



The professional society for health economics and outcomes research

Improving healthcare decisions

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The Honorable Alex M. Azar II
Department of Health and Human Services
200 Independence Avenue, S.W.
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President-Elect

Nancy J. Devlin, PhD
Office of Health Economics
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Dear Mr. Azar:

Past President

Shelby D. Reed, RPh, PhD
Duke University
Durham, NC, USA

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is pleased to respond on behalf of its membership to the U.S. Department of Health and Human Services call for comments on “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.” We strongly agree that these are important issues to address with input from a wide variety of stakeholders, and thank the Department for this opportunity to provide our comments.

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ISPOR is a scientific and educational society with many of its members engaged in some aspect of health economics and outcomes research (HEOR) related to evaluation of pharmaceuticals. Our membership includes over 20,000 individuals across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government (including some HHS employees), and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

As you will see below, we have chosen to respond only to selected sections in your call for comments. We selected those areas and questions which we feel are best informed by the research and expertise of our disciplines and our membership. This response was formulated with the assistance of ISPOR’s most senior and representative Council, the Health Sciences Policy Council, and informed by a survey of our full membership. It was reviewed by and approved by our current President and myself.

ISPOR would be happy to answer any questions about our response, as well as to participate in any follow-up consultations on these issues.

Sincerely,

Nancy S. Berg
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Underpricing or Cost-Shifting (p.21)

There were several government reports in the 1990's that examined the issue of whether the Medicaid Best Price rule (BP) implemented by OBRA [1] in 1990 caused any cost-shifting of drug costs to non-Medicaid sectors [2-5]. Without summarizing them in detail, our view is that the evidence seems suggestive of the BP causing – or at least being associated with - a reduction in rebate levels, although it may not be conclusive. For example, CBO [4] found evidence that rebates decreased during the early years of the BP, but that finding was based on data that did not include pre-OBRA rebate levels. The other research did not find evidence of systematic differences in price changes for drugs before vs. after OBRA, although there were a few specific exceptions. A subsequent economic paper indicated that, in 2002, the top 200 prescribed drugs with larger Medicaid market shares had larger price increases relative to those with smaller Medicaid market shares [6], and a more recent report concluded that the evidence for the effects of Medicaid drug rebates on non-Medicaid sectors was “compelling” [7].

More recently, Sachs et al [8] clearly outlined how Medicaid BP considerations could affect a variety of innovative value-based contracting approaches, including indication-based pricing, outcome-based pricing, drug licenses, and drug mortgages. The concern is that if a drug's effective price is reduced in specific cases, e.g., for lower-priced indications, for cases where the drug was not effective, for high-volume users (under drug licenses), or due to deferred payments (drug mortgages), those specific cases may be seen as affecting the BP. If they did, some potentially efficient pricing/contracting approaches, as well as research into such approaches by the Center for Medicare and Medicaid Innovation, could be inhibited. Sachs et al suggest however, that some of these concerns could be alleviated by the regulatory flexibility available to CMS or by careful contracting provisions. Empirical evidence on these points was not presented, and given the confidentiality of many existing arrangements and the novelty of some of them, such evidence may be difficult to generate. Nevertheless, given other potential impediments to these innovative approaches (e.g., [9]), it would seem that the fewer regulatory hurdles there are to improving the efficiency of the drug market, the better; more research is certainly needed in this area.

Biosimilar Development (p. 23)

The United States has been slow to develop and approve biosimilars compared to Europe. There are several reasons for the seeming delay. Development and manufacturing must be cost-effective and efficient to ensure price competitive products and reliable supply chain. Cost of manufacturing will increasingly become a determinant in setting price floors and discounts as more biosimilars come to market. Intellectual property (IP) regulation is more complex for biosimilars. The number of patents for biologics may be higher than for small molecule generics with potential patents covering the compound as well as the methods of use and manufacturing processes [10]. Patent litigation has been a factor in preventing the many biosimilar medications approved by the FDA from launching [11]. Of 11 biosimilars approved by the FDA, only 3 have launched [12] which may reduce potential competition and healthcare system savings.

Biosimilars that have come to market have not provided the level of price discounts that payers have been expecting, which may point to overly optimistic prediction based on experience with small molecule generics; however, even in the small molecule space, several competitors often need to be on the market before significant price reductions occur. This - along with ambiguity on interchangeability and on rebate volume by innovators - has made payers reluctant to put incentives in place for providers and pharmacists (and patients) to switch over from the branded biologic.

