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November 15, 2016

The Connecticut Health Care Cabinet
Program Management Office
PO Box 1543
Hartford, CT 06144

Via Electronic Mail

Re: Study of Cost Containment Models: Pharmacy Strategies

Dear Governor Wyman, Director Schaefer, and the Members of the Connecticut Health Care Cabinet:

Thank you for the opportunity to submit comments on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding your recent study and proposals addressing health care cost containment. PhRMA represents the country's leading innovative biopharmaceutical research companies. Our members are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. New medicines are an integral part of the health care system, providing doctors and patients with safe and effective treatment options, and improving quality of life. PhRMA's members spent nearly $59 billion in 2015 to research and develop medicines. In addition, the innovative biopharmaceutical industry contributes significantly to Connecticut's Medicaid prescription drug spend by providing nearly $556.7 million in rebates to the state in 2015.

Although we believe that many of the proposals suggested may have difficulty navigating current federal and state law and regulations, these comments will focus on the proposals that have a direct impact on innovative biopharmaceutical manufacturers. Further, we note that the legislature has passed legislation to study drug prices and we look forward to working with them as they begin their study.

Strategies to better understand drug pricing through the enactment of legislation

First, PhRMA opposes disclosing perceived components of drug pricing to the Attorney General because 1) such disclosure does not account for a medicine's value to patients and society and such disclosure is a precursor to price controls 2) such disclosure will not help a patient understand their price at the pharmacy counter which is set by the insurer and 3) list prices are a required starting point for negotiating a drug's net price and do not reflect trends in net pricing, the true price paid by the purchaser.

Proposals requiring the disclosure of perceived price components single out the biopharmaceutical industry, but in reality, there are a variety of stakeholders involved in determining what consumers ultimately pay for a medicine including insurers, pharmacy benefit managers, wholesalers, and government agencies like Medicaid. The important role that these entities play in setting drug prices and in drug coverage is overlooked by this proposal.

The Proposal Also Does Not Consider the Value the Biopharmaceutical Industry Brings to the Healthcare System.

It is important to remember that these advances are also helping to control health care spending. Greater patient access to prescription medicines means less doctor visits, fewer hospital stays and a decrease in costly medical procedures, all of which translate into lower health care costs overall.

Disclosure of Proprietary Information Will Not Help Patients

The reporting requirements in the proposal would drive up administrative costs, disclose proprietary information, and would in no way benefit patients. This proposal does nothing to address how much consumers ultimately pay for a medicine, an amount determined by insurers, not biopharmaceutical companies. Data shows that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need, far more than other health care services covered by an enrollee's health plan. This is contrary to the purpose of insurance—to spread the costs of health care utilization so that patients can access affordable needed care.

For example, today a patient pays only about 5% for out-of-pocket hospital costs but 20% or more for their medicines, typically. Insurers are also increasing utilization management techniques to aggressively restrict a patient's access to medicine.

Requiring Disclosure of Proprietary Information Could Harm Competition

The proposal would require biopharmaceutical manufacturers to reveal a significant amount of proprietary and trade secret information related to specific pricing, sales and marketing costs, and research and development (R&D) information to the state. In many cases, this information is highly confidential because it helps companies compete, and contracts often prohibit companies from disclosing it.

The biopharmaceutical industry is one of the most heavily regulated industries in the U.S. Companies already report extensive information on costs, sales, clinical trials, and total R&D expenditures. Requiring information on production and distribution costs for individual products may not be feasible as R&D is long term and manufacturers pursue research efforts that include many failures before the development of one FDA approved drug. Accounting for these related discovery costs could be nearly impossible. Further, neither HHS nor the FDA is permitted to disclose this type of information, even if requested.

Disclosing such proprietary information, even in the aggregate only chills the ability of insurers and PBMs to negotiate drug pricing. In fact, the Federal Trade Commission has indicated that disclosure of proprietary information would not lead to lower prices but would likely lead to increased prices. Simply put, revealing competitors' pricing and discount information removes incentives to provide discounts in the marketplace. In a letter to the New York legislature in 2009, the Federal Trade Commission's (FTC) Office of Policy and Planning, Bureau of Competition and Bureau of Economics cautioned that disclosure of similar information would jeopardize the competitive market and remove incentives to provide discounts and additional rebates and "...may increase pharmaceutical prices".

