

Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule

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Abstract In recent years, drug manufacturers and private payers have expressed interest in novel pricing models that more closely link a drug's price to its value. Indication-based pricing, outcome-based pricing, drug licenses, and drug mortgages have all been discussed as alternatives to paying strictly for volume. Manufacturers and payers have complained, however, that Medicaid's "best-price rule" inhibits their ability to enter into these new pricing arrangements. This article examines the best-price rule and assesses to what extent, if any, it might frustrate the goal of paying for value. We conclude that the best-price rule is not as serious a problem as it is sometimes made out to be but that it is also not simply a convenient excuse for refusing to try something new. The law here is complex, and moving to a pay-for-value model for drugs will require close coordination among manufacturers, payers, and regulators.

Keywords Medicaid, best-price rule, pharmaceutical pricing, value-based payment, outcome-based pricing

Even in today's polarized political landscape, a consensus has emerged: Americans deserve better value for their health care dollars. The focus on value sits well with liberals and conservatives, health insurers and pharmaceutical manufacturers, and a host of disparate stakeholder groups. All agree on the goal; the real debate is how best to achieve it.

Prescription drugs are a case in point. Drugs are sold on a price-per-dose basis. The more pills, milligrams, or milliliters a patient takes, the more the patient and the insurance company pay. That encourages manufacturers to market their drugs broadly, even for patients who are less likely to benefit from them. At the same time, physicians who receive a percentage of the

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dollar value of the drugs they administer may too readily prescribe those drugs. The result is that many patients receive little or no benefit from their prescription drugs—yet they pay precisely the same amount as those who do benefit.

To sever the link between sales volume and revenue, several alternatives to the price-per-dose model—including outcome-based pricing, indication-based pricing, drug licenses, and drug mortgages—have been proposed. But the practical barriers to these new models are formidable. Assessing a drug's value is exquisitely difficult and ethically fraught. Solid data on the real-world performance of drugs in subpopulations or for off-label uses are often lacking. Implementing and monitoring complex contractual arrangements will require large, ongoing investments, including the adoption of robust information technology systems that can link patient outcomes with drug prices (Neumann et al. 2011). Privacy concerns may inhibit providers from sharing granular data on patients with drug manufacturers.

The legal barriers are also significant. In particular, Medicaid's best-price rule may be the pharmaceutical industry's most commonly invoked objection (PhRMA 2016). By law, drug manufacturers cannot charge state Medicaid programs more than the "best price" that they offer for the drug in the private market. Under these novel pricing models, however, manufacturers may charge less when their drugs perform poorly—implying that the drug's "best price" is quite low. Drug manufacturers are reluctant to offer performance-based rebates that would cut so deeply into their Medicaid payments. The Centers for Medicare and Medicaid Services (CMS) is concerned enough about the problem that, in a July 2016 program notice, it encouraged drug manufacturers to seek the agency's guidance on whether and how their value-based purchasing arrangements interact with the best-price rule (CMS 2016).

A number of articles have flagged the best-price rule as a potential obstacle to novel pricing arrangements; typically, the rule is invoked as a monolithic barrier against the nebulous idea of "value-based" pricing. Yet no article has examined the rule in any detail (Gottlieb and Patel 2016; ICER 2015). To fill that gap, we explore how the best-price rule may or may not serve as an obstacle to different types of value-based contracting, how manufacturers and insurers can mitigate the rule's effects on contracting practices, and the possibility of developing contractual, regulatory, or legislative solutions that remove or mitigate the best-price rule as an obstacle.

The Medicaid Best-Price Rule

Medicaid is legally entitled to deep discounts off of typical private market prices for prescription drugs. For innovator drugs that were initially

marketed under new drug applications approved by the Food and Drug Administration (FDA), Medicaid is entitled to a minimum rebate of 23.1 percent off the average manufacturer price. However, if the lowest price available from the manufacturer is lower even than the postrebate price, Medicaid is entitled to that “best price.”

