Provident Perspectives:

Potential Upcoming Changes to Drug Pricing Under Medicare Part B

Examining Potential Pending Changes to Pricing and Reimbursement for Drugs under Medicare Part B and Their Effects on Investment & Consolidation Activity

Provident Healthcare Partners

Introduction

In an effort to curb rising drug prices in the U.S. and their increasing burden on healthcare expenditure, the Trump Administration announced multiple initiatives through the Center for Medicare Services (CMS) designed to lower Medicare Part B drug pricing and reimbursement, which has risen at a rate of 11.5% a year on average dating back to 2015.

The new CMS interim final rule follows an executive order signed by President Donald J. Trump on Sept. 13, 2020 which included an order to test a "most-favored nation" (MFN) pricing model for certain high-cost Medicare Part B and Part D drugs. CMS posted the interim final rule (IFR) and public comment information in late November 2020. The rule is specifically designed to lower prescription drug costs by paying no more for Medicare Part B drugs and biologics (for the application of this piece, "drugs") than the lowest price that drug manufacturers receive in other similar countries.

In addition, the most-favored nation model will pay providers a flat add-on amount for each dose of an eligible drug, rather than a percentage of each drug's cost, removing the tie between drug cost and the add-on amount, which was typically 6%.

According to CMS, the most-favored nation model — mandatory for Medicare providers and suppliers who receive separate Medicare Part B fee-for-service payments for the model's included drugs, with certain exceptions — will operate for 7 years, from Jan. 1, 2021 to Dec. 31, 2027. During this time, CMS will monitor and evaluate the impact of the model on patient access, program costs and the quality of care.

These changes in reimbursement have the potential to greatly affect the profitability and cash flow streams of provider groups who participate in Medicare Part B, including specialties such as oncology, ophthalmology (specifically retina), urology, and gastroenterology, among others.

Provident believes that while a program such as this may not be implemented in its current form, drug pricing is firmly on the radar of the government and the uncertainty of future cash flows for businesses that participate heavily in Medicare Part B will further drive consolidation and an emphasis on scale.

What is the "Most Favored Nation" Proposal?

The new Most Favored Nation (MFN) payment model announced by CMS is intended to more effectively control the price of certain high-cost Medicare Part B drugs. In order to do so, Medicare will pay no more for those drugs than the lowest price that drug manufacturers receive in other similar countries. This legislation would represent a stark shift in reimbursement for these drugs from the current "buy and bill" model, where physicians generally purchase Part B drugs and are reimbursed by Medicare for the average sales price of those drugs plus 6%. This existing model provides little incentive for physicians dispensing these drugs to keep costs down, which has contributed to the steady increase of Medicare Part B reimbursement in recent years.

Aside from the change in pricing methodology, there are several key changes outlined in the MFN proposal that stand to impact physician groups in a significant way. The first of which is the elimination of the vendor model; previously physicians could access the Part B drugs required through a centralized vendor that negotiated prices on behalf of a group of providers, while the new ruling calls for the individual groups themselves to engage with CMS directly to negotiate prices. This places an increased administrative and regulatory burden on provider groups and stands to adversely impact smaller providers without the necessary scale to negotiate attractive reimbursement rates for their practice.

The scope of the program has expanded since the initial proposal was put forth in 2018. While the initial plan was to implement the program in half of the country, it has been amended to a mandatory nationwide program covering all Medicare-participating physicians, group practices, and other providers receiving Medicare Part B fee-for-service payments for the models included drugs.

The challenges inherent within this model are expected to contribute to a sizeable decrease in Medicare Part B reimbursement. According to CMS' own estimates, the program would reduce reimbursements by ~65% once fully implemented, with roughly one-third of those projected savings coming from patients losing access to care.