Many Factors Impact the Price of Medicines

The calculations behind drug pricing are complex but include some of the following factors:

- Prevalence of the disease and current and projected value of treatment to patients, society, and the health care system.
- Severity and complexity of the disease and impact on patient quality-of-life and mortality
- Capital costs, e.g., specialized facilities; manufacturing, packaging & shipping costs and infrastructure to ensure integrity of supply chain.
- Research and development costs, e.g., successes and failures across therapeutic areas and over time and need to ensure sufficient returns for future research and development investment.
- Competitive landscape and patient benefits versus existing therapies.
- Degree to which drug changes medical practice e.g., prevents other more costly medical procedures.
- Expected government and private discounts and rebates and utilization management procedures.

When considering the potential correlation of increased prices with increases in drug spending, it is imperative to account for the rebates and discounts that are commonly given by manufacturers on drug purchases after the initial acquisition of medicines, as these price concessions significantly lower the net prices of drugs. Specifically, the IMS-sourced information provided that, "Net of rebates and discounts, prices for branded drugs on the market for at least two years grew by 5.5% from 2013 to 2014, less than the net 6.8% growth rate from 2012 to 2013." IMS has refined its numbers recently and reports that net drug prices increased 4.9% in 2013, 5.1% in 2014, and 2.8% in 2015.

Strategies to maximize state purchasing and regulatory powers to reduce pharmaceutical costs

PhRMA opposes efforts to include Medicaid populations in aggregate purchasing programs that include other state programs, or any other private or public agency, because it could jeopardize the health of vulnerable patients and also result in higher numbers of uninsured residents. PhRMA notes that Connecticut is one of the best states in the country with regards to its aggressive management of its preferred drug list and the proposals to aggregate drug purchasing in Connecticut will face many federal hurdles and likely not achieve the savings envisioned by these proposals.

First, the Medicare program, the Medicaid and Medicaid expansion programs, and plans offered through Access Health CT all provide drug benefits, as required by state and federal law. Indeed, federal law specifically defines that the drug benefit must be made available to beneficiaries in all of these programs. Thus, these benefits would have to be severed, which might not be possible under federal law, to purchase prescription drugs across programs. Many of the managed care organizations already providing Medicare Advantage, Medicaid, and exchange plan benefits contract with pharmacy benefit managers with much greater purchasing power than the Connecticut agencies noted would have.

It is important to note that there is no federal authority for anyone to waive the benefits and protections of the Medicare or Medicaid programs, including the drug benefit requirements.[1] Further, **Any attempt to combine Medicaid with other programs requires a federal waiver.** Approval is not likely because there are well-established limitations for combining the federally-funded Medicaid program with programs funded exclusively by a state. Specifically, the Centers for Medicare and

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[1] Social Security Act § 1860D-1 – 1860D-4; Social Security Act § 1927.

Medicaid Services (CMS) can approve such a combination only if it is in the "best interest" of Medicaid. As established by court precedent, this generally means that Medicaid patients must be likely to benefit by combining the non-Medicaid population with Medicaid to negotiate prices (i.e., preventing the non-Medicaid population from spending down to Medicaid eligibility too quickly based on their drug expenses). This criterion cannot be met with respect to almost all other state program beneficiaries.

State as a regulator

With respect to California Proposition 61, PhRMA is glad that voters recognized the flaws of Prop 61 and understood the devastating consequences it could have on veterans and patients across California. Conversations about the cost of medicines are important, but Prop 61's flawed policy was not the answer to the challenges people face accessing their medicines.

Proposition 61 was opposed by a broad coalition of 200 organizations representing patient advocates, doctors, clinics, veterans, businesses, labor unions and many others who warn this deceptive, deeply-flawed scheme would be bad for patients, harmful for veterans and expensive for taxpayers.

California's misleading 2016 ballot initiative proposed a "price ceiling" for state-purchased drugs, tied to the price paid by the US Department of Veterans Affairs (VA), which is unworkable and unenforceable. Representatives of the VA and the US General Accounting Office (GAO)[2] have warned that a mandatory extension of VA contract pricing to other sizable populations, including state government purchasers, could undermine the VA's ability to obtain favorable pricing for drugs and the continued availability of drug products to the VA. Analysis of similar past proposals shows that passage of this flawed California measure could have significantly increased VA and Department of Defense (DOD) prescription drug prices. This measure could have resulted in higher prescription drug copays and reduced access to medicines for the over 21 million veterans nationwide that served our country in uniform.

Previous attempts to extend VA pricing to other groups were curtailed over concerns that prescription drug prices for the VA would increase. The VA and drug manufacturers negotiate special discounts for the benefit of veterans, retirees, active duty military and their families in recognition and appreciation of their dedicated service to our country. Under federal law, drug manufacturers extend discounts to the VA and DOD for innovative drugs and may also negotiate additional discounts for drugs to be included on the VA and DOD formularies.[3] These discounted prices are intended to support and assist our nation's veterans and military personnel. They would not be sustainable if applied to additional programs in California or other states.

