

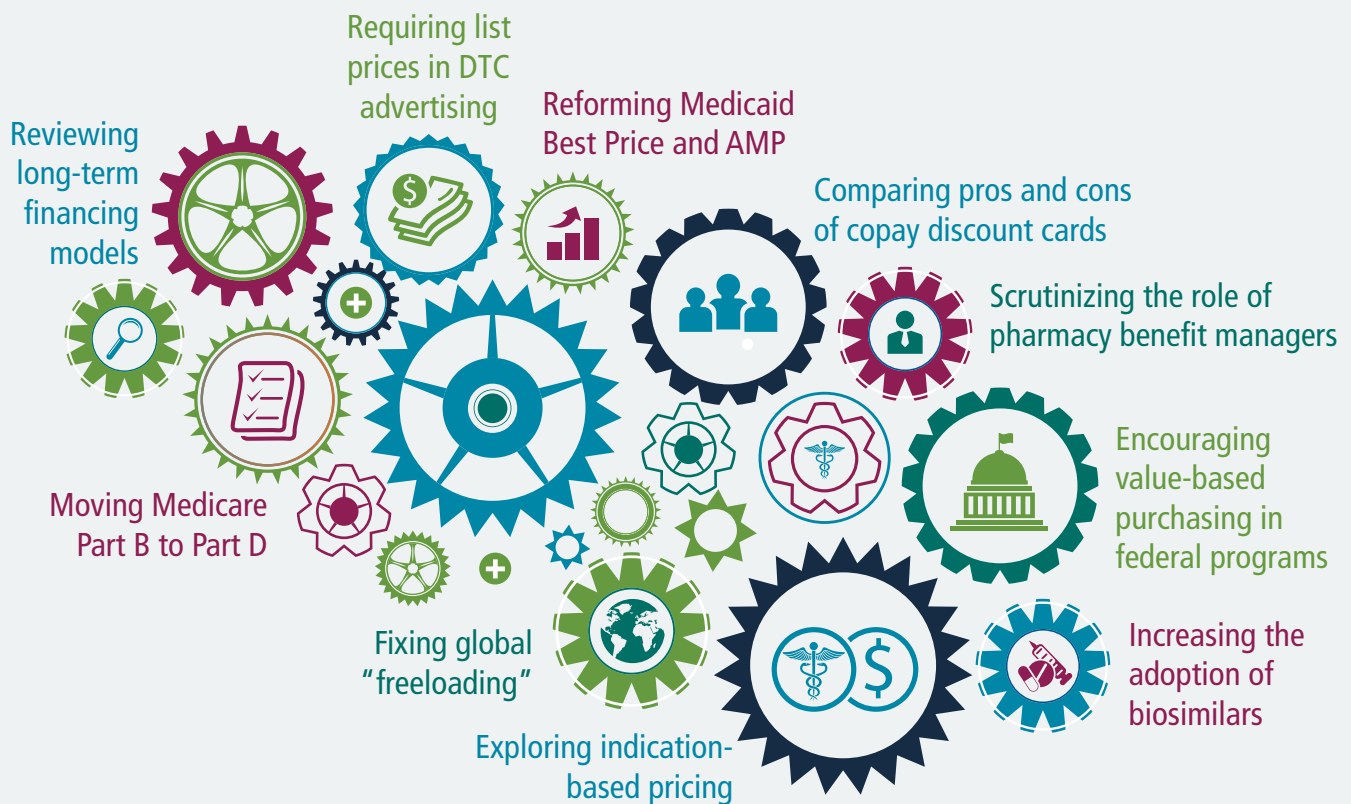
Upending the Medicare Part B Program

The International Pricing Index (IPI) Proposed Model

Introduction

In May 2018, the Trump Administration released the *American Patients First Blueprint*,¹ which promised to increase competition, improve negotiation, lower drug prices, and decrease patient out-of-pocket costs for all Americans, including Medicare beneficiaries. However, the document lacked details or mechanisms about how the healthcare industry would achieve these goals. Shortly after the announcement, the Department of Health and Human Services released a policy statement and request for information in the *Federal Register*.² Since then, proposals have come at a breakneck speed, including a guidance released in August 2018 and then codified in a November proposed rule allowing Medicare Advantage plans to use step therapy for Part B medicines.³ The constant stream of attacks on Medicare have left little time for real consideration of stakeholder input or dialogue about the effects and outcomes of policy proposals on varying stakeholders.