Most-Favored Nation Highlights	
Eliminating the Vendor Model	Individual providers will need to negotiate terms with drug manufacturers & distributors themselves, rather than a centralized vendor doing so on behalf of a larger group of providers
Reimbursement Tied to Other Countries	The rule is designed to pay no more for Medicare Part B drugs and biologics than the lowest price that drug manufacturers receive in other similar countries
Flat Add-On Amount	The new model will pay providers a flat add-on amount for each dose of an eligible drug, rather than a percentage of each drug's cost, removing the tie between drug cost and the add-on amount, which was typically 6%
Decrease in Access & Utilization	CMS estimates 19% of Medicare Part B drug utilization may be eliminated because patients can no longer access the drugs in question from their providers

Expected Impact & Mitigation on Physician Specialties

Oncology

Oncology is one of the physician specialties most-exposed to changes in Medicare Part B reimbursement for a few reasons. For one, cancer rates increase with age, leading to many Medicare beneficiaries being diagnosed for some oncology-related indication at some point in their lives. Additionally, on a fee-for-service basis, oncologists and cancer care clinics predominantly source their revenue from the margins between buying and billing drugs. Outside of radiology and clinical trials, there is little oncology providers can do to overcome drastic cuts in reimbursement for key therapeutics.

For this reason, it is no surprise that the oncologist community has been one of the most vocal in leading the opposition towards the implementation of the MFN rule in its current state. Fortunately for some of the leading oncology physician organizations in the U.S., groups that are participating in pilot programs through the CMS Centers for Innovation will be exempt from the MFN ruling so as not to interfere with their current studies.

Ophthalmology

The retina sub-sector also stands to face potential headwinds from the implementation of the MFN proposal in its current form. Retina providers, which are especially reliant on income streams from Part B drugs such as Eylea and Lucentis, will encounter a less attractive reimbursement profile for key Part B drugs

There are some avenues by which the negative impacts of the IFR on retina practices could be offset. Industry stakeholders believe that under the Biden administration, the primary focus on drug pricing reform would be shifted to Part D subscriptions, which are not applicable to ophthalmology. Also, biosimilars and other new therapies coming to market stand to reduce system-wide costs. The introduction of these new products can diversify the drug mix at healthy reimbursement levels for retina practices.

Gastroenterology

Gastroenterology providers who operate their own outpatient infusion suites and clinics will be particularly exposed to rate changes for Remicade, which has already observed modest but consistent declines in reimbursement from both CMS and commercial payors over the past decade. Infusion revenues and the costs of those drugs are the single largest line items on most GI financial statements, meaning that any abrupt changes in cash flow from such operations could greatly disrupt groups' profitability in the short and intermediate term.

Luckily for many GI groups, since infusion margins tend to flow between 10%-20%, they are not the most profitable ancillary services a clinic relies on. Other ancillaries, such as anesthesia, pathology, clinical trials, and endoscopy represent other avenues for growth to offset future cuts in infusion reimbursement.

Urology

Urology providers generating a significant amount of cash flow from Denosumab, which has seen annual spending increase by 4.5% in the past 5 years, would be exposed to rate changes under the MFN rule. Several other drugs frequently used by urology providers, including OnabotulinumtoxinA, are also slated to be included in the initial list of 50 Part B drugs subject to the new pricing model.

Consistent with other physician services sub-sectors, the uncertainty brought forth by the proposed MFN rule figures to drive consolidation activity across the sector, as providers align with strategic partners with increased scale and mitigate the risk to their practices.

Contestation From Industry Stakeholders & Legal Challenges

Broad Pushback

Broadly speaking, the MFN ruling as it currently stands has received verbal or legal contestation from most corners of the U.S. healthcare system. Provident believes that while any aggressive drug cost containment measures would receive pushback from industry stakeholders, the contestation against MFN has been particularly strong. This is largely due to the lack of time that the fragmented physician services community has had to prepare for these sweeping changes.

Verbal & Legal Challenges

Pharmaceutical Research and Manufacturers of America (PhRMA), Association of Community Cancer Centers (ACCC), Global Colon Cancer Association (GCAA), and National Infusion Center Association (NICA), and the American Academy of Ophthalmology are all sample organizations that challenged the legality of the MFN ruling.

Delayed Onset

Multiple lawsuits have already achieved success; the Pharmaceutical Research and Manufacturers of America's request for a temporary restraining order successfully delayed the drug model's start from January 1st, 2021 to January 15th. Then, Biotechnology Innovation Organization's lawsuit further delayed the onset of the program until January 26th.