In fact, the VA and the GAO have, on multiple occasions, warned that extending VA pricing to other sizable health care programs could undermine these special price considerations provided to those who serve our country. After enactment of the 1990 Omnibus Budget Reconciliation Act (OBRA), which factored VA pricing into state Medicaid rebate calculations, the GAO found that VA and DOD prescription drug costs increased by tens of millions of dollars in one year.[4] That requirement was later repealed. In the mid 1990's, Congress considered extending the VA's Federal Supply Schedule (FSS)

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[2] Now renamed the "Government Accountability Office."
[3] These discounts are also extended to the Coast Guard and Public Health Service.
[4] US General Accounting Office, "Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions." Page 16, September 18, 1991 http://gao.gov/assets/220/214927.pdf.

prices for drugs to state and local governments. The VA analyzed the potential impact and warned that such a proposal could increase its drug spending by about $250 million annually, in 1990 dollars. In 2000, the GAO examined the impact of expanding VA prices to Medicare, and similarly warned against such expansion, stating: "[The policy] could also raise the prices paid by private and federal purchasers, as increases in the prices manufacturers charged their best customers would, in turn, increase FSS prices."[5]

Higher prescription drug costs for the VA and DOD could translate to higher co-pays and reduced access to medicines for veterans, active duty military personnel and their families, and retirees. As part of the 2016 National Defense Authorization Act, Congress voted to increase co-pays that military retirees and dependents of active duty military pay out of pocket by 25%. If the ballot measures in CA and OH had passed, and VA and DOD drug costs went up, we could expect added pressure to increase prescription drug co-pays that veterans, military retirees and dependents of active duty military have to pay out of pocket. Alternatively, the VA and DOD could deal with higher drug costs by deciding to omit certain drugs from their formularies – further limiting veterans, military personnel, and retiree access to needed medications.

Regulating the Biopharmaceutical Industry as a Utility

The innovative biopharmaceutical industry invests significant research and development and takes on much risk to bring a medicine to market. According to Tufts University, it takes 10 years and $2.6 billion to bring a medicine through the approval process. Only 12 percent of drug candidates that enter clinical trials receive FDA approval.

While innovative biopharmaceutical companies are awarded with limited patents to reward their significant discoveries and associated financial risk, it is important to note that medicines are the *only* part of the healthcare system where costs decrease over time for patients and states. When brand name medicines face brand competition within a therapeutic class or when a brand's patent expires and generic drugs immediately enter the market, prices drop, often significantly. Today, nearly nine out of ten prescriptions are filled with a generic medicines that often cost pennies on the dollar, saving money for both patients and the healthcare system overall—we do not see savings like this anywhere else in the healthcare system.

Efforts to impart price controls on innovative manufacturers could chill the research and develop of new medicines by taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce Connecticut patients' access to medicines as is seen abroad.

Strategies to optimize safe and effective use of medications

We are encouraged by the Cabinet's attention to proposals that would optimize adherence to medications. Medicines provide great value to patients and society by saving and extending lives and preventing unnecessary hospitalizations and other costly health care services. The U.S. health care system could save $213 billion annually if medicines were used properly. A substantial body of evidence demonstrates that better use of prescription medicines reduces spending on other medical care. For

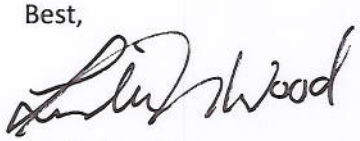
[5] US General Accounting Office, "Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes." Pages 17-18, August 7, 2000 http://www.gao.gov/assets/240/230510.pdf.

example, an article in *Health Affairs* found that just an extra $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated $3 to $10 in savings on emergency room visits and inpatient hospitalizations.

Notably, the Congressional Budget Office has acknowledged that increased use of medicines among Medicare beneficiaries decreased other medical spending. Researchers have found similar patterns across Medicaid populations. For example, research has shown that a 1% increase in prescription drug utilization decreases inpatient Medicaid costs by as much as 0.41%.

Thank you again for the opportunity to comment on these proposals and we look forward to working with you on the important issue of healthcare cost containment.

Best,



Leslie Wood

Biopharmaceutical Sector Impact on Connecticut's Economy

The biopharmaceutical sector is committed to bringing new treatments and cures to patients. This commitment to innovation supports high-quality jobs and is a vital part of every state's economy and our global economic competitiveness.

The biopharmaceutical sector directly accounted for 12,573 jobs in Connecticut in 2014, and supported another 48,864 jobs in Connecticut for a total of 61,437 jobs. These additional jobs were with vendors and suppliers to the biopharmaceutical sector and with businesses that serve its employees, in sectors ranging from transportation and construction to health care and IT.