Figure 1. Sample of What Is Up for Consideration



The proposals beg the main question: What is the problem with Medicare that the Administration hopes to solve? More importantly, are the best interests for patients being carefully considered? If the current Medicare Part B system is viewed as broken, with providers ordering drugs based on price in order to get an additional fee, would another change to the system for Part B drugs really lead to better access and lower costs to beneficiaries? Enter the new Medicare Part B demonstration proposed model called the International Pricing Index (IPI),⁴ which creates more questions than answers, particularly related to patient access.

Background

Currently, there are 2 paths to prescription drug coverage in the Medicare program. Part B covers in-office infusions administered by a healthcare provider and Part D covers oral prescriptions and sometimes physician-administered drugs.

Over the last 2 decades, there have been several significant legislative changes to how Medicare pays for most Part B drugs. More recently, the market has begun to change further due to the shift to value-based payment in healthcare and growth in Medicare Advantage enrollment. Finally, more and more biosimilars are entering the market, which will continue to increase competition in Medicare Part B.

Part B (Fee-for-Service)		Part D
Covers physician-administered drugs, with few exceptions	Drug Coverage	Covers self-administered, oral, and some physician-administered drugs
No prior authorization	Prior Authorization	Varies by plan
Patient is responsible for 20% of allowable amount, after annual deductible	Patient Cost-Share	Varies by plan
Buy-and-bill	Drug Acquisition	Pharmacy or specialty pharmacy
Physician bills for both the drug and the administration	Billing	Pharmacy bills for drug

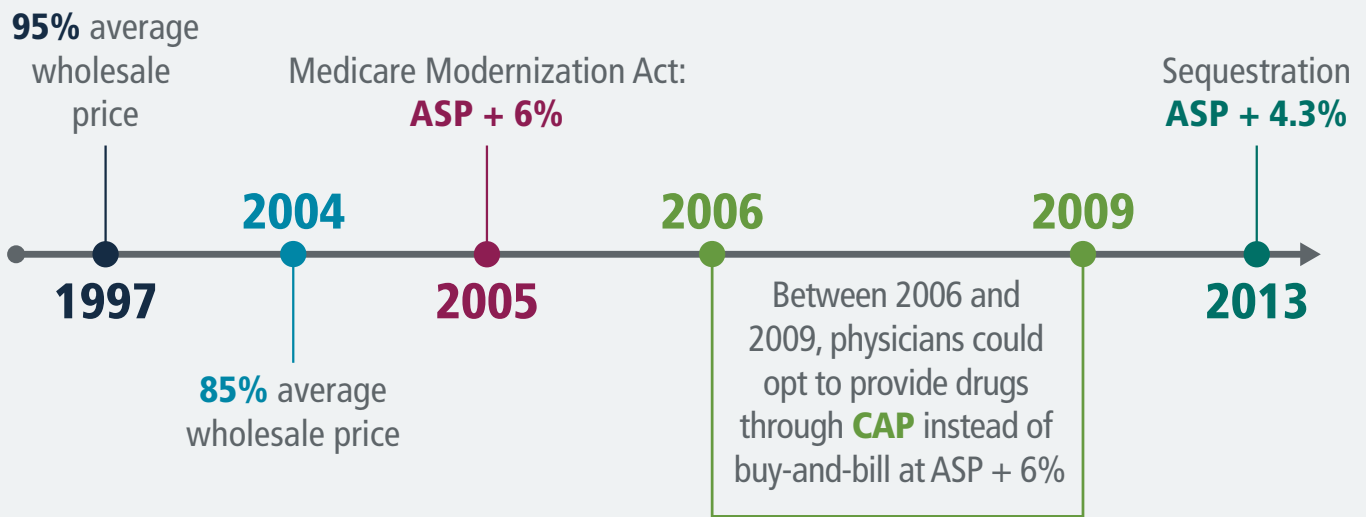
In 2005, payment changed from a percentage of the average wholesale price to the average sales price (ASP), a price that averages sales (net of discounts and rebates, including those given in the private market) to determine what Medicare reimburses. As a result of this change, drug prices decreased by 33.9% from 2003 to 2005, while the federal government and beneficiaries saved over \$100B on just Part B drugs from 2005–2017 and \$4.4B in 2005 alone.⁵ Medicare then pays providers this price, plus 6%, to cover storage and handling of physician-administered drugs. After that switch, spending on Part B drugs decreased by 8%.⁶ Currently, Medicare pays providers ASP plus 4.3% under sequestration.

