ELLIS HEALTH POLICY

MEMORANDUM

TO: Interested Parties

FROM: Philip Ellis, Ph.D.

DATE: January 8, 2021

SUBJECT: Effects of the Most Favored Nation Model for Part B Drugs

Recently, the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule that would implement substantial changes in the way that many drugs are paid for under Part B of Medicare. Federal payment rates would be tied to the lowest price for each drug in a set of developed countries (mostly in Europe), adjusted for differences in purchasing power – an approach labeled the Most Favored Nation (MFN) model.

In its regulatory impact analysis, CMS estimated that those MFN prices are currently about 65 percent lower than the prices now paid under Part B, on average. However, the agency's Office of the Actuary (OACT) estimated that drug manufacturers would be able to negotiate higher prices from those foreign purchasers such that the regulation would ultimately reduce Part B payment rates by about 25 percent. OACT also estimated that significant reductions in access to and use of Part B drugs would occur due to resulting market disruptions. Overall, OACT estimated that the MFN model would yield $91.2 billion in federal savings over the 2021-27 period (assuming that it was implemented on 1/1/2021). OACT also noted the considerable uncertainty surrounding its estimates.

I was asked by PhRMA to review and evaluate those estimates and to assess the effects of the MFN model on drug manufacturers' revenues from Medicare.[1] For reasons discussed below, I judged the OACT estimate to be toward the low end of the likely range of outcomes. I developed two additional scenarios and reached the following conclusions about them:

- **My central estimate is that the MFN model will reduce Part B prices by about 40 percent.** Federal spending will fall by about $185 billion over the 2021-27 period and drug manufacturers' revenues from Medicare sales will decline by about $365 billion – a 54 percent reduction relative to baseline projections. I estimate that access to and use of affected Part B drugs will decline by about one-third for care received from non-340B providers and by about 10 percent for care from 340B providers.

[1] The rule is available here: https://innovation.cms.gov/media/document/mfn-ifc-rule. Subsequent court decisions have delayed implementation of the MFN model. Nevertheless, I have used 1/1/2021 as the model's start date for my analysis in order to be comparable to OACT's estimate.

- **My high-end estimate is that the MFN model would reduce Part B prices by about 55 percent.** Federal spending would decline by about $240 billion over the 2021-27 period and manufacturers' revenues from Medicare sales would fall by about $490 billion – a 73 percent reduction. Reflecting greater market disruptions under this scenario, I estimate that access to and use of affected drugs would decline by about one-half for care from non-340B providers and by about 20 percent for care from 340B providers.

Background Information

I will assume that readers are familiar with the basic provisions of the MFN regulation and its impact analysis – as well as the prior policies that those provisions modify – and will not try to summarize them further here. Another source of useful information regarding the proposal and its estimated effects is a report issued simultaneously by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), Health and Human Services (HHS).[2]

In particular, Table 4 of the ASPE report shows the overall volume-weighted price ratios by country for the top 50 Part B drugs (those that would initially be subject to the MFN model). The relevant measure is the adjusted price ratio, which is adjusted for differences in per capita income and purchasing power across countries in the way that would occur under the rule. Among the relevant countries with GDP per capita that is at least 60 percent of the U.S. level, that ratio ranges from a low of 1.00 in Spain to a high of 2.27 in Korea.[3] Put another way, that table indicates that prices for Part B drugs are equal to U.S. prices in Spain, on average, once adjusted for purchasing power. But adjusted prices in South Korea are 44 percent of U.S. prices – with the other relevant countries falling in between Spain and South Korea.

Also of particular help is Table 10 in the rule itself, which shows baseline (pre-MFN) expenditures under the fee-for-service Medicare program for drugs included in the MFN model through 2027 – that last year in which that model would operate, according to CMS. Over the relevant period of 2021 to 2027, those expenditures are projected to total $338.8 billion. Of that total, $73.6 billion will be paid to providers obtaining drugs through the 340B discount program (who are already paid a lower rate by Medicare under current laws and regulations). Those figures include out-of-pocket (OOP) liabilities for Medicare beneficiaries for those Part B drugs, which generally amount to about 20 percent of the Medicare payment rate.

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[2] See Assistant Secretary for Planning and Evaluation (ASPE), *Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs* (November 2020), https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf.

[3] I excluded Luxembourg from my analysis on the grounds that it is both a very small country and a distinct outlier on drug prices. In the event that the MFN model is implemented, drug manufacturers would probably find it in their financial interest to cease selling certain drugs to Luxembourg, rather than having those prices determine the payment rate under Part B. As discussed in the text, such responses could also occur more broadly.

