

December 31, 2018

SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5528-ANPRM,
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: RIN 0938-AT91; Administrations Advanced Notice of Proposed Rule Making for Medicare Program; International Pricing Index Model for Medicare Part B Drugs

The Drug Pricing Lab at Memorial Sloan Kettering Cancer Center is pleased to submit comments regarding the Administrations Advanced Notice of Proposed Rule Making [CMS-5528-ANPRM], which focuses on testing an alternative model for payment for Part B drugs. We support the proposal for a number of reasons we list and offer several recommendations to the Administration regarding their study design that would improve the study's validity.

We support and encourage the Administration's efforts to evaluate possible improvements to the purchasing and reimbursement process for Part B drugs. We do so for several reasons:

"Buy and Bill" not fit for current health care system because of the prices of drugs.

"Buy and Bill" was designed at a time when Part B drugs were relatively inexpensive. It is not optimized for the current health care system, where Part B drugs can cost more than \$10,000 per dose, and hundreds of thousands of dollars per year. The Drug Pricing Lab [tracks](#) introductory prices of cancer drugs from the perspective of Medicare costs and payments, and prices for those products have risen more than 100-fold since the beginning of Medicare after adjusting for inflation. While inexpensive Part B drugs did not cause any particular financial strain on physician office practices, current drug prices do. This means that relying on "Buy and Bill" can harm access for patients who receive their care in small practices. Academic research has repeatedly noted that the system can leave some practices '[under water](#)' on certain drugs.

Another source of financial strain for practices is uncollected coinsurance, which is set to 20% for Part B drugs. While many beneficiaries have additional coverage for their coinsurance, approximately one in eight beneficiaries do not.

"Buy and Bill" not fit for the current health care system because of the reimbursement formula.

While the original reimbursement formula for Part B drugs anchored reimbursement to the expected acquisition cost (i.e. Average Wholesale Price, AWP), there have been multiple changes to the reimbursement formula. In 2005 payment was fixed as a percent mark-up (or 'profit') over the anticipated acquisition cost of the drug (Average Sales Price, ASP). Currently the mark-up is 6%, while mathematically it is 4.3% due to 2013 budget sequestration. It is apparent why this percentage mark-up could distort prescribing behavior. The absolute profits earned by doctors and hospitals will be larger when the price of the drug is higher. While lobbyists for the pharmaceutical and physician industries steadily maintain that this profit incentive does not distort prescribing, all empiric data suggest it does.

We recently [reviewed](#) this literature. In all studies we identified, those drugs that delivered higher profits were preferred over those with lower profits. The effects tend to be [more pronounced](#) in physician practices than hospital outpatient departments. As important, no rational system would put the economics of drug payment and profit in the hands of individual physicians who prescribe drugs and can thus prefer one over another, or alternatively favor expensive treatment over palliative care, when their decision may not be in the best interest of the patient.

“Buy and Bill” not sophisticated enough to accommodate transition to payment and pricing based on value.

Several payment reform notions for Part B drugs require sophisticated handling of the products with high fidelity and non-corruptible systems of ownership and reconciliation. While large hospitals and provider networks may possess such capabilities, smaller practices do not. [Indication specific pricing](#) is one such example of a promising payment reform that would require tracking of individual doses that could be of the same product but have different prices based on the indication for which it is used. Such a system could not reliably be implemented at the practice level, and at the practice level concerns about diversion are more pronounced.

“Buy and Bill” results in price taking by Medicare.

The underlying formula for Part B drug reimbursement anchors payment to the ASP, making Medicare a price-taker rather than an agency empowered to pay prices that would be acceptable to manufacturers but lower than the current levels, thus getting a better price for both taxpayers and patients.

We also support individual elements of the ANPRM that we discuss below. In each case we offer our perspective on how the Administration should approach the design of the pilot evaluation of their approach.

CMS' prior effort at competitive acquisition through sophisticated purchasing intermediaries was a good idea but poorly implemented. Another evaluation, in a controlled manner, is in order.

The 2003 Medicare Modernization Act introduced the [Competitive Acquisition Program \(CAP\)](#) for Part B drugs. The program's launch was by all measures unsuccessful. While there are competing theories for this failure, we believe the problems can be addressed with revisions and support of the Administration's exploration of CAP in a more refined approach. Specifically, the original CAP program incorporated many low-cost Part B drugs that are functionally supplies kept on hand more than they are cost or revenue generators. This created a large amount of logistical complexity for very little economic advantage. The program was also made voluntary, meaning that physicians and hospitals that could make more money in "Buy and Bill" had no incentive to participate. We encourage the Administration to address both of these shortcomings by:

- a. Making CAP participation mandatory in the intervention regions, as proposed.
- b. Limit the scope of included drugs in a manner that co-optimizes logistical feasibility of participation while capturing those products that have very high unit costs, meaning that each transaction in Part B run by a CAP vendor rather than through "Buy and Bill" could yield substantial savings to Medicare and the beneficiary while creating the least possible logistical burden on practices and hospitals.
- c. Those Part B drugs that have low unit prices should remain in the "Buy and Bill" system.