Regeneron's lawsuit, which was inspired by competitive concerns with its retina drug Eylea, has also been heard by a judge, without a ruling yet.

Some legal experts have speculated that due to the delayed timing of the MFN implementation and it being the product of the departing Trump Administration, the new Biden Administration may choose to not move forward with the program in its current state.

Pharma's Expected Reaction

Pharmaceutical manufacturers and sponsors have their own interest in preventing the continued utilization of successful therapeutics from being disrupted due to changes in drug pricing and reimbursement. In order to counteract the MFN ruling, pharmaceutical companies could increase prices for drugs in other countries, which would raise the index price and counteract declines in reimbursement domestically.

If this program is to be successful in the eyes of the Federal Government and CMS, this could be the preferred outcome in the long term as it would achieve the goal of "leveling the playing field" between what providers in the U.S. pay for drugs compared to their counterparts in other countries.

Concluding Thoughts from Provident

The MFN interim rule by CMS in its current state could decrease Medicare Part B utilization by up to 19% within four years, representing a significant challenge to the fragmented physician and provider communities that purchase and administer these drugs to patients. Should the program complete its roll-out in its current form, these pricing changes could expand to commercial payors as well, who tend to follow the lead of CMS in reimbursement.

With the threat of potential reimbursement changes, providers within subspecialties such as oncology, retina, GI, and urology could view mergers and acquisitions as a means to partner with larger strategic organizations in their given sub-specialties, accelerating their current consolidation timelines.

In the long run, pricing is expected to return to equilibrium, as pharmaceutical companies counteract domestic cuts in reimbursement by raising prices internationally. In the short and immediate terms, however, there will continue to be uncertainty in the future reimbursement for Part B drugs, especially as the MFN ruling sees likely future delays as a result of lobbying efforts.

Lastly, Provident believes there could be a lack of conviction to implement such an aggressive long-term drug plan by the Biden Administration, given their stated focus on combatting the COVID-19 pandemic, and this interim rule's potential negative impacts on healthcare providers.

Provident will continue watching this story closely, and report on any significant changes in the weeks ahead.

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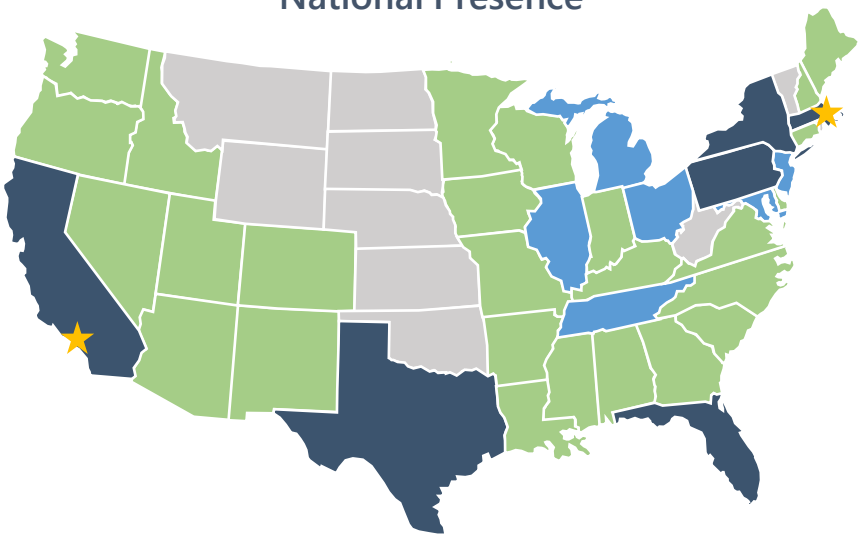
National Presence



21+	Years of Healthcare Investment Banking
140+	Healthcare Deals Closed
12-15	Landmark Deals Per Year
26	Banking Professionals

Note: The above map represents states where Provident clients were headquartered. Provident has successfully closed transactions with clients operating in 45 states and Puerto Rico.

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