CMS' Proposed Part B Price Controls: Hurdles and Unintended Consequences

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On October 25, 2018, the Center for Medicare and Medicaid Services ("CMS") issued an Advance Notice of Proposed Rulemaking ("ANPR") to solicit comments regarding a proposal which, if implemented, would change how certain Medicare Part B prescription drugs are obtained and would effectively impose price controls on those drugs. The ANPR reflects CMS' preliminary thinking and is several steps away from becoming a final rule. CMS is accepting comments on the ANPR through December 31, 2018.

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Part B drugs are administered in outpatient clinical settings, such as doctor offices and hospital outpatient departments, and include high-cost specialty drugs that treat conditions such as cancer and ophthalmological disorders. Currently, Part B drugs are purchased by healthcare providers, such as doctors or outpatient hospital facilities, directly from wholesalers or distributors. CMS provides reimbursement to providers at the rate of the Average Sales Price ("ASP") plus a 4.3 percent "add on," which is supposed to cover the cost of processing the drug order, storage and handling. The ANPR proposes that certain Part B drugs instead would be purchased by vendors, who would then distribute them to providers. CMS's reimbursement to those vendors would be based on a formula designed to bring Part B drug prices in closer alignment with lower international prices for those drugs. The proposal is highly controversial because foreign governments typically pay less for prescription drugs than do government and commercial purchasers in the United States because many foreign governments impose price controls. CMS would effectively be importing those controls and imposing them on Part B drugs in the United States. Further, CMS seeks to undertake this unprecedented action without Congressional authorization.

As we discuss below, it is far from certain that CMS' proposal will be put into effect. If CMS proceeds to issue a final rule that is consistent with the ANPR, it is certain to be challenged in court. Moreover, beyond the legal issues, there are many legal and operational hurdles to restructuring the delivery and reimbursement mechanisms for vital prescription drugs. There are some indications that the Trump administration may be using the ANPR as leverage to convince the pharmaceutical industry to agree to other potentially more palatable concessions.

The Proposed Model for Medicare Part B Drugs

- CMS raises two principal arguments for changing the Part B program. First, it claims that the "add on" formula incentivizes physicians and hospitals to purchase costly prescription drugs because the higher the drug price, the larger the "add on" they receive. Second, it claims that a study conducted by the Department of Health and Human Services ("HHS") shows that the acquisition cost for prescription drugs in the U.S. is significantly higher than in other industrial countries. CMS argues that the Medicare program is therefore incurring unnecessary costs.

- CMS proposes to address its concerns with a new model for certain Part B drugs, which it calls the International Pricing Index model ("IPI Model"). Under the IPI Model, CMS would contract with private-sector vendors that would purchase Part B drugs and supply them to physicians and outpatient hospital facilities. CMS would provide reimbursement to the vendors based on a formula that is anticipated to reduce Medicare spending by $17 billion over five years. The key components of the IPI Model are identified below.

- **IPI Model purchase price:** The amount of reimbursement that CMS would provide for each Part B drug in the model would be determined based on a weighted average of the ASP and a "Target Price" that CMS would set. The Target Price would be determined based on calculations intended to reduce Medicare spending on drugs covered by the model by 30 percent and to bring the purchase price of such drugs closer to what other countries are paying for them. In the first year of the program, the purchase price would be 80 percent ASP and 20 percent Target Price. Each year, the percentage of ASP contribution would go down, and Target Price contribution would rise. By the fifth year, CMS would pay just the Target Price.

- **Vendors:** CMS envisions that the following types of entities would apply to be vendors: group purchasing organizations, wholesalers, distributors, specialty pharmacies, physician or hospital groups, and Part D sponsors. The vendors, among other things, would purchase the applicable drugs and distribute them to providers. CMS does not explain how vendors would be compensated for their services, except to say that providers would pay vendors for distribution costs.

- **Physician/hospital compensation:** The ANPR proposes that physicians and hospitals would receive a fixed payment per patient encounter or per month for administering a particular drug. Thus, the revenue that the provider would receive for administering a Part B drug would no longer depend on the price of the underlying drug. Further, CMS is considering providing bonus payments to

physicians or hospitals that prescribe lower-cost drugs or practice "evidence-based utilization."

- **Drugs included in the model:** The ANPR proposes that in the first two years, the model would cover unspecified single-source drugs and biologics (i.e., products without generic competition) because this group of drugs accounts for a significant percentage of Part B expenditures. The model would be expanded over time to cover other drugs.

- **Geographic scope:** Providers in unspecified geographic regions selected by CMS would be required to participate in the IMI Model. CMS anticipates that the selected geographic areas would account for about 50 percent of Medicare Part B's spending on prescription drugs.

- **Timing:** CMS anticipates that it will issue a proposed rule in spring 2019. After a notice and comment period, CMS could then issue a final rule. CMS anticipates implementing its proposal in spring 2020.

Potential Unintended Consequences

If CMS issues a final rule that is consistent with the ANPR, it could have a variety of adverse ramifications on the delivery of healthcare in the United States and potentially the rest of the world:

- It is axiomatic that price controls almost always result in shortages. This scenario could easily arise as a result of the IPI Model. Some pharmaceutical companies may refuse to sell drugs at capped prices altogether or will sell only a limited volume of such drugs to Part B vendors.