Importantly, those expenditure figures do not include payments for Part B drugs under the Medicare Advantage (MA) program, which currently accounts for about 45 percent of Part B enrollment – and which is projected to grow to about 53 percent of enrollment by 2027. Taking those expenditures into account, I estimate that spending under Medicare (including OOP costs) on affected Part B drugs will be $675 billion over the period from 2021 to 2027. I should note that the interim rule does not explicitly regulate payments for Part B drugs by MA plans. Even so, OACT estimated federal savings on MA because cuts in FFS costs reduce payment rates to MA plans. I have effectively assumed that MA plans would also reduce their payment rates for Part B drugs to roughly match the rates on the FFS side, which is largely what happens in MA with other payment rates for Part A and Part B services.

Scenarios Estimated

After reviewing the interim final rule and the ASPE report, I concluded that the OACT and ASPE estimates regarding the likely reduction in Part B prices resulting from the MFN model were probably too small. That is, **I judged that Part B prices for affected drugs would probably fall by more than 25 percent**. Instead, a 25 percent reduction seemed more like an estimate at the lower end of the likely range, in my judgment.

One factor in my thinking is that large increases in foreign prices would be needed to yield that outcome. Over the full set of relevant countries, the average increase would be roughly 20 percent. But for the countries with lower prices that would be affected, the average increase would be nearly 30 percent. Certainly, one would expect foreign prices to rise to some extent, because the MFN model effectively applies those prices to a much larger share of the market. In other words, the MFN model greatly increases the manufacturer's cost of giving a price concession to the country with the lowest (adjusted) price. But at the same time, manufacturers already have fairly strong incentives to limit price concessions to those countries – and yet are evidently unable to do so.

Of course, estimates of proposals that have no real-world analogue are inherently difficult to generate, and a wide range of outcomes is plausible.[4] Partly for that reason, I explored two addition scenarios: 1) a central estimate reflecting my conclusions about the

[4] Reflecting this uncertainty, the interim rule contained the following (quite notable) statement: "It should be noted that this model does not have a reliable precedent in the U.S. market; consequently, there is an unusually high degree of uncertainty in these assumptions, particularly with respect to the behavioral responses. To illustrate this uncertainty, three potential financial effects are included in this analysis; a full range of potential behavioral effects are presented under an Extreme Disruption scenario where non-340B utilization of affected drugs drops to zero percent and under a Pricing-Effects Only scenario where all currently projected utilization is assumed to be retained. The OACT estimate reflects one reasonable set of assumptions for potential changes in manufacturer, provider, and supplier behavior. Other estimates outside the range of the three scenarios could be reasonable as well, due to the wide range of potential responses." See page 182 (emphasis added).

expected effects (on average) of the MFN model on Medicare spending and manufacturers' Medicare sales; and 2) a high-end estimate of the effects that the regulation would have.

My thinking was informed by the following thought experiment. If foreign prices were to remain unchanged, Part B prices would fall by 65 percent, on average, as indicated in the rule. In that case, prices and costs for foreign countries would not rise at all; foreign counties, as a group, would be held harmless and drug makers would bear the full brunt of the MFN model's price reductions. At the other end of the spectrum, I thought, would be a scenario in which prices in Medicare and foreign countries were equalized at a level that essentially held manufacturers harmless globally – with increases in their foreign revenues roughly offsetting declines in their Medicare revenues. By my rough calculations, that balance point would be reached with prices that were below Medicare's current prices by 15 percent to 20 percent.[5]

For my central estimate, I assumed that the price negotiation between manufactures and affected countries would essentially "split the difference" between those two endpoints. That is, I assumed that Part B prices would fall by about 40 percent. This outcome is sometimes called the "Nash Bargaining Solution" after the Nobel Prize winning economist John Nash who developed the (more sophisticated) bargaining theory behind it.[6] It also reflects observational data indicating that 50-50 splits of gains or losses are a common outcome of bargaining, for various hypothesized reasons. For the Medicare analysis, I further assumed in my central estimate that utilization would ultimately fall by about one-third for non-340B providers and by about 10 percent for 340B providers. Those are larger declines than OACT had estimated, to reflect the larger price decrease.[7]

As noted above, I essentially adopted OACT's estimates for the changes in prices and utilization in my low-end scenario – with a decline in Part B prices of about 25 percent and a decline in non-340B utilization of about 20 percent. For my high-end scenario, I assumed a decline in Part B prices of about 55 percent. From the rule, it appeared that OACT estimated a decline in utilization among non-340B providers that would be about four-fifths as large as the price reduction. Using that relationship as a rule of thumb, I assumed under my high-end scenario that utilization of Part B drugs would be reduced by about 50 percent among non-340B providers (and by about 20 percent among 340B providers).