While the regulatory process is appropriately rigorous and should remain so, building confidence among end users is key to biosimilar success in the market. To attain biosimilar approval, developers must provide a body of analytical, pharmacokinetic, pharmacologic, and clinical data to demonstrate there are no clinically meaningful differences between the original biologic and the biosimilar. However, the biosimilar must overcome inertia to switching treatments from the providers when long-term switching data are not available, especially in diseases where the consequences of treatment failure are severe, such as oncology. Patients also can slow uptake: a recent trial in the autoimmune space showed a 25% discontinuation rate in patients switched to the biosimilar from the branded innovator. This phenomenon is known as the “no-cebo” effect where objective clinical signs did not change but subjective patient perceptions around effectiveness did change [13]. Any uncertainty about equivalent tolerability (e.g., due to immunogenicity) can add to the inertia around moving to biosimilar usage [14,15]. Data from Europe and regulatory agencies suggest that the risk of immunogenicity in biosimilars is not different than the risk of immunogenicity in other biologics [16]. To the extent that tolerability evidence from pre-approval studies is not seen as sufficient in this regard, post-approval evidence – both pursued by manufacturers and sanctioned by regulators – would be most useful.

Perceived price discounts (or lack thereof) appear to be a driver of biosimilar adoption or non-adoption according to payers; however, established position and market share seems to be the main reason for the incumbent product to remain the leading product even with price erosion [15]. Educating providers (physicians and pharmacists) and patients on the interchangeability and appropriate use of biosimilars will be a key component to getting appropriate uptake in the market. However, in order to do so, biosimilar manufacturers and payers should think about how to develop data to support the efficacy, effectiveness, and/or tolerability of the product in the approved indications. Post-approval data collection including real-world evidence (RWE) to support effectiveness and tolerability claims should be considered as part of the product development strategy and payer, provider, and patient acceptance of new biosimilars.

Value-Based Arrangements and Price Reporting (p.25)

HHS would like to encourage payment based on value, but manufacturers and payers may find it challenging to develop such programs given the existing Best Price (BP) regulations that provide Medicaid program with lower prices, compared to the commercial market.

Research suggests that Medicaid BP provisions are a potential barrier—though not the most significant—to the development of outcomes-based agreements in the US: the additional effort required and the lack of data infrastructure are generally seen as more significant barriers [17].

A recent policy analysis has suggested 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” [8].

Nonetheless, it is clear that the analytics underlying the development of value-based contracts are complex, with contracts based on achieving outcomes derived from clinical trials and real-world evidence. Under Medicaid BP, manufacturers are likely inhibited to some degree from offering greater rebates in value-based contracts and may be prevented altogether from offering value-based contracts to smaller payers. Removing value-based contracts from Medicaid BP calculations would free manufacturers from this constraint. However, given the other obstacles, it should not be assumed that this would lead to an outpouring of new outcomes/value-based contracts for innovative medicines. To encourage these contracts, HHS will need to consider additional policy support.

Furthermore, under anti-kickback statutes, there is uncertainty around how government enforcement agencies would view VBP arrangements, which do not fit squarely into prior safe harbors.

Greater flexibility and regulatory transparency are needed in government pricing regulations to support VBP arrangements.

Indication-Based Payments (p.26)

Indication-based payments, also called indication-based pricing (IBP), offers the potential for prices for a drug in different uses (indications or groups of patients) to reflect value, so aligning health system costs with the value delivered. It can lead to lower prices for some indications and more new indications being launched [18,19]. New indications for drugs with very low patient populations may be able to justify a high price for the health gain delivered, but if there is an established indication at a lower price, it may not be commercially viable to develop the new indication.

There has been criticism of IBP in that it can push up the prices of some indications [20]. This in part depends on where prices are at the moment if only a single price is available. It also ignores the potential role of having more competition with IBP because competing drugs overlap on some indications but not others [21]. A number of US payers are looking to use IBP to increase price competition and so drive better value [22].

There are issues around the implementation of IBP [22], including the “best price” issue addressed elsewhere in the response [8]. It should be possible to negotiate or set blended prices that combine the different indication value and expected patient numbers, even if it is not possible to have different (discounted) prices in a health system. Overall, making IBP available as an option for payers and manufacturers is likely to drive better value through the US health care system.

Long-Term Financing Models (p.27)

High-cost curative or highly beneficial innovative medicines create challenges for our mixed public-private insurance system that operates on annual budget or premium basis. Patients can change health plans often. As noted in the solicitation, this raises the question of long-term

financing: how to spread the payments over multiple years and different payers. ISPOR would support HHS efforts to explore “novel value-based pricing” models that address this issue. Our members and the related research community have produced a small body of literature and thinking that could begin to help define possible models to explore.

In addition to being high-cost, these innovations often involve uncertainty about the duration or size of health benefit. These features would seem to call for some sort of annuity payments that spread the cost over time with possible linkage to an outcomes- or performance-based adjustment. In addition, there is the issue of having multiple payers sharing these costs and benefits for and with their patients.