Under 42 U.S.C. § 1396r-8(c)(1)(C), *best price* is defined as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States,” “inclusive of cash discounts . . . and rebates.” But the statute goes on to exclude several large governmental purchasers from the best-price calculation. For instance, prices charged to the Department of Veterans Affairs (VA) are exempt from the rule, a significant exclusion in light of the lower prices the VA pays on many costly drugs. Prices charged for pharmaceuticals covered by Medicare Part D, including through Medicare Advantage plans, are also exempt (42 U.S.C. § 1396r-8(c)(1)(C)(i)(I)–(VI)). Discounts obtained by these purchasers need not be passed on to Medicaid.

In the abstract, the scope of the best-price rule is quite broad: if a pharmaceutical company wants to extend a large discount to a payer in any type of contracting arrangement, it must make that discount available to Medicaid as well. In practice, however, the rule is only triggered when a discount exceeds the mandatory statutory rebate of 23.1 percent, not by smaller discounts. The rule is also more likely to deter or reduce discounts on drugs with large Medicaid-eligible populations.

Types of Innovative Contracts and the Medicaid Best-Price Rule

Public and private payers have expressed interest in innovative models of pharmaceutical contracting that link price to value, not just volume. Does the best-price rule impede adoption of these new models, as drug manufacturers have claimed? If so, why and what can be done about it? To get traction on these questions, we identify and describe a number of these new models and their relationship to the best-price rule.

Indication-Specific Pricing

Drugs are often useful for many different indications or diseases. Sometimes these indications are very closely related to one another, such as the use of Keytruda to treat two different types of cancers that overexpress the same proteins. In other cases, the indications are quite distinct, such as

the use of Avastin to treat both cancer and macular degeneration. But the same drug may have different value when used to treat different diseases—and companies may want to charge or pay different prices for it as a result (ICER 2015).

CMS, however, determines a drug's "best price" for each drug, not each indication of the drug. Manufacturers may be reluctant to enter into indication-based contracts if the price for the cheapest indication becomes the best price for Medicaid purposes. To be clear, the rule does not prohibit companies from entering into such agreements, and at least one company's efforts to engage in indication-based pricing have been highly publicized (Express Scripts 2015). But the rule implicitly limits the price differential permitted between indications before the "discount" offered on the cheaper indication triggers the best-price rule.

At least two self-help strategies would allow manufacturers to mitigate the impact of the best-price rule, although the first may be incompletely responsive and the second may be socially wasteful. First, companies may enter into contracts that use weighted average pricing for multiple indications, rather than setting an individual price for each indication. Say that the manufacturer of a drug used to treat both cancer and macular degeneration wants to price the former indication at \$10 per unit and the latter at \$100 per unit (each dose in the treatment of macular degeneration requires much less of the drug by volume). Where an insurer knows that the drug is likely to be used roughly an equal number of times for the two indications across its patient population, the two companies may enter into a contract pricing the drug at \$55.

Because contracts are typically signed at the level of a networked insurer, rather than an individual physician or practice, a provider network containing both oncologists and ophthalmologists might enter into such an agreement, but they might not. Especially when the prices of indications are far apart or when patient populations are skewed (e.g., a privately insured population without many macular degeneration patients), it may be difficult to reach agreement over a single composite price. In addition, patients' out-of-pocket spending may be linked to the composite price, meaning that both cancer patients and those with macular generation would pay the same per ounce of the drug.

Second, companies may engage in product differentiation, turning one drug into two for best-price purposes. Consider Colcrys (colchicine), which FDA has approved for the treatment of both acute gout flares and familial Mediterranean fever. Although Colcrys is approved for multiple indications, its manufacturer sought approval only for a single drug product. As a

result, the FDA supplied Colcrlys with a single National Drug Code (NDC). Because it has just one NDC, it appears that the best-price rule would treat Colcrlys as one drug even though it has been approved for different indications. As a result, Colcrlys's best price is calculated without regard to whether it has been prescribed for gout flares or Mediterranean fever.