- CMS may not attract sufficient interest from the drug-purchasing vendors that are the lynchpin of the IPI Model. CMS has not specified how much compensation vendors would receive, let alone whether it would be sufficient to make it profitable for them to take title to costly prescription drugs and undertake the variety of complex logistical tasks required for them to purchase and distribute prescription drugs. In any event, it may take a long time for those vendors to become operational. CMS previously attempted to implement a model that involved vendors purchasing Part B drugs (between 2005 and 2008), but that effort was unsuccessful. There may be significant disruptions to the distribution of Part B drugs if CMS attempts to operationalize the IPI Model before there are a sufficient number of vendors that are willing and able to implement it.

- Pharmaceutical manufacturers may seek to raise the international price benchmark either by raising prices in certain countries or by refusing to sell covered drugs to countries that will not agree to sufficient price increases. Pharmaceutical manufacturers will likely start making calculations regarding whether the benefits from sales in a country with lower reimbursement will exceed losses in the United States incurred as a result of a lower international price.

- The limited applicability of the IPI Model may distort the market in numerous ways. If, for example, the IPI Model covers certain Part B drugs but not others, providers will be incentivized to prescribe drugs not covered by the model because they will receive greater reimbursement. Similarly, if the IPI Model is applied in some markets and not others, there invariably will be arbitrage as entities seek to purchase drugs in markets covered by the IPI Model and seek to resell them in markets that are not covered by the IPI Model.

- The IPI Model may result in pharmaceutical companies deciding to shift R&D activities away from drugs covered by the Part B program to outpatient drugs that are not subject to price controls. As a result, there may be significantly less investment in drugs that are administered in outpatient clinical settings. That could have long-term public health consequences because drugs that require physician administration often treat serious illnesses.

Potential Legal Challenges

If CMS proceeds to issue a final rule that is consistent with the ANPR, the final rule may be subject to legal challenge on the grounds that CMS lacks the statutory authority to replace the statutory reimbursement formula with price controls. CMS claims that it has authority to implement the IPI Model under Section 1115A of the Social Security Act, a provision which authorizes CMS to develop test models and to waive statutory requirements where necessary to implement those models. However, it is far from clear that this authority extends to the imposition of price controls. Although one of Section 1115A's objectives is to reduce government expenditures, the focus of the statute is on developing new systems for delivery and coordination of patient care. This can be clearly seen in the fact that the statute includes a non-exhaustive list of 23 potential models, all of which involve methods of providing patient care. None of these models have anything to do prescription drug pricing.

Even if the ANPR were to be put into effect, affected pharmaceutical companies have the option to refuse to sell to CMS at capped prices. In such circumstances, patients could sue CMS for failure to satisfy its statutory obligation to provide reimbursement

for drugs that are reasonable and necessary to treat their illnesses. Patients may argue that CMS cannot evade that obligation by insisting on paying unreasonably low amounts for Part B drugs.

Potential Alternatives to the IPI Model

There are some indications that the Trump administration is using the IPI Model as part of its ongoing efforts to extract concessions from the pharmaceutical industry.

Shortly after the ANPR was announced, Food and Drug Administration ("FDA") Commissioner Scott Gottlieb was quoted at an HHS press conference as saying that the Administration might not pursue the ANPR if pharmaceutical companies agreed to shift certain Part B drugs into the Part D program. Although FDA does not have jurisdiction over drug pricing issues, Dr. Gottlieb has spoken about drug pricing periodically and has launched FDA initiatives aimed at reducing drug pricing through promoting competition. Dr. Gottlieb's comments appear to reference a proposal in a drug pricing "Blueprint" issued by the White House earlier this year to transition certain drugs from Part B to Part D to take advantage of the competitive aspects of the Part D program.

Part D plans are administered by private insurers, which employ Pharmacy Benefit Managers ("PBMs") to develop a formulary of drugs that are covered under the plan. PBMs can negotiate with a pharmaceutical company to include its drug on preferred tiers of the Part D plan's formulary—which would drive purchases of the drug—in return for the company's willingness to provide significant rebates to the plan. Part D plans thus can negotiate drug prices, whereas Part B plans must provide reimbursement based on the statutory formula discussed above. Earlier this year, Dr. Gottlieb noted that although moving certain drugs from Part B to Part D may be particularly appealing because, while historically many Part B drugs, such as TNF inhibitors and monoclonal antibodies, were one-of-a-kind therapies, there are now many therapeutically equivalent drugs in those classes. Part D plans would be able to capitalize on this development in negotiating prices for many drugs that are currently covered by Part B.

While Dr. Gottlieb and the Administration may be hoping that the threat of price controls will encourage the transfer of drugs from the Part B program to Part D, there would be obstacles to such a move. Federal statutes specify which drugs are covered by the Part B and D programs, and it is unclear whether CMS' waiver authority would apply to a demonstration project that switched drugs from one category to the other. Additionally, the Part D program currently only covers patient-administered drugs. The

program would have to be restructured to cover drugs administered in physician offices and hospitals.

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Pharmaceutical companies, providers and other constituencies can provide comments regarding, among other things, CMS' lack of authority to issue the type of regulation contemplated by the ANPR, the potential for the ANPR to disrupt the provision of life-saving Part B drugs to patients and the long-term ramifications of the imposition of price controls on future pharmaceutical research and development. Indeed, the ANPR may result in an unusual alignment of pharmaceutical companies, providers and patient groups, all of which may be adversely impacted by the proposal. Additionally, the pharmaceutical industry and other stakeholders may wish to consider whether it is feasible to engage the Trump administration in discussions about other possible measures.

Please do not hesitate to let us know if you have questions.

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