but unless a person carries secondary insurance the co-payment may be as high as $400 per treatment. Medicare also covers treatments with Avastin through off-label prescribing, as described above, with a copayment of less than $20.

Conclusion

CMS continues to operate the Part B and D programs consistent with the statute and governing regulations. Prescription drugs, both those covered by Medicare Part B and Part D, account for a large portion of Medicare spending, and we are working to make sure that we are paying appropriately for drugs. We plan to continue monitoring payment for and access to Part B drugs. CMS and other agencies within HHS are continuing to work with all interested parties to ensure that patients receive appropriate and high quality care. We look forward to continuing to work with Congress on our ongoing efforts to preserve and protect Medicare for future generations. I look forward to answering any questions you may have.

[8] http://www.nei.nih.gov/news/pressreleases/042811.asp

Effect of Generic Competition on ASP Pricing for High Volume Part B Drugs

Although many of the high dollar volume drugs and biologicals that are paid under Medicare part B are single source (branded) and their ASPs are not influenced by generic competition, when generic competition occurs, the decrease in ASP can be substantial. The table below illustrates the actual decreases in ASP for several "top 50" ASP drugs, four quarters after the introduction of a generic counterpart.

Drug	Common Use	Allowed Charges Year Prior to Generic Counterpart	Change in Price (by quarter) compared to Allowed Charges Prior to Introduction of Generic Counterpart				Comment
			1st qtr price change (%)	2nd qtr price change (%)	3rd qtr price change (%)	4th qtr price change (%)	
ELOXATIN	Treat colorectal cancer	$326 million	-22%	-30%	-54%	-52%	ASP has rebounded to baseline due to withdrawal of generics (patent litigation agreement)
CAMPTOSAR	Treat colorectal cancer	$124 million	-41%	-71%	-83%	-86%	ASP has continued to fall; currently less than 10% of baseline
CELLCEPT	Oral immunosuppressant	$180 million	-28%	-24%	-45%	-61%	
PROGRAF	Oral immunosuppressant	$256 million	-10%	-18%	-18%	-19%	ASP has continued to fall; currently 30% of baseline
PULMICORT RESPULES	Nebulized asthma treatment	$267 million	-24%	-33%	-23%	-35%	

- The "Allowed Charges" column reflects the impact of both price and utilization on Medicare spending, while the "Change in Price" columns reflect changes to price only.
- The price drop associated with Camptosar is unusually high. No definitive cause for this price drop has been identified, but may be linked to the number of generics in the marketplace.
- Cellcept and Prograf payments are made to pharmacies.
- Pulmicort is dispensed by pharmacies/DME suppliers.
- No biologicals are on this list. Price decreases for biologicals/biosimilars, once they become available on the market, may be of lesser magnitude because manufacturing facilities for biologicals are believed to be much more expensive to build and operate than facilities that make chemical-based drugs.