Biopharmaceutical Sector Supported Jobs in Connecticut

12,573 Direct Sector Jobs

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48,864 Other Jobs Supported by the Sector

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61,437 Total Jobs Supported by the Biopharmaceutical Sector in Connecticut

Types of Direct Biopharmaceutical Sector Jobs in Connecticut

14%	Life Physical and Social Science	10%	Business and Financial Operations
15%	Office and Administrative Support	7%	Sales and Related
15%	Production	7%	Computer and Mathematical
12%	Management	4%	Transportation and Material Moving
8%	Architecture and Engineering	9%	Other*

Total wages and benefits paid to Connecticut's workers in jobs supported by the biopharmaceutical industry amounted to **$5.2B in 2014**, resulting in an estimated **$1.3B in tax revenue** for the state and federal government.

Taxes Paid by Workers in Jobs Supported by Biopharmaceutical Sector in Connecticut

Federal Taxes Paid	$1.1B
State Taxes Paid	$175.9M
Total Taxes Paid	**$1.3B**

Average Compensation per Employee in Connecticut

$157,577
Per Employee in Direct Jobs with the Biopharmaceutical Sector

$69,744
Per Employee Across All Connecticut Jobs

The biopharmaceutical sector's economic output represents the value of the goods and services produced by the sector. In 2014, the biopharmaceutical sector directly generated **$8.2B in economic output** in Connecticut and **supported another $9.8B** through the sector's vendors and suppliers and through the economic activity of its workforce.

Biopharmaceutical Sector Output in Connecticut

Direct Economic Output:	$8.2B
Indirect Economic Output	$9.8B
Total Output Supported by Biopharmaceutical Sector	**$18.0B**

Economic Output per Employee in Connecticut

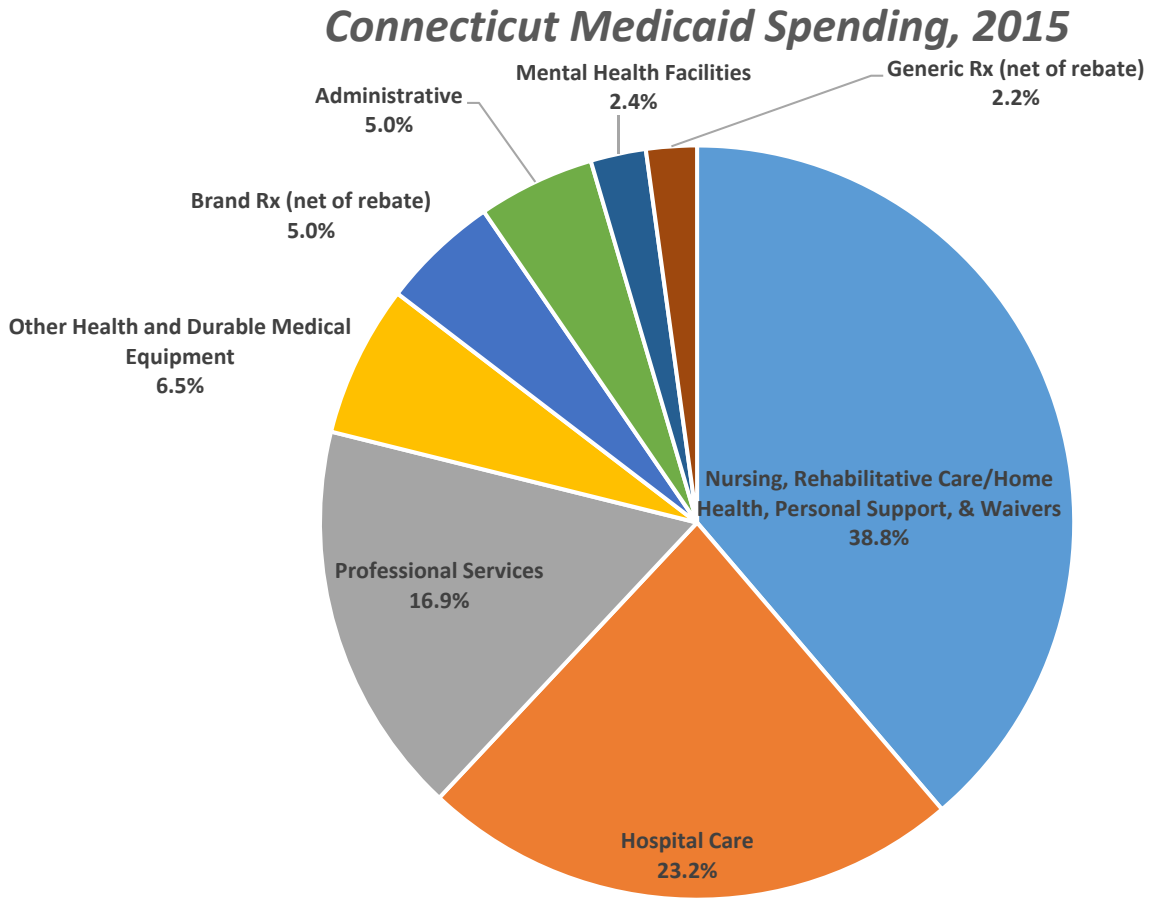
$652,035
Per Employee in Direct Biopharmaceutical Sector Jobs

