All Foam, No Beer: Broad Uptake of Value-Based Pricing for Prescription Drugs Unlikely Without Serious Legislative Change

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Introduction

On November 20, 2015, the U.S. Department of Health and Human Services convened a “Pharmaceutical Forum: Innovation, Access, Affordability and Better Health” in Washington, D.C. to address the issue of value-based pricing. Although widely touted as a critical information exchange to launch value-based pricing as a new paradigm for prescription drugs, the conference instead focused on many of the larger pricing trends affecting prescription drugs in the American market. With the exception of one dedicated session entitled “Value-based and Outcome Based Pharmaceutical Purchasing Programs” at the end of the day, and several references by Dr. Mark McClellan during a morning panel, very little was actually said about value-based pricing, and how such models could be expanded in both private payer and government (Medicare and Medicaid) programs. More importantly, there was virtually no discussion of the structural factors that limit the adoption of value-based pricing as a viable tool for public and private payers.

As is explained below, policymakers to date have failed to recognize that the principal reasons value-based pricing has not taken hold in both commercial and government markets are the Medicaid and Medicare programs’ legal and regulatory structures. More specifically, application of “Best Price” principles (in Medicaid and 340B) and Medicare Part B “Average Sales Price” (or ASP) requirements as they are currently constructed create an artificial floor prohibiting true innovation in drug pricing. And until regulators acknowledge this floor, and address it, value-based pricing is unlikely to expand in the United States market.

What Is ‘Value-based Pricing’?

There is no agreed-upon definition of what “value-based” pricing actually is in the prescription drug and biologicals context. At its core, value-based pricing is the practice of making drug prices contingent on clinical outcomes, either by extending discounts on drugs that do not perform, or charging a premium for drugs that do. A recent survey by IMS Consulting identified...
the preferred definition as “the ratio of benefits to cost” or value = benefit/cost, with benefit defined as “improvement in efficacy versus standard or care.” The American Society of Clinical Oncology (ASCO) has developed a definition of “net health benefit” pricing model, setting recommended prices for cancer drugs based upon clinical benefit, toxicity, and numerous other factors. In contrast, the Center for American Progress has articulated a model in which new therapies would be paid at rates similar to older therapies, but would receive a supplemental payment if they proved greater efficacy than their older counterparts.

In yet another model, researchers at 3M Health Systems have developed a model based upon overall care cost reduction, valuing new medications not only on the basis of direct health care costs avoided, but based upon overall systemic savings from future hospitalizations and other care costs. And most recently, Dr. Peter Bach of Memorial Sloan Kettering has developed the “Drug Abacus,” which allows providers to calculate what the cost of a drug should be based upon factors including the cost of development, benefit to patients, impact on the public health burden, side effects, novelty of mechanism, and whether the treatment is for a rare disease.

The numerous definitions suggest that policymakers (and market participants like drug manufacturers and payors) have not yet arrived at a clear definition for what a value-based arrangement is. One element that is inherent in each of the definitions, however, is that the net price of a drug or biologic is dependent on how it actually performs in patient care. And as will be seen immediately below, the few value-based contracting arrangements that have actually been entered into in the United States have each used this metric as the basis for their measure.

Recent Examples of Value-Based Pricing

Notwithstanding the challenges explained above, there are a few publicly disclosed examples of value-based drug pricing arrangements in the United States. Most recently, in November 2015, Amgen announced an agreement with Harvard Pilgrim to set reimbursement for Repatha, a new PCSK9 inhibitor developed to reduce so-called “bad cholesterol” (or LDL-C), based upon the value the drug delivered in patients. According to media reports, in exchange for value-based reimbursement that is predicated upon both (i) patients meeting LDL-C reduction levels equivalent to the clinical trial outcomes, and (ii) patients taking no more than a set number of the medication in a prescribed period, Harvard Pilgrim agreed to provide Repatha unique formulation positioning.