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[5] These calculations are based on the data in Table 4 of the ASPE report and also reflect the assessment noted in the rule that "at this point the market size of the included countries is roughly the size of the Medicare Part B market for many of the MFN Model drugs." See page 192.

[6] See, for example, https://en.wikipedia.org/wiki/Bargaining_problem.

[7] As discussed in the rule, some decline in access and utilization is likely to occur because the proposal reduced only what Medicare pays providers for Part B drugs; it does not establish mechanisms for providers to obtain those drugs at prices at or near Medicare's payment rates. (An earlier version of the proposal would have established a vendor system that was intended to achieve that objective.) In its central estimates, CMS assumed that utilization of affected drugs through 340B providers would not be substantially affected. 340B providers are able to obtain Part B drugs at much lower prices and are already paid a reduced rate for those drugs by Medicare. As a result, the estimated impact on utilization through those providers was much smaller.

Estimated Effects of the MFN Model

My estimates of the MFN model's effects under all three two scenarios are shown in Table 1 below. Under the central estimate, federal savings would be about $185 billion, while the decline in Medicare revenues for manufacturers would be about twice as large, around $365 billion. The difference between federal savings and costs to manufacturers largely reflects the fact that Medicare beneficiaries (or their sources of third-party insurance) will capture some of the savings via reduced out-of-pocket liabilities and reduced premiums for Part B and for Medigap plans. The figures also capture reductions in federal Medicaid payments for Medicare's out-of-pocket costs and premiums (with some Medicaid savings also accruing to states). The effects under the high-end estimate are, not surprisingly, much larger – and the effects under the low-end estimate are correspondingly lower.[8]

Table 1. Estimated Effects of MFN Model Under Different Scenarios
Effects over 2017-2027 in $ Billions

SCENARIO	Federal Savings	Reduction in Manufacturer Revenues from Medicare Sales	Baseline Medicare Sales	Percentage Reduction in Medicare Sales
Low-End Estimate	$110	$220	$675	33%
Central Estimate	$185	$365	$675	54%
High-End Estimate	$240	$490	$675	73%

The figures also reflect my estimates of the MFN model's effects on payments to MA plans. As noted above, lower costs in fee-for-service Medicare translate into lower federal payments to those plans – an effect that was incorporated into the rule's regulatory impact analysis. That analysis was silent, however, on the issue of what providers would ultimately be

[8] My low-end estimate of federal savings is close to OACT's estimate of about $90 billion. It is worth noting that OACT also generated estimates for two other scenarios: 1) a "Pricing Effects Only Illustration" in which utilization would not decline; and 2) an "Extreme Disruption Illustration" in which "it is assumed that non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model" (see page 187 of the rule). In the first scenario, federal savings were estimated at $165 billion, and in the second scenario they were estimated at $302 billion. Broadly speaking, those findings are similar to my central and high-end estimates, respectively.

paid by MA plans for Part B drugs. I assumed – for purposes of estimating the effects of the MFN model on manufacturers' revenues – that MA plans would pay rates roughly equal to Medicare's fee-for-service rates. In part, that conclusion reflects the fact that payment rates under MA plans for doctors and hospitals are generally similar to fee-for-service rates.[9] Additionally, it would be difficult for MA plans to operate profitably if their revenues declined sharply but their costs did not.

In conclusion, it bears repeating that any estimates of the effects of the MFN model are subject to more than the usual degree of uncertainty regarding policy initiatives, given its unprecedented features. A wide range of responses – by drug manufacturers, providers, other countries, and beneficiaries – could plausibly occur that would substantially affect federal payments, revenues for manufacturers, care for Medicare enrollees, and other outcomes of interest. In particular, the risk of unintended consequences and unanticipated effects is inherently greater with such an endeavor into uncharted waters.

[9] See Congressional Budget Office, "An Analysis of Private-Sector Prices for Hospital Admissions: Working Paper 2017-02" (April 4, 2017), https://www.cbo.gov/publication/52567; and "An Analysis of Private-Sector Prices for Physicians' Services: Working Paper 2018-01" (January 12, 2018), https://www.cbo.gov/publication/53441.