$184,235
Per Employee Across All STATE Job Sectors

**Other occupations include areas such as Installation, Maintenance, & Repair, Healthcare Practitioners, Arts, Design, & Media, and Building & Grounds Maintenance, among others.*

Source: TEConomy Partners, The Economic Impact of the Biopharmaceutical Industry: U.S. and State Estimates, Report prepared for PhRMA, May 2016.

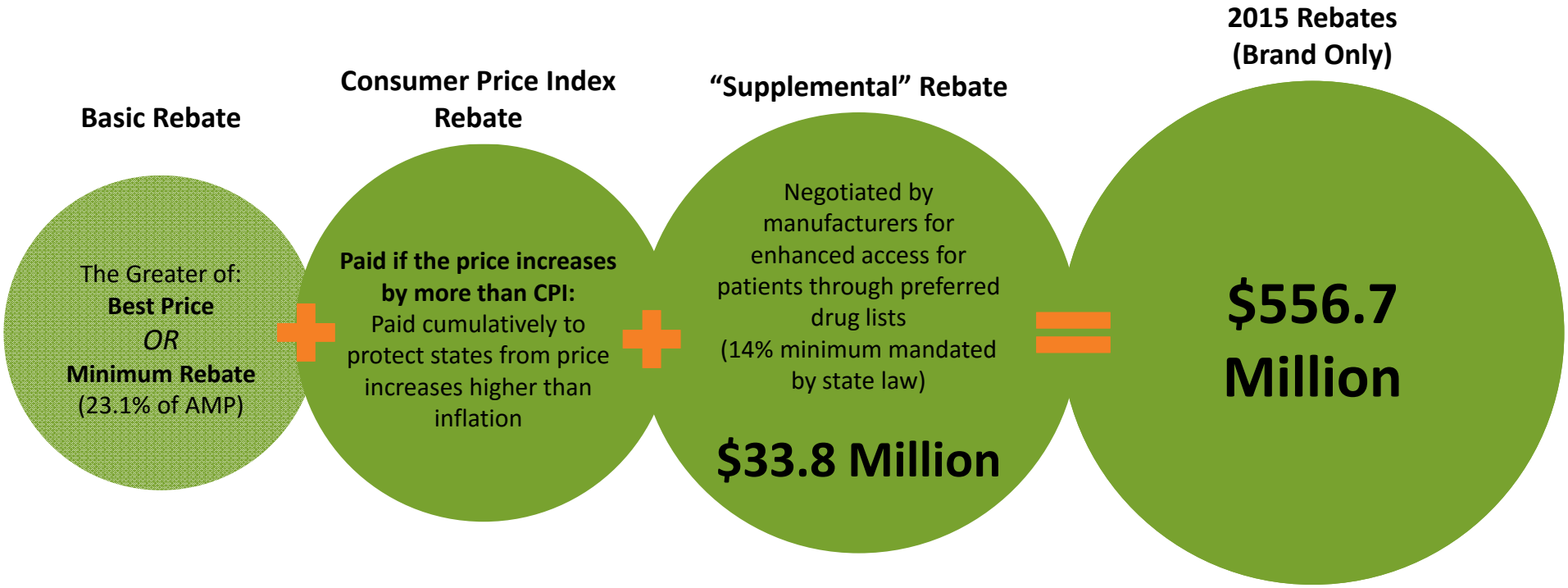
Retail Spending on Prescription Medicines Is a Small Share of Total CT Medicaid Spending



How the Medicaid Drug Rebate Works

FOR BRAND DRUGS IN CONNECTICUT

To ensure coverage of prescription medicines for Medicaid enrollees, under Federal law the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to provide rebates in exchange for Medicaid coverage of their drugs.



AMP – Average Manufacturer Price
Best Price – Lowest price drug sold to any non-government purchaser excluding certain sales (VA, Part D and 340B)