Contrast Colcrlys with sildenafil. Like Colcrlys, sildenafil has been approved for multiple indications. However, each indication has been approved for sale as a separate drug product, with Viagra indicated for erectile dysfunction and Revatio indicated for pulmonary arterial hypertension (although these products do contain different doses of sildenafil). Viagra and Revatio have separate NDC identifiers, and the best-price rule treats these as separate drugs. If indication-specific pricing is sufficiently financially attractive to pharmaceutical companies, they might devote resources to seeking new NDC approvals even when the medical rationale for doing so is thin or nonexistent.

Beyond these self-help strategies, CMS may have the regulatory authority to define *drug* as "indication" and avoid this problem entirely. As written, the best-price statute contains no definition of *drug*. The statute does, however, contain a series of cross-references to the Food, Drug, and Cosmetic Act and seems to understand the concept of "drug" in terms of FDA-approval status. In the FDA context, a drug is defined chiefly by its intended use, not by its chemical composition. When the FDA considers whether a drug is safe and effective, those terms are inseparable from the drug's intended use—a side-effect profile may be safe for one indication and not for another. In short, although it may be logistically simplest to equate *drug* and *product* through the mechanism of the NDC identifier, it is not obvious that defining *drug* for best-price purposes as equivalent to *product* is legally required.

CMS could issue a guidance document declaring its intention to apply the best-price rule to a "drug" as understood in the FDA context—a chemical compound approved for a particular indication. Although CMS could of course accomplish this same goal through formal rule making, the process is laborious and appears to be unnecessary. By defining *drug* with reference to the FDA definition, CMS would simply be explaining how it plans to interpret the Medicaid statute and its own regulations in calculating the best price for a given drug.

Such a guidance document not only would solve the Viagra/Colcrlys dilemma above but also might even create modest additional incentives for companies to seek FDA approval for new uses of old drugs. There are many

drugs like Colcryst, with multiple FDA-approved indications. But there are also many drugs whose secondary uses are not FDA approved, with large off-label markets. Scholars and policy makers have long recognized the difficulty in encouraging companies to invest in the study and approval of new uses for these drugs (Eisenberg 2005), with little if any practical results. To the extent that permitting indication-based pricing contracts is appealing to manufacturers, permitting them only for FDA-approved indications might provide a modest financial incentive for companies to invest in the FDA approval process.

Outcome-Based Pricing

Patients do not value drugs for their own sake; they value the health benefits that the drugs provide. But most people who are prescribed a drug never realize those benefits. That insight has prompted interest in a novel pricing model, variously referred to as “outcome-based pricing” and “pay for performance.”

Outcome-based pricing could be implemented as a simple rebate. A drug manufacturer might sell the drug at a given price but owe the rebate to the drug’s purchaser if it failed to confer a benefit—like patients getting a money-back guarantee. Alternatively, patients could pay a base rate for the drug with the obligation to make further payments only when they meet particular health milestones (e.g., remission for a cancer drug)—like companies getting a bonus for performing a job especially well.

However it is implemented, outcome-based pricing could promote value in at least three ways. First, drug manufacturers might tailor their marketing toward those patients who are most likely to respond to their drugs, reducing wasteful spending for patients who are unlikely to benefit. Second, outcome-based pricing might spur drug manufacturers to invest in research that identifies patient subpopulations most likely to respond to their drugs, and these findings would in turn allow for better targeting of costly drugs. Third, outcome-based pricing may appeal to a public that believes (justifiably or not) that it is unfair to ask a patient who does not benefit from a drug to pay as much as someone who does.

Outcome-based pricing has garnered some recent interest in the industry (see table 1). Amgen, for example, recently agreed to provide rebates to Harvard-Pilgrim Health Care if its lipid-lowering drug Repatha failed to hit cholesterol-reduction targets. Humana has at least 15 such contracts with pharmaceutical companies, although it has been less willing than other payers to divulge the specific products (Kelly 2016). Novartis has

Table 1 Selected List of Publicly Reported Value-Based Contracts in the United States: Outcome-Based Pricing Arrangements