Replacing the percent-based mark-up (i.e. 'profit') for Part B drugs with a flat fee payment is a good idea.

The rationale for percent based mark-up of Part B drugs rests in the notion that certain parts of "Buy and Bill" economics are related to the underlying cost of the drug, such as the cost of financing purchase of expensive drugs and the absolute financial impact of uncollected patient obligations. Under CAP, if the doctor or hospital no longer faces either the cost of purchasing the product or the losses from failed patient obligation collection, a flat fee for storing, preparation, and handling of the products is vastly more logical. The Administration should seek comment in its next round of rule-making regarding how this flat fee should be determined and involve pharmacists with expertise in the technical aspects and burden associated with these processes for the included Part B drugs with an aim to, for instance, arrive at two or three different fee levels.

The fee levels should not be determined in any manner in relation to the underlying price of the products.

The aggregate amount of fees should match very closely the amount of mark-up the practice or hospital would have earned under the “Buy and Bill” model. The reason for this is to maintain the integrity of the pilot at the time of evaluating the impact of the proposed policy changes. The general principle undergirding our recommendation is that as few aspects of the system of payment and practice economics should be perturbed under the pilot so that the impact of the major policy changes can be isolated.

For this reason, the Drug Pricing Lab does not support a bonus pool or other type of incentive arrangement for encouraging the use of fewer drugs or lower priced drugs. The important questions in this model relate to the shift from the percent mark-up to the flat fee, and the removal of “Buy and Bill” substituted for CAP. We would only apply the flat fee to drugs included in the CAP program, not those drugs left under “Buy and Bill” for the same reason as above.

The International Pricing framework for determining how much Medicare and beneficiaries should reimburse purchasing intermediaries for Part B drugs is a good idea, for several reasons.

The incentive system for pharmaceutical innovation relies almost exclusively on the rewards successful innovators can derive during the monopoly pricing period for their products. While scenarios vary, there is little question that for most pharmaceutical corporations that reward is gleaned from sales across all channels either directly or through marketing partnerships. This means, in general terms, that from the pharmaceutical corporation’s perspective the total size of the reward is a product of prices and volumes of sales in every country. For policymakers in any country, the US included, thinking about how that reward is apportioned across countries is therefore logical. With the IPI model the US will be entering the international reference pricing arena, an important step in acknowledging the reward structure for innovation.

Many OECD countries already use their market power as purchasers, and have the political and societal support domestically to say ‘no’ when a drug is priced well beyond what its benefits justify to manage the cost to their taxpayers for pharmaceuticals. In the US, we have historically lacked the political will to take these steps, but it is logical to leverage other countries that do. While the pharmaceutical lobby and its extensive network of patient and practitioner lobbies will argue that other countries set prices and thus drug corporations are facing unfair markets, there is no evidence for this argument. Manufacturers are free to choose whether to market their drugs in other countries; this often entails negotiation to determine price and patient access details. When this step fails to produce a mutually acceptable price, manufacturers are under no obligation to market their products. Although the industry argues that countries will take away their IP rights if they do not accept lower prices, evidence suggests the opposite. Compulsory licensing is rarely, if ever, considered by OECD country governments to address price disagreements, although there are numerous examples of

manufacturers refusing to offer their products, including NovoNordisk's Tresiba and AstraZeneca's Forxiga in Germany, as well as Vertex' Orkambi in a number of countries.

The Administration should contemplate a systematic framework for selecting countries to include in the IPI basket. The parameters for this framework should be suggested in the next round of rule-making. We would propose that the countries included have no recent history of 'marching in' or otherwise taking away IP from drug corporations over a period such as five years prior to their inclusion. The 'marching in' actions that qualify for exclusion from the IPI should be restricted to those taken by the government as a result of unsuccessful price negotiations between the drug corporation and the government at the time of market entry, but exclude those actions that follow findings of anti-competitive behavior between corporations.

The Administration should contemplate focusing on products that have been on the US market for some period of time before they are included in the model, while avoiding newly launched products for a period of one year. This will allow the products to enter other OECD markets, which typically occurs after US launch.

Caution on ASP calculations.