A recent ISPOR Special Task Force on U.S. Value Assessment Frameworks recommended that both public and private payers should “consider cost-effectiveness analyses, as measured by cost per quality-adjusted life year (QALY), as a starting point to inform payer and policy maker deliberations”, but allowing for novel elements, such as extra value for a cure. The Task Force also emphasized further research is needed to make incorporation of novel elements feasible. In any case, cost-effectiveness analysis can help to define the economic value that needs to be financed long term.

Possible alternative financing models include [23-26]:

- 1) Amortizing drug costs over time
- 2) A carve-out reinsurance model
- 3) Declining patient co-payment tied to adherence
- 4) Health currency/social impact bond

As yet, there is no consensus on the relative merits or feasibility for these alternatives. Further discussion, experimentation, and evaluation are needed [27,28].

Fixing Global Freeloading (p.29)

Normally defined as free riding, this occurs when a payer suppresses their willingness to pay and seeks to use preference concealment or monopsonistic bargaining power to drive down prices. In the context of pharmaceuticals, this would have the effect of (potentially) increasing short-term efficiency by increasing the number of patients that get access to the treatment, but reducing long-term dynamic efficiency by reducing R&D incentives and therefore the amount of innovation. The Council of Economic Advisers (2018) express concern that non-US markets contribute less than they should to global R&D, meaning that the US contributes disproportionately to global R&D and that the overall amount of R&D could be higher, even if the US contributed less [29].

Observing different prices or different mark-ups above marginal cost in different parts of the world is not evidence of free riding. Efficient pricing of pharmaceuticals requires prices above marginal cost during the on-patent period. However, mark-ups should reflect underlying willingness to pay which will vary, depending on factors such as per capita income, and which will impact health budgets and preferences for additional health expenditure. We would not expect poor populations in low-income countries to contribute to R&D costs by paying prices above those of off-patent generic products [30].

Given the need to use patents to reward innovation, efficient levels of expenditure on global R&D is achieved when each health system is rewarding the health gain from new innovation at prices that reflect the willingness to pay for health gain of the population they serve [31]. This could, in theory, lead to lower prices in the US and a lower contribution to R&D, as the Council of Economic Advisers suggest. For example, it has been argued that the existence of a tax subsidy for health insurance policy premiums artificially raises prices [32]. However, the impact on R&D contributions in other countries is less clear. It depends on whether prices reflect income-constrained willingness to pay for health gain, in which case the resulting amount of R&D would be efficient, or reflect the use of monopsonistic bargaining power to drive prices below willingness to pay and so not contribute efficiently to global R&D.

More research is needed in this area before conclusions can be drawn about willingness to pay for health gain. A small number of studies have been published, but they have been criticized for the number and type of assumptions that have to be made.

Accuracy of National Spending Data (p.31)

Prescription drug costs are reported in estimates of annual health spending [33] but are based on measures of gross price such as manufacturer's suggested list price (also known as the Wholesale Acquisition Cost or WAC) or the price that the drug wholesaler pays (also known as the Average Wholesale Price or AWP) [33]. It is widely acknowledged that the use of WAC or AWP for estimating prescription drug costs over-estimates the true costs of prescription drugs because they don't reflect discounts or rebates. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has had great interest in this topic, not solely because of the impact on national health spending estimates, but also because prescription drug costs are often a key driver of pharmacoeconomic cost-effectiveness results that assess the value of prescription drugs. In 2010, the ISPOR Drug Cost Task Force published a "Best Research Practices" document for measuring drug costs in cost-effectiveness analyses conducted in Medicare, Medicaid, and other U.S. government payers perspectives [34]. This report acknowledged the critical need for using actual costs rather than measures of gross costs in cost-effectiveness analyses and proposed sensitivity analyses to address this uncertainty. More recently, Levy et al (2018) suggested that the upper and lower bounds for sensitivity analyses be determined by two publicly available drug price measures, the National Average Drug Acquisition Cost (NADAC) and the Veteran's Affairs Federal Supply Schedule (VAFSS) [41]. In general, the NADAC averages around 90% of WAC and the VAFSS averages around 50% of WAC. Setting plausible ranges for sensitivity analyses, along with a mid-point for the base-case analysis may provide better estimates of the true drug costs for both national health spending estimates and pharmacoeconomic cost-effectiveness analyses than using WAC or AWP.