Manufacturer(s)	Payer(s)	Drug (Indication)
Amgen	Cigna CVS Health Harvard Pilgrim	Repatha (cholesterol)
Sanofi Regeneron	Cigna	Praluent (cholesterol)
Amgen	Harvard Pilgrim	Enbrel (rheumatoid arthritis)
Eli Lilly	Harvard Pilgrim	Forteo (osteoporosis)
Eli Lilly	Harvard Pilgrim	Trulicity (diabetes)
Novartis	Aetna	Entresto (cardiovascular)
	Cigna	
	Harvard Pilgrim Humana	
Novartis	Humana	Gilenya (multiple sclerosis)
Merck	Aetna	Januvia and Janumet (oral diabetes drugs)
	Cigna	
P&G and Sanofi	Health Alliance Medical Plans	Actonel
AstraZeneca	Harvard Pilgrim	Brilinta (acute coronary disease)
AstraZeneca	Harvard Pilgrim	Bydureon (diabetes)

Notes: In addition to these experiments with outcome-based pricing, Express Scripts has launched its Oncology Care Value Program, an indication-based payment system for cancer drugs. Building an indication-based formulary is also part of CVS Health's strategy for 2017.

signed at least four outcomes-based contracts, with major payers—Aetna, Cigna, Humana, and Pilgrim—around Entresto, its heart failure drug (Herman 2016; Teichert 2016). Novartis will receive less than the full price of Entresto if it fails to reduce the proportion of readmissions for patients with congestive heart failure. And a white paper published by Lilly and Anthem (2016) extols the virtues of outcome-based pricing (Eli Lilly and Anthem).

Manufacturers, however, have expressed concern that the best-price rule inhibits their efforts to launch outcome-based pricing initiatives (CMS 2016). If a manufacturer pays a \$75 rebate on a \$100 drug that fails to work, the “best price” for that drug is \$25, not \$100. By the same token, if a drug manufacturer sells a drug for \$25 with the promise of \$75 in future payments if the drug is effective, \$25 is the drug’s “best price” as long as someone pays only that amount.

Could the “best price” somehow be treated as the average price for the drug, exclusive of any outcome-based payment? Absent a change to the

law, the argument would be difficult to sustain. With indication-based pricing, as we explain above, it is possible to argue that the same chemical compound is actually a different drug depending on the indication for which it is prescribed. That's not true for outcome-based pricing, where the same drug is differentially priced depending on whether it works.

Congress could always adjust the best-price rule to accommodate outcome-based pricing. In the meantime, however, drug manufacturers may have more room to contract around the best-price rule than they appreciate. Instead of granting a rebate if a drug fails to work for a particular patient, manufacturers can offer a rebate based on the performance of the drug across a patient population. To return to the earlier example, a drug manufacturer might sell a drug for \$100 but offer a rebate based on the drugs' performance across 1,000 patients. If the drug is 75 percent effective, for instance, the manufacturer might agree to offer a rebate of 25 percent, in which case the best price for the drugs sold to the 1,000 patients would be \$75. And because Medicaid, by statute, already obtains a rebate of 23.1 percent off of the average price, the Medicaid best-price rule would at most have only a small marginal effect on revenues. Manufacturers could further cap the amount of any population-wide rebate, thus setting a floor on the possible discount.

CMS may also have some regulatory flexibility. As it stands, CMS rules provide that "best price must be determined on a unit basis" (42 C.F.R. 477.506(e)(2)). But the Medicaid statute doesn't contain a "unit basis" requirement for best price; it is silent on the matter. Given that, CMS could perhaps amend its rules to enable the best price of a drug to be calculated with reference to a weighted average of the price that a manufacturer receives through an outcome-based pricing arrangement. CMS could also use rulemaking to clarify how manufacturers should calculate the best price given that the "real" price of the drug will not be known at the moment of sale and may not be known for some time.

Drug Licenses

Poor adherence to medication is a major problem, but the price-per-dose model penalizes patients who take their medicine on schedule. Monthly or annual pricing could eliminate this perverse incentive. Imagine that a patient prescribed a diabetes medication is charged a flat monthly fee and can then use as much of the medicine per month as the physician thinks is clinically warranted. Neither the patient nor the physician retains a financial incentive to skimp on the medication or to adulterate clinical decisions with financial motives.