The Administration has proposed that during the time the model is running, the calculation of ASP will incorporate those sales that flow through the IPI model. Doing so would lead to the discounts obtained by the IPI vendor to 'bleed over' into net ASP calculations that would affect reimbursement levels not only in the non-model regions under Medicare, but also affect commercial reimbursement rates (many commercial contracts base reimbursement on ASP-plus type structures).

While we can see the benefits of allowing the ASP sales to model vendors to be incorporated into national ASP calculations, as we anticipate this would reduce total spending by Medicare and commercial insurers, we do not favor this approach under the model due to several potential negative effects:

- a. Manufacturers deciding whether or not to sell at a discount to the model vendors will not be able to wall off the impact of discounts to those vendors from the rest of their US market. This will make them reluctant to participate. Crudely put, if the model vendor has perhaps a quarter of the US market, a dollar discount to the model vendor might be a dollar in lost revenue per unit sale to the model vendor, but if that sale is incorporated into the ASP calculation nationwide, it will equal a \$0.25 discount (or thereabouts) on ASP reimbursement in non-model regions in Medicare and in commercial contracts throughout the US. This reduced reimbursement will reduce the spread between "Buy and Bill", thus putting downward pressure on prices in those other regions. This may be long term desirable but will impede manufacturers participation in the model.

- b. We think, from an experimental perspective, it is vital that the model isolate the interventions in the model regions from the system outside the model in every way the Administration can. This will allow for a clean evaluation of the impact of the key pilot impacts, as contemplated in the enabling legislation that formed CMMI. We strongly encourage the Administration to ‘wall off’ sales to the model vendor from the ASP calculation.
- c. On a more technical point, we do not favor gainsharing or any type of profit sharing between Medicare and the model vendor, again on experimental design grounds. What is being evaluated is setting reimbursement rates based on market prices, and then letting the market participants manage within those rates. If vendors are more or less successful in doing so, that should be gauged by the access they obtain for patients, not the profits they can generate.

Caution on the handling of 340B hospitals under the model.

While the Drug Pricing Lab has raised many concerns about the 340B program and produced evidence that the program has problematic distorting incentives, we would encourage the Administration to keep the 340B hospitals in the model but and “keep them whole” with respect to the current profits they earn between the acquisition price of included Part B drugs and the Medicare reimbursement of ASP minus 22.5%. We hold this position regardless of the court outcome regarding the suit by the American Hospital Association. In other words, for those Part B drugs included in the model (and in the model regions), 340B hospitals should receive payments for the money they would have made prescribing and delivering them even if under the model they do not take possession of the drug compared to what they would have earned under the policy of ASP minus 22.5% reimbursement.

The principle underlying this recommendation is that like the physicians and hospital operating under “Buy and Bill” without benefit of the 340B discounts, the model should test the policy actions of interest without altering other important market forces that could dilute the ability to assess the impact of the pilot.

The Administration should proceed with the pilot under an assumption that it may either prove successful or unsuccessful, and thus alterations in the market that are potentially temporary should not have long term consequences even in the case of programs that are currently structurally problematic themselves.

We would propose the Administration explore a confidential reporting structure, where the 340B hospitals report their actual acquisition costs for Part B drugs during the model period. Even though under the pilot they will not be buying those drugs that are given to Medicare patients, they still will be buying those given to patients with other types of insurance coverage.

The Administration would then pay the 340B entities directly for the difference between their actual acquisition costs and the reimbursement amount under current rules. For instance, if a \$1 ASP drug is obtained by a 340B hospital for \$0.50, CMS would reimburse the 340B hospital that is included in the pilot the difference between the reimbursement level of \$0.775 and \$0.50, or \$0.275.

We appreciate that this will add costs to the model during its testing period, and propose that these be accounted for separately. We would expect this gross up payment to decline over the period of the model, as the ASP for the model vendors declines under the declining reimbursement levels that will be a result of the IPI index, as the formula for 340B hospital reimbursement should remain ASP minus 22.5%.

We note for the Administration that the Drug Pricing Lab supports transitioning the 340B supplemental revenues earned through the buying and re-selling of outpatient drugs to a direct subsidy that could be targeted, as we [recently](#) articulated.

We encourage the Administration to incorporate a large array of quality measures that can be determined through the analysis of Medicare claims alone, and that can be used to determine if there are health benefits or harms under the model. These include several in use under the PPS-exempt quality measurement program currently included in Medicare. The Center for Health Policy and Outcomes at Memorial Sloan Kettering has also [published](#) on models for evaluating risk-adjusted long term survival for Medicare beneficiaries, demonstrating that these metrics are robust to the exclusion of information on cancer stage and diagnostic timing. Other work from the Center for Health Policy and Outcomes includes an examination of a large [array](#) of hospitalization events related to cancer treatment that could in some cases be avoidable.

Respectfully submitted,



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www.drugpricinglab.org