In 2006, the Centers for Medicare & Medicaid Services (CMS) implemented a Competitive Acquisition Program (CAP), to allow providers to acquire drugs from a third-party vendor, as an alternative to the current buy-and-bill system where providers purchase medications and are reimbursed by payers. CAP was an effort to increase competition and lower prices. The test failed, with only 1 vendor even joining the program, many providers dropping out, and resulting in an increase in Medicare spending.⁷

While the current ASP system works well for many, providing patients and physicians with treatment choice, the Administration appears to be identifying problems in Part D (eg, using a “middleman” like pharmacy benefit managers) and then importing them into Part B (eg, calling for use of a vendor in Part B).

One of the justifications for Part B policy proposals is the questionable hypothesis that providers make prescribing decisions based on cost.⁸ Earlier this year, Xcenda tested this hypothesis and reviewed whether prescribers of physician-administered drugs disproportionately prescribe therapies with higher reimbursement rates to financially benefit from larger add-on payments. To do this, we analyzed claims data for Medicare Part B fee-for-service beneficiaries receiving physician-administered drugs for rheumatoid arthritis, breast cancer, and non-small cell lung cancer in the office setting.⁹ If the criticism of the ASP-based Medicare Part B payment rate is true, and prescribing really is driven by the reimbursement differences among drugs with similar clinical effects, then one would expect to see this reflected in utilization patterns. But the lack of a strong, positive correlation between drug payment and utilization suggests that **physician prescribing is not driven by payment per drug administration.**

Figure 2. Payment for (Most) Medicare Part B Drugs



Key: ASP – average sales price; CAP – Competitive Acquisition Program.

Part B Reform Proposals

In the *American Patients First Blueprint*, along with subsequent releases and rule-making, the Administration has been making a lot of changes to the prescription drug benefit under Part B.



Introducing Automated Reporting on Pricing Data¹⁰

While it is unknown whether inaccurate data reporting is one aspect that leads to higher drug costs, CMS began requiring manufacturers to use a new automated system to submit ASP data for Part B drugs.

Introducing Step Therapy Into Medicare Advantage Plans¹¹

In August 2018, CMS released guidance permitting Medicare Advantage plans to implement step therapy for Part B drugs beginning in January 2019, thus differentiating coverage between Original Medicare and Medicare Advantage.



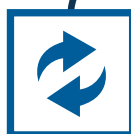
Reducing Wholesale Acquisition Costs (WAC)¹²

A “whack” to WAC—with a decrease in payment from WAC plus 6% to WAC plus 3% (1.35% after sequestration), beginning January 1, 2019—is touted by the Administration as a way to help curb expenses related to new drugs covered by Part B with high launch prices.



Revising the Competitive Acquisition Program (CAP)⁷

Next came the CAP Request for Information, with CMS seeking comments by the end of September 2018 on elements of a revised CAP model or a model based more on the Medicare Payment Advisory Commission’s (MedPAC’s) Drug Value Program.



Introducing the International Price Index (IPI)⁴

In October 2018, CMS asked for feedback on a model that would base Part B drug prices on an international market basket and combine elements of the CAP.

Overview of the IPI Proposed Model

In late October 2018, CMS put forward an Advanced Notice of Proposed Rulemaking that looks to upend the current ASP buy-and-bill structure of the Part B program and replace it with government-set prices in a vendor-led purchasing model. The IPI would take the prices from 14 countries and use them to derive a target price for a drug, creating an index of international prices (known as the IPI), as opposed to the ASP with an add-on payment that is currently used. This new model would include a vendor who would be paid the target price and would be responsible for negotiating with manufacturers, with the target price acting as a ceiling. The vendor would also need to ensure that all federal and state laws are met in order to nationally distribute Part B drugs—and this compliance check would have to be done in an extremely short period of time after more details are released in a proposed rule.