From the standpoint of the best-price rule, however, drug licenses pose risks. If patients use a great deal of the drug on a monthly basis, or if physicians prescribe the drug in higher than expected quantities, the average unit price of the drug per patient may end up being lower than forecasted. If even a single patient uses more of the drug than estimated, the average price of the drug for that patient may set the best price of the drug for the entire Medicaid population.

The drug manufacturer could limit this risk by adopting strategies much like the ones proposed in the outcome-based pricing context. First, manufacturers might offer a license price based on a drug's average usage across a patient population, rather than its particular usage by individual patients. Second, the manufacturer could set a floor for the average price, limiting the possible discount to be applied for best-price purposes. This approach, however, might mitigate the benefits of a drug license by reverting to price per dose in some scenarios.

CMS's regulatory flexibility on drug licenses may also rise or fall with its flexibility on outcome-based pricing. It is the unit-price requirement in CMS's rules that creates the problem for drug licenses and the best-price rule, not the Medicaid statute itself. As such, CMS might be able to amend its rules to clarify that the unit price may be set on an average, population-wide basis.

Drug Mortgages

Drugs vary in when and how they deliver their benefits. This often has unfortunate consequences for pricing. For instance, new drugs can cure hepatitis C with an eight- to twelve-week course of treatment. But while the benefits of the cure accrue over a lifetime, the costs of the drugs must be recouped within a much shorter eight- to twelve-week window of treatment.

Drug companies have been roundly criticized for pricing these drugs highly, at \$500–1,000 per pill. Yet even the most skeptical observers—including the UK National Institute for Health and Care Excellence (2015)—have concluded that the lifetime benefits of the drugs outweigh their costs in several patient subpopulations. If these drugs had delivered the same clinical benefit to patients, commanded the same lifetime cost, and been taken daily for the rest of their lives, the “price per pill” would have fallen to levels that would have looked downright cheap. The current approach to financing drugs encourages pharmaceutical companies to develop drugs patients will take for the rest of their lives, rather than cures that provide far more benefit in the long term.

A “drug mortgage” has been proposed as a solution to this problem. Much like a home loan, a drug mortgage would spread out payments over time, enabling patients (or, more likely, their insurers) to avoid a large one-time payment for a drug that confers a lifetime of benefits. Drug mortgages make a great deal of sense for cures and other drugs that require only a short course of treatment but offer substantial health gains. Mortgages will be less helpful, however, for drugs that must be taken over an extended period to treat chronic conditions. Payments for those drugs are already spread out, leaving mortgages with little to do.

In our judgment, the best-price rule should pose no impediment to drug mortgages. A home’s price does not change when a buyer and seller enter into a long-term financing arrangement. The same holds true for a drug, even though the buyer can obtain the drug without making a large initial outlay. The drug’s price is simply the sum of the net present value of the future mortgage payments. To the extent there is confusion on that front, CMS should consider issuing guidance to clarify matters.

Drug mortgages do face other daunting legal obstacles. Who would, for example, be liable for the “mortgage payment”—the patient or the insurer? If the patient, would a drug mortgage survive a personal bankruptcy? How much would a drug company end up forfeiting as a result of defaults or other delayed payments? How much would this increase the market price of these mortgages? What does the law have to say about any of these issues? Compared to questions like these, the best-price rule is no obstacle at all.

CMS Authority

Beyond the tweaks to the best-price rule that we have discussed, regulators have one more potential tool in their arsenal. In the Affordable Care Act, Congress established the Center for Medicare and Medicaid Innovation (CMMI) and conferred on it extraordinary authority to waive statutory rules in order to experiment with different ways to pay for health care.

Could CMMI relax the best-price rule to foster novel pricing models? Only to some extent. According to 42 U.S.C. § 1115A(b), CMMI’s charge is to run demonstration projects to address “deficits in care” or “potentially avoidable expenditures” for Medicare and Medicaid beneficiaries. Although drug sales to Medicare Part D plans do not trigger the best-price rule, sales through Parts A and B (and sales to Medicare Advantage plans for drugs that would otherwise be covered under Parts A and B) are

considered in calculating the best price. CMMI could thus relax the best-price rule for drugs purchased through Medicare Parts A and B, if it determines that the adoption of a value-based purchasing model might reduce expenditures or improve quality. Although making this determination could be challenging—among other things, it would involve trading off expenditures between Medicare and Medicaid—it would be within CMMI’s authority.