Similar types of arrangements have existed in the past. For example, in 2009 Merck agreed to a value-based arrangement with Cigna for Januvia and Janumet, tying drug discounts to formulary placement based upon how well individuals with Type 2 diabetes were able to control blood sugar using the respective drugs. In that same year, Procter & Gamble (now Sanofi) agreed to reimburse Health Alliance for medical costs to treat covered non-spinal, osteoporosis-related fractures in post-menopausal members taking drug prior to fracture by proportionally reducing Health Alliance’s cost of purchasing Actonel. Yet, these examples have been few and far between, particularly when compared with European value-based pricing arrangements. In the United States, the pricing model is very rarely used.

Legal Barriers

There are several legal barriers, principally affecting manufacturers, that limit adoption of value-based pricing programs. These barriers include Medicaid Best Price, 340B pricing, Medicare ASP, and Fraud and Abuse (anti-kickback) concerns.

a. Medicaid Best Price. The Omnibus Budget Reconciliation Act of 1990 created the Medicaid Drug Rebate Program to reduce state prescription drug costs. Under the Act, manufacturers are required to pay quarterly rebates to state Medicaid agencies to have their drugs covered by state Medicaid programs. As part of this compact, under section 1927(b)(3) of the Social Security Act, manufacturers must provide CMS with the Average Manufacturer Price (“AMP”) for each of its National Drug Codes (“NDCs”) on a monthly and quarterly basis. Manufacturers must also provide CMS with the “Best Price” for each innovator NDC every quarter – the lowest price at which they sold any single unit of product to a commercial purchaser or payor. Note that Best Price is not an average: it is set by the single lowest price obtained in the quarter, and can be set by a single sale to a single customer. CMS uses AMP and Best Price to calculate a unit rebate amount (“URA”) every quarter for each drug. The

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4 S. Abedi, The Payer Perspective, How a Broader “Value” Understanding Can Benefit Brand Teams, Pharmaceutical Executive (December 2015) at 40. Payers were surveyed to identify preferred definitions. The IMS Survey also evaluated benefit definitions of “reductions in mortality,” “safety improvements versus standard of care,” and “level of satisfaction with existing treatment.”


URA is the payment manufacturers must make to state Medicaid programs across the country for each unit of drug prescribed to a Medicaid patient. A key portion of the URA for innovator drugs is the “basic rebate:” the greater of (i) 23.1% of AMP or (ii) AMP minus Best Price. For this reason, manufacturers are loath to offer discounts that will set an active Best Price: any sale below 76.9% of AMP will create incrementally more Medicaid rebate liability.

A significant reduction in the price of a covered drug therapy due to the trigger of a value-based discount (for example, if a patient uses more than the label indicated amount of doses at a fixed cost per treatment, or if a drug is not successful in a given patient) could, even for one dose sold, trigger significant increases in rebate payments due to the Medicaid Best Price rule. Absent a very clearly articulated policy exemption, the current Medicaid Drug Rebate Program creates a practical floor (at 76.9% of AMP) below which prices cannot drop without incurring additional rebate liability—especially for those products with a significant Medicaid market—and damps manufacturers’ ability to implement innovative pricing models that could drive increased competition and price reduction in both the commercial and public sectors.

b. 340B Pricing. The Veterans Health Care Act of 1992 established section 340B of the Public Health Service Act, which requires manufacturers to provide discounted outpatient drugs to thousands of eligible health care entities, known as covered entities, as a condition of Medicaid coverage. The statute requires manufacturers in the Medicaid program to charge eligible entities a price that does not exceed the “340B ceiling price,” set at the quarterly AMP minus the URA. Thus, again, given the potential to increase URA through the setting of a low Best Price, manufacturers’ 340B obligations serve as a brake on the adoption of value-based pricing arrangements.

c. Part B ASP Pricing. The Medicare Part B Program is a reimbursement, as opposed to discount, program (i.e., there are currently no mandatory Medicare Part B discounts or rebates permitted by the Medicare statute). Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act to establish the use of the ASP methodology for reimbursement of Medicare Part B covered drugs and biologicals. ASP is the volume-weighted average manufacturer sales price net of all rebates, discounts, and other price concessions to domestic purchasers, excluding sales that are exempt from Medicaid Best Price (again, under current law, almost every commercial sale is therefore to be included in ASP).

