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January 25, 2021

Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-5528-IFC

Dear Ms. Richter:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) interim final rule (IFR) entitled "**Most Favored Nation (MFN) Model**" published in the *Federal Register*, vol. 85, no. 210, pages 76180 to 76259. We appreciate your staff's work on the IFR, particularly considering the competing demands on the agency.

In the IFR, CMS describes a model that the agency will test through the Center for Medicare & Medicaid Innovation (CMMI) in all states and U.S. territories over a 7-year period, from January 1, 2021, through December 30, 2027. The MFN Model will replace the payment rates established under section 1847A of the Social Security Act (i.e., the average sales price payment method) for a select list of drugs and biologicals (hereafter referred to as *drugs*) that have the highest amounts of Medicare spending under Part B with a system that would base Part B drug payment rates on drug prices from other developed nations and test an alternative add-on payment. Specifically, the model will:

- Be mandatory for most Part B drug providers (hereafter referred to as *MFN provider participants*) such as physician offices, hospital outpatient departments (including 340B hospitals), ambulatory surgical centers, and home health agencies, and will exclude certain other providers (e.g., critical access hospices, cancer hospitals, rural health clinics, and federally qualified health centers);
- In the model's first year (2021), will include the top 50 Part B drugs in terms of allowed charges in the baseline period (2019); CMS will add drugs to the model annually to include

drugs that rise to be among the top 50 drugs based on updated annual Part B spending (using data with a 2-year lag) and, to ensure consistency, drugs already included in the model will remain in the model (with limited exceptions);

- Exclude certain drugs such as vaccines, immune globulin, compounded products, and drugs with COVID-related emergency use authorization from the Food and Drug Administration (FDA);
- Be phased-in over 4 years with payment in:
 - Year 1 (2021) equal to 75 percent of each product's average sales price (ASP), 25 percent of the MFN price, and a large, fixed add-on payment (which does not vary across MFN drugs),
 - Year 2 equal to 50 percent of each product's ASP and 50 percent of the MFN price plus a large, fixed add-on payment,
 - Year 3 equal to 25 percent of each product's ASP and 75 percent of the MFN price plus a large, fixed add-on payment, and
 - Year 4 (2025) and subsequent years equal to 100 percent of the MFN price plus a large, fixed add-on payment;
- Establish the MFN price using drug prices of Organisation for Economic Co-operation and Development (OECD) countries with a gross domestic product (GDP) that is 60 percent or more of the U.S.'s GDP; and
- Use international pricing data stated in U.S. currency that is obtained from publicly available data sources.

The Commission commends the agency for its efforts to reduce the prices Medicare pays for Part B-covered drugs. Obtaining good value for Medicare's program expenditures is a central tenet of the Commission's work on Medicare payment policy. The Commission is concerned about the prices Medicare pays for drugs, and we have made recommendations in the last several years that would improve Medicare payment policy for provider-administered drugs within Medicare Part B (2017) and for outpatient drugs delivered by private plans in Part D (2016 and 2020).¹ We believe both sets of recommendations would improve Medicare payment incentives while using market competition to reduce or constrain growth in drug prices.

Although we share CMS's goal of reducing drug prices paid by Medicare, the Commission has significant concerns about the structure and potential effects of the MFN model on beneficiary access to needed drugs and urges the agency not to proceed with its implementation. The model's design does not ensure beneficiaries' continued access to Part B drugs because it places excessive

¹ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system Medicare*. Washington, DC: MedPAC.

financial risk on providers, with minimal demands on manufacturers, and thus could unintentionally affect providers' prescribing patterns by:

- Curtailing some providers' ability or willingness to furnish MFN drugs under Part B, which would reduce some beneficiaries' access to care,
- Creating incentives for providers to prescribe drugs that are outside the MFN Model, particularly in those instances in which some drugs in a therapeutic class are excluded from the model, and
- Creating incentives for dosing regimens that include more frequent administrations due to the large magnitude of the fixed add-on.

We acknowledge that there may be a role for pricing data from other countries to help inform Medicare's payment for drugs. Nonetheless, for the reasons we list below, we contend that the MFN Model manifests a number of serious flaws that will preclude the model from achieving its intended results, and devoting agency resources to this effort will delay the pursuit of potentially more productive approaches to addressing the problem of unsustainable spending growth for drugs under Medicare Part B.

Instead, the Commission suggests that the agency use approaches (which would require changes to the statute) that we recommended to slow price growth and to bring down the prices Medicare pays for existing Part B drugs including: (1) establishing an ASP inflation rebate, which would protect beneficiaries and the Medicare program from the potential for rapid price increases for individual drugs and (2) using consolidated billing codes for reference biologics and their biosimilars, which would increase competition among these products. We believe our recommended policies would be an important step forward, but we also acknowledge that additional steps would be needed, and MedPAC intends to pursue further approaches to address high launch prices and to improve the price competition and value for Part B-covered drugs.

The remainder of this letter offers comments on certain aspects of the MFN Model. We focus on the following concerns:

- Beneficiaries' access to care may be reduced under the MFN Model
- Financial risk is placed on providers rather than manufacturers
- Publicly available data sources may not provide consistent and accurate sales data to set the payment rate of MFN drugs
- The large magnitude of the fixed add-on payment could create adverse incentives for providers
- There is potential for conflicting incentives for manufacturers and providers because some drugs within a therapeutic drug class will be included in the model while other drugs will not

Beneficiaries' access to care may be reduced under the MFN Model

The IFR will reduce MFN provider participants' payments for Part B drugs, with a four-year phase-in, to the lowest GDP-adjusted price among OECD countries with a GDP that is at least 60 percent of U.S. GDP. The rule does not place any requirements that manufacturers offer MFN drugs to physicians or hospitals at the price Medicare will pay under the MFN Model.