Reducing the impact of rebates (p.34)

One impact of rebates stems from the lack of transparency of those rebates. This lack of transparency creates at least two issues that complicate health care decision-making: uncertainty about the correct drug cost to use in economic analyses such as cost-effectiveness analysis, and lack of clarity about the price-related incentives of the different agents in the drug delivery chain. Both of these issues can affect the efficiency of the drug market and its role in health care delivery. However, there may be offsetting considerations that either mitigate the

negative effects of non-transparency, or where non-transparency actually contributes to greater efficiency of markets.

As discussed in the previous section, in 2010 ISPOR published a series of Good Research Practices Reports for Measuring Drug Costs in Cost-Effectiveness Analysis [34-40]. They stated, in part: “The assignment of prices or costs to pharmaceuticals can be crucial to results and conclusions that are derived from pharmacoeconomic cost effectiveness analyses (CEAs). ... Drug cost measurements should be fully transparent and reflect the net payment most relevant to the user’s perspective. ... Drug transaction prices not only ration current use of medication but also ration future biomedical research and development [35].” Poor drug cost measurement due to lack of transparency of rebates can result in drug coverage and utilization that is not proportionate to its net benefit to patients and society, and in turn, distort incentives for drug development that would contribute the most value to future patients. However, the NADAC and VAFSS benchmark prices mentioned above are potential bounds for the sensitivity analysis of drug price that is expected in a well-done CEA, and may capture the potential variation in rebates across payers for any given drug [41]. On average, such corrections could yield CEA results that do reflect the drug’s value.

Nevertheless, some specific issues remain. For example, Medicare-mandated acquisition cost and reimbursement can differ between sites of service (teaching versus non-teaching hospitals) and within sites of service (340b vs non-340b). Similarly, Medicare patients and commercially insured patients could have multiple different price points for the same product based on differential rebates. If CEAs or other value assessments are highly sensitive to price (as they often are), either the value-appropriateness (if one decision is made for all cases) or the consistency (if the decision varies) of individual treatment decisions may be affected.

There also are market situations where some non-transparency of discounts or rebates may be useful in allocating resources according to willingness to pay without being affected by referencing, such as the case of differential pricing discussed above [30]. While these arguments probably apply more strongly on an international basis than strictly within the United States per se, the proprietary nature of private contracting does have considerable legal precedent.

ISPOR does not have a position on policies that would restrict or reduce the use of rebates. However, our Society supports, and would provide a forum for discussion of, studies of the effects of policies in this area.

Inform Medicare Beneficiaries About Cost-Sharing and Lower-Cost Alternatives (p. 41)

The increased use of coinsurance for brand medicines is one source of increasing out-of-pocket (OOP) expenditures among Medicare beneficiaries. Part C and Part D have increased the complexity and variance among Medicare plans, making it much more difficult for individuals to understand their health plans. Beneficiaries are often unaware of the price of their prescribed drugs and the portion of the price they will ultimately pay. Increasing transparency of drug benefits will allow beneficiaries to make better informed decisions about their OOP expenses and health.

There already exists a tool for public use that can determine the amount of cost-sharing for drugs based on type of coverage. The Q1 Group has created a website called Q1Medicare.com [42]. It contains an abundance of information that would be useful to all individuals with Medicare. There is also a tool called Drug-Finder [43]. This will show the expected OOP price a Medicare beneficiary will have to pay for a specific drug based on location and drug plan. (*) Although this is available to the public, Medicare beneficiaries may have difficulty independently accessing and navigating online tools, such as Drug-Finder. Therefore, it could be beneficial to have a third-party agent directly provide this information to beneficiaries.

There are two favorable opportunities to inform beneficiaries about cost-sharing and lower-cost alternatives. The ideal time to inform the beneficiary is when the drug is being prescribed. Before writing a prescription, the physician can inform the beneficiary of their expected OOP expense for the recommended drug, but also share the prices of any lower-cost alternatives. This would be the most efficient method because beneficiaries would know the approximate price they will pay before going to the pharmacy, thus lowering the amount of abandoned prescribed drugs. However, if this is too great a burden to place on physicians, then pharmacists could take on the role. Pharmacists are already required to ask individuals if they would like more information on the drug they are picking up. This would be an opportune time to incorporate an option for individuals to receive information on cost-sharing and lower-cost alternatives. Perhaps individuals can select an option to receive OOP information on the drug electronically and directly from the insurer of the drug plan. This can lower the burden placed on pharmacists, albeit shifting more onto the insurer.

The biggest challenge would be translating a tool such as Drug-Finder into software that is quick and easy for physicians and/or pharmacists to use. This would require cooperation between the government, insurance companies, Q1 Group or other developers of similar tools, providers, and pharmacies. This solution would give more autonomy to Medicare beneficiaries and should lead to lower OOP spending in the long run.

** This price is calculated for each plan by averaging the negotiated retail price for a particular drug across all pharmacies in the plan's service area.*

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