12 23.1% is known as the “minimum rebate percentage,” and it applies to most innovator drugs. A second part of the innovator URA is the additional rebate, which acts as a brake on manufacturers’ ability to increase prices faster than inflation. The additional rebate is the principal driver of Medicaid rebate liability in older innovator products.

13 Allocation of price concessions using a “bundled arrangement” mechanism could alleviate this concern, but CMS’s guidance regarding “bundled arrangements” does not address value-based contracting with sufficient specificity to remove the Best Price risk entirely. For instance, one that would specifically exempt from Best Price discounts provided in a bona fide value-based contract arrangement.

Because sales under a value-based purchasing agreement risk having certain sales priced at very low rates, they risk dragging down the ASP for the product, and therefore reducing the amount at which doctors are reimbursted by the Medicare Part B program. Any reduction to ASP runs the risk that doctors will be reimbursted less for the drug than they paid to acquire it, which can be devastating to the commercial viability of a physician-administered drug or biologic. For this reason, manufacturers of Part B products are simply commercially unable to enter into value-based arrangements without some protection of their ASP-based reimbursement.

d. Fraud and Abuse. The federal Anti-Kickback Statute is a criminal statute that prohibits the exchange of, or offer to exchange, anything of value, in an effort to induce (or reward) the referral of federal health care program business. It is unclear whether and how value-based purchasing arrangements fit within the limits of the Anti-Kickback Statute. For example, the pricing arrangement itself, which does not neatly fit into the rebate or discount model, may itself be considered by HHS OIG to be an improper inducement to stimulate utilization. Similarly, follow up testing and evaluation of medication health impacts may be an unlawful inducement if not appropriately structured. Given the statute’s broad scope, both Congress and the Office of Inspector General have excluded certain transactions from consideration. But, no such clarity exists for value-based purchasing agreements.

e. Other Considerations. Finally, there are a series of other considerations that must be evaluated. For example, value measurement criteria and even communication of agreements that are a part of certain value-based arrangements could implicate Food and Drug Administration “pre-approval marketing” or “off label marketing” concerns, leading to civil or criminal enforcement actions. Similarly, off label communications or uses could implicate coverage itself under the Part D program, which does not cover certain off label uses. Similarly, HIPAA privacy laws may limit the exchange of personal health information for purposes of implementing value-based agreements, inhibiting the transfer of needed information between participants in the value-based data chain.

f. The CMS Innovation Center. Some have suggested that the CMS Innovation Center could create a demonstration program that could avoid most, if not all, of the legal barriers described above. However, the Center for Medicare and Medicaid Innovation (CMMI) waiver authority created by section 3021 of the Affordable Care Act is restricted to the “requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(a)(2)(A)(ii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b),” SSA § 3021(d)(1).

15 Eli Lilly & Company, a drug manufacturer, and Anthem, a Health Plan, on January 29, 2016 together issued a Policy paper calling attention to this issue, and urging Congress and CMS to clarify the law. See http://thinkanthem.com/sites/default/files/ProjectIndy_ValueBasedContracting_1.29.15.pdf.

16 Lilly and Anthem also have recently spoken to this issue in a joint White Paper, addressing the conflict between the FDA drug approval cycle and the need for health plans and drug manufacturers to communicate about emerging new technologies. See http://thinkanthem.com/sites/default/files/ProjectIndy_FDACommunication_1.29.15_v2.pdf.
and those provisions do not include the Medicaid Best Price provisions. Thus, CMMI does not have the authority to create a program that could implement a value-based pricing arrangement.