CMS is marketing the model as an improved CAP approach that will pay physicians and hospitals for drug-related costs and allow for more flexibility in drug ordering and distribution by having vendors compete. Providers in the office and hospital outpatient departments (along with other providers, possibly) would be forced to participate in the model and would receive a flat fee and the current payment for drug administration. CMS anticipates choosing geographic areas that would include 50% of Medicare Part B spending for separately payable drugs.

Along with specialty pharmacies, CMS suggests that group purchasing organizations, pharmacy benefit managers, distributors, manufacturers, and provider groups are among those that could become vendors. However, these other groups have been relatively quiet about their interest in stepping up to take on additional risk, even if they would not be required to physically take ownership of the drugs. While the model would be phased in over 5 years, it would affect more providers and patients than just those directly within the model, making its reach much further, especially compared to other proposals in the past.

The proposed timeline is aggressive. CMS anticipates a proposed rule in the spring of 2019 and implementation 1 year later.

Model Payment Methodology

The program lacks specific details about the proposed payment methodology, but the vendor would be reimbursed by CMS on a payment based on a set international reference price. That average international price would be calculated using a standard unit that is comparable to our Healthcare Common Procedure Coding System (HCPCS) codes. CMS is looking at 14 countries to calculate the IPI, including Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom. Although the countries CMS is considering for this reference pricing methodology have similar economies to the United States and/or the German market basket, patient access in these countries is vastly different. The IPI would be the ratio of Medicare spending using ASP prices for all drugs in the model to international prices. But the calculation itself is somewhat misleading, because the goal of this proposal is price control. Ultimately, CMS would use this calculation to establish a target price, which would be about a 30% reduction in Medicare spending, phased in over 5 years.



Further, CMS plans to establish a flat fee that reflects 6% of historical drug costs, in addition to the current payment providers receive for drug administration. Again, there is limited information on how exactly CMS would calculate this payment and how it might affect the payment for drug administration. Considerations for the new add-on payment include redistributing the 6% into a set payment amount per encounter or per month that would be based on (1) class of drugs, (2) physician's specialty, or (3) physician's practice. This payment would essentially try to help make providers "whole." The model seeks to decrease overall ASP, meaning that providers not participating will experience a decrease in reimbursement. It is unclear whether in the future, the flat fee will be calculated based on a declining ASP. There would also be a potential "bonus pool" for providers who prescribe lower-cost drugs or practice evidence-based utilization management.

Potential Impacts

Two groups that the IPI model would affect if CMS moves forward with implementation are patients and providers.

Patients

Potential impacts of the model on patients include delays to treatment, reduced access to innovation, and the potential for reduced cost-sharing.



Delays to Treatment: Any bonus pool tied to utilization management could open the door for both third-party vendors and providers to use utilization management tools in a space that has traditionally been shielded from these cost- and payer-driven efforts because of the complex nature of Part B medicines and the diseases they treat. Additionally, since vendors will be negotiating based on what is essentially a ceiling price, they are likely to use aggressive cost-driven utilization management tools often seen in the commercial market. Potential delays and disruptions to care could also occur because of a patient's inability to get the prescription in-office (due to operational delays or simply not being available) or difficulty getting an appointment.

Reduced Access to Treatments and Providers: If implemented, the IPI pricing model could have a significant impact on pharmaceutical research and development, and could stifle innovation in the pharmaceutical industry, resulting in potentially fewer new drugs for patients. Personalized medicines could also be hit hard in the model, slowing the momentum for these breakthrough medicines. Another way that the model could negatively affect access is for patients who live in rural areas, where the distance between a patient and their provider can be significant, even without the additional, mandatory requirement for providers to participate in the IPI model. Depending on the geographic location of the patient, the new model could require the patient to take on the additional stress and cost of travel to get an appointment with a provider.

Unclear Focus on Quality Improvement: Although improving quality of care for beneficiaries is stated as an intended goal of implementing the IPI model, CMS provides limited information about how quality will be improved or measured. Additionally, with the focus on this model as a way to decrease costs, there may be a diminished potential for outcomes-based contracting, which could have focused more on quality of outcomes and possibly lowered costs for patients.