Indeed, the success of future CMMI initiatives may depend in part on moderating the effect of the best-price rule. In phase 2 of its controversial demonstration project to change how it pays for drugs delivered in outpatient settings—the Part B demo—CMMI hoped to experiment with indication-based and outcome-based pricing for Medicare. Without a waiver of the best-price rule with respect to drugs under Parts A and B, drug manufacturers may be reluctant to enter into novel pricing arrangements with Medicare, including with Medicare Advantage plans, stifling the possibility of private-sector innovation.

At the same time, however, CMMI’s authority is limited. It cannot waive Medicaid rules in order to reduce private medical spending, as some have suggested (ICER 2015), unless it can also show that waiving those rules could improve quality or reduce spending for Medicare or Medicaid.

It is remotely possible that CMMI could make such a showing. Relaxing the best-price rule might, for example, encourage drug manufacturers and private payers to experiment with outcome-based pricing. If the approaches work for private payers, the pricing models could be adapted for public programs, whether through future CMMI demonstration projects, Medicaid waivers, or binding recommendations from the Independent Payment Advisory Board. Medicare and Medicaid would essentially “learn” from the private sector in much the same way that Medicare’s adoption of new pricing models has changed how private insurers pay for care.

But the link between private drug pricing and the public programs is much attenuated. It is hard to see how relaxing a price cap for Medicaid would save the program money in the short run. And the long-run possibility that Medicare or Medicaid might someday adopt novel pricing models does not suggest that a demonstration project waiving the best-price rule will itself yield lower expenditures. It instead establishes that future changes could yield programmatic savings.

We are thus dubious that regulators have the authority to waive the best-price rule for private payers (other than Medicare Advantage plans). Although CMS has recently indicated its willingness to communicate with pharmaceutical companies and insurers about the ways in which these

contracts may implicate the best-price rule, comprehensively eliminating the constraints that the best-price rule creates for private payers will require legislative action.

CMS may nonetheless have some flexibility on the margins. Recall that Medicaid will pay either a drug's best price or 23.1 percent off of the "average manufacturer price" (AMP), whichever is lower. Value-based contracts may affect not only a drug's best price but also the calculation of the AMP. At present, companies may be subject to substantial penalties if they miscalculate the AMP in reporting to CMS (42 U.S.C. § 1396r-8(b)(3)(C)), and the prospect of penalties likely discourages companies from engaging in more value-based contracting. CMS should therefore offer guidance to companies on how to calculate AMP in light of value-based pricing—and exercise its discretion to forgo enforcement actions against companies who misreport their AMP due to uncertainty in the law regarding value-based contracts. An exercise of enforcement discretion along these lines would not eliminate the obstacles to value-based contracts, but it could help if Congress declines to address the problem itself—as seems likely.

Conclusion

In our judgment, the best-price rule poses an impediment to some, but not all, of the novel pricing arrangements that are under discussion in the private sector. Where the best-price rule is an obstacle, however, drug manufacturers can often restructure their contracts to avoid or mitigate the best-price rule's impact. And even when the best-price rule does limit companies' ability to engage in the full range of innovative contracting arrangements, CMS may have some regulatory flexibility to address the problem. Among other things, it could issue guidance to clarify when pricing models raise best-price concerns, enable indication-based pricing by adjusting the unit-price requirement, exercise enforcement discretion with respect to the AMP, and relax the best-price rule for Medicare demonstration projects.

The best-price rule is thus not as serious a problem as drug manufacturers sometimes make it out to be. But it is also not simply a convenient excuse for refusing to try something new. The law here is complex, and fostering the adoption of new pricing models will require close coordination among manufacturers, payers, and regulators. CMS's recent openness to clarifying the effect of the best-price rule offers reason for cautious optimism that such coordination may be in the works. Perhaps we are on the cusp of a new era of paying for value in prescription drugs.

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