**Practical Barriers**

While the above focuses on the legal barriers holding back meaningful value-based pricing, there are also significant practical barriers that need to be addressed. First, value-based pricing arrangements often face significant implementation costs, including monitoring health outcomes, utilization, and other metrics, which may negate the cost benefits of the arrangement in the first instance. Second, challenges to measuring health effects may preclude use of a value-based pricing arrangement. For example, while the effect of products such as PCSK9 cholesterol-lowering drugs are relatively easy to measure through regular cholesterol monitoring examinations, the efficacy of many cancer drugs, cardiac drugs and drugs in numerous other therapeutic classes is far more complex to evaluate. Third, in many cases, including the complex therapeutic classes noted above, there may not be a suitable data infrastructure available to actually determine utilization, efficacy, and outcomes. And finally, even if the legal and practical elements are aligned, the economic incentives of existing reimbursement models may not drive manufacturers, payers or beneficiaries to adopt value-based pricing arrangements.

**A Possible Solution**

The legal barriers described above are not new, and Congress, when faced with a similar challenge in 2003, found a solution which could be replicated today. More specifically, Congress faced precisely the same pricing and reimbursement problem when creating the Medicare Prescription Drug program (Part D) in 2003. The solution Congress developed was elegant and effective—exempt Part D drug prices from Medicaid Best Price. By doing so, Congress permitted manufacturers to negotiate deeper discounts and rebates with Part D prescription drug plans without having to navigate the impact of such actual pricing levels on Medicaid rebates, 340B prices and ASP reimbursement.

Similarly, HHS and the Congress can create a legislative pathway for “bona fide value-based pricing arrangements,” and exempt such prices from inclusion in Medicaid Best Price and ASP calculations. By both defining legitimate value-based pricing arrangements, and explicitly exempting such arrangements from Medicaid and Medicare constraints, Congress has the ability within reach to open markets to innovative pricing arrangements.

Defining the universe of exempt commercial arrangements would be more difficult than in Part D. Yet, we believe the creation of a set of carefully articulated commercial pricing arrangements exempt from Best Price (and therefore ASP) can be achieved, which would lift the most significant regulatory barrier to value-based pricing arrangements, open up a creative new era in pharmaceutical contracting, and preserve the integrity of the Medicaid, 340B and Medicare Part B regimes. (A corresponding anti-kickback safe harbor, and clarity of “off label” policy, would also further this goal.) Regulators and the Congress were able to achieve this result a decade ago, and should readily be able to do so again.

**Conclusion**

In his opening remarks at the November 2015 HHS Forum, Andy Slavitt, then-acting Administrator of CMS, noted:

“The truth is we don’t have enough public information on the effectiveness of new drugs in the real world or about prices and rebate structures. As a result, anecdotes—whether about pervasive generic price increases or other things—draw significant attention. And in order to avoid reacting to misinformation, we must increase the transparency of the information available about drug pricing and value. How do we make public the information that will allow us to understand prices and value? How do we educate the public on the cost of these medicines, the value chain, the measures of effectiveness? How do we create visibility into price increase? How do we help the public have an informed debate over the size of Federal and State expenditures or the unit costs or patient value created? We want ideas on the best way to take steps to improve transparency.”

Acting Administrator Slavitt was only partially correct. Unfortunately, he (and others) have failed to acknowledge that the real driver holding back meaningful value-based pricing initiatives is not the lack of information, but rather the fundamental pricing structure of the Medicare Part B, Medicaid and 340B programs. Given the impact of Medicaid Best Price and Medicare ASP pricing, and the spillover effect these statutory “floors” have on the ability of manufacturers to engage in true value-based pricing, there are more fundamental statutory problems to be addressed. Transparency would be helpful, but it is not the issue. Rather, CMS, and HHS, would be better served by addressing the statutory barriers that are the real problem.

Policymakers faced the issue before when setting up the Part D program, and solved the problem by exempting Part D Drug pricing from Medicaid Best Price constraints. A similar solution is needed now. Without it, both public and private payers are unlikely to have meaningful access to value-based pricing in the near future.

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17 Congress did not have to address the Part B ASP issue because, by definition, Part D drugs could not be covered in the Part B program. 42 U.S.C. 1860D-2(e)(2)(B).