Potential for Reduced Cost-Sharing: While the Advanced Notice of Proposed Rulemaking states that beneficiaries would not see an increase in cost-sharing—and estimates that about 20% would likely see a decrease—it is not clear whether the savings would actually trickle down to patients. CMS anticipates that as Medicare costs for participating Part B drugs decrease under the IPI, beneficiaries' out-of-pocket expenses will be proportionately decreased through reduced coinsurance payments for these drugs; however, given that so many Medicare beneficiaries already have supplemental coverage, it is more likely that **these savings will be realized by plans, not patients.**

Providers

Although some providers may welcome a model that eliminates the financial risk associated with buy-and-bill, the impact of the IPI on providers extends beyond individual providers.



Reducing Provider Choice: If the proposed IPI model is implemented, providers may be limited in their choice of drugs to prescribe and see a loss in autonomy due to the mandatory participation requirement. This is also seen with the addition of step therapy to Medicare Advantage. There is a movement to put the plan ahead of providers in terms of patient care.

Loss of Revenue (including for those not in the mandated model): An overall reimbursement cut could lead to closures and consolidating practices, particularly small practices located in rural communities. The new model may hurt providers who are not required to participate, given that they will experience reduced revenue because ASP will drop, and thus ASP plus 4.3% will be based on a lower ASP base. This reduction will disproportionately affect small and rural providers—subsequently hitting patients in rural areas especially hard. Additionally, removing providers' ability to negotiate Part B drug prices greatly decreases their negotiating power for all physician-administered drugs.

Winners and Losers: For those providers who buy drugs below ASP, and for those drugs that still must be stored, tracked, and report any wastage, the additional set add-on fee would not “make them whole” (ie, cover all provider costs). Further, it is not clear how the new set add-on fee will affect the current additional add-on fee for drug administration. What is clear is that CMS is creating a system of winners and losers—because not all providers will remain neutral or gain under the IPI model.

Interaction With Other Models Remains Unclear: Providers may be forced to choose between participation in this demonstration over another option, such as the Oncology Care Model, that may result in more success in lowering costs, while still maintaining quality. CMS will need to determine how to work through other ongoing payment models, and how the IPI will fit into future potential models.

Reduced Negotiating Power: Providers in the model will still have to buy and bill for physician-administered drugs for non-Medicare patients. Depending on the makeup of a practice, pulling only Medicare purchases out of that negotiation may have huge impacts on providers' ability to negotiate volume-based discounts. For providers with a large percentage of Medicare patients, the IPI has the potential to severely limit their negotiating power.

Looking Ahead: Potential for Reforming the Add-On Payment as an Alternative to the IPI

In view of the success of the current ASP system and the broader evolution of Part B toward value-based payment, as well as the extreme disruption that likely would be caused by the IPI proposal, many stakeholders have called for alternative reforms that build on the current market-based system, while enhancing incentives for competition. One potential reform under consideration is making changes to the ASP add-on payment formula.

The concept of changing the add-on payment that physicians receive has been under consideration for many years. In 2015, MedPAC suggested a policy that converts all or part of the current 6% add-on to a flat fee add-on in their report to Congress,¹³ and more recently, Peter Bach, MD opined on the change in a Senate Finance Committee hearing.¹⁴ A change to the add-on fee was also the center piece of the Obama Administration's proposed Part B Drug Payment Model.¹⁵ Key provider groups have also considered the issue in comments on the IPI model.¹⁶

When considering changes to the add-on payment, policy makers should ensure that providers who buy and bill for drugs are kept "whole" and do not lose revenue when they prescribe drugs in-office. It is important to keep varying specialties, as well as differences in provider size and practice composition, in mind to create a system that minimizes "winners and losers" among specialties and does not exacerbate the issue of hospital consolidation. For example, some smaller practices lack the purchasing power of larger organizations and rely heavily on the add-on payment in order to continue to serve their patients and keep their doors open.

What's Next?

What does all of this mean, and what steps can be taken to advocate against the IPI model but still prepare for potential changes?

- **Meet with and/or have discussions with CMS** now to ask questions and express concerns regarding a mandatory demonstration using the key points addressed above.
- **Prepare for the potential release of a proposed rule** in Spring 2019—if CMS chooses to move forward from the advance notice to the proposed rule stage, it likely will likely be here soon.
- **Model the potential impact** of the new, set add-on payment on provider practices and patient access to care in order to help CMS understand the real effect that this proposed IPI policy could have on patients and providers.

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