The IFR includes an impact estimate by the CMS Office of the Actuary (OACT), as well as an analysis by the Assistant Secretary of Planning and Evaluation (ASPE) for the Department of Health and Human Services. OACT's estimate assumes there will be a reduction in Part B drug utilization in response to the model because the actuaries expect some manufacturers to continue their current pricing strategies under the model and not lower prices. Due to this assumption, Medicare's actuaries expect that some providers under Part B will stop administering certain drugs to some Medicare beneficiaries, given the cost relative to the payment.² Specifically, the Medicare actuaries' model assumes Part B drug utilization by non-340B providers would be reduced by 20 percent in the first year to 30 percent in year 7. Some of this decline (11 percent in both year 1 and year 7) reflects a shift to other providers (340B providers or providers not included in the MFN Model, like critical access hospitals) and some of this decline (9 percent in year 1 to 19 percent in year 7) reflects reduced utilization (what the IFR refers to as "no access"). OACT also notes that the MFN 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."³ To help illustrate the range of effects, OACT estimates two additional scenarios: a pure pricing effect scenario (where Part B drug utilization is not reduced) and an "extreme disruption" scenario (where utilization by non-340B providers is eliminated entirely).

In contrast, ASPE's analysis does not include a reduction in utilization of drugs, in part because they assume "...that manufacturers prefer to sell their products, even at lower prices, as long as net revenues (net sales prices minus production and distribution costs) remain positive; and [the analysis also assumes] that providers and suppliers are committed to maintaining effective treatments for beneficiaries either by negotiating lower prices, accepting reduced revenue, or finding effective Medicare Part B or Part D alternative treatments."^{4, 5}

Comment

The Commission is very concerned about the potential reductions in beneficiary access that may occur under the model. CMS indicates the agency will monitor beneficiary access and, based on the literature and interviews with experts, expects providers not to turn away beneficiaries needing

² The Medicare actuaries' analysis in the IFR states that "while there are significant savings as a result of this model, a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."

³ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2020. Most Favored Nation (MFN) Model. Interim final rule. *Federal Register* 85, no. 229 (November 27): 76180–76259.

⁴ Centers for Medicare & Medicaid Services. 2020, op. cit.

⁵ ASPE's analysis is based on a review of the literature and economic theory, discussions with experts, and analysis of the market and competitive dynamics at the individual drug level for the 50 drugs in their model.

high-complexity care. But, the IFR does not require manufacturers to reduce their prices to the MFN level, and it is unclear what CMS will do if some manufacturers do not do so.

OACT's and ASPE's analyses respectively reach different conclusions about the effects of the MFN Model on beneficiary access to Part B drugs. OACT assumes that Part B drug utilization will be reduced because some manufacturers will refuse to lower their products' prices and some providers will stop offering those products to Medicare beneficiaries. By contrast, ASPE assumes Medicare beneficiaries will maintain access either as a result of manufacturers lowering their price or beneficiaries shifting to alternative providers or products.

The effect of the MFN model on beneficiary access is likely to vary by drug. A manufacturer of a Part B drug with greater Medicare market share may be less likely to discontinue marketing its drug to MFN provider participants. To maintain market share, such a manufacturer may be more likely to lower its drug price to the MFN drug payment amount. On the other hand, a manufacturer of a Part B drug with low Medicare market share may be more willing to discontinue marketing its drug to MFN provider participants. The IFR notes that a manufacturer might refuse to negotiate lower prices for its drug if doing so threatens its ability to sell in other segments of the U.S. at a positive margin.

The extent to which therapeutic alternatives exist for a given product may also affect manufacturers' willingness to reduce their prices. For products with multiple therapeutic alternatives, providers may have leverage to obtain significant price concessions and acquire the products for prices that are within the MFN payment amount. For products without therapeutic alternatives entirely, or without therapeutic alternatives for certain subpopulations, providers may have less leverage to secure substantial discounts. Efforts to address pricing of products without therapeutic alternatives is challenging, but the IFR lacks tools to bring leverage in those situations.

In addition to the potential for lack of access to some products, OACT's estimate assumes some patients will shift to excluded providers or 340B providers, which raises concerns about disruptions in patient care. For example, a patient receiving chemotherapy from an oncology practice may have to switch to a provider not subject to the MFN Model if their oncology practice is unable to obtain needed drugs from the manufacturer at the MFN-determined price. The timeframe for implementation (less than two months from the release of the IFR) of such a substantial change in policy raises additional concerns about disruptions to beneficiaries' care. Patients who need to seek out other providers may experience delays in treatment; for certain conditions, such as cancer, such a delay in care could be detrimental to patients' health outcomes. Providers who furnish drugs covered under the MFN Model will need to modify their billing systems and the Model may affect how they order and purchase the drug and manage their drug inventory.

Financial risk is placed on providers rather than manufacturers

The MFN Model as designed seeks to lower prices substantially using pricing metrics outside the U.S. market, and it puts financial risk on providers to negotiate with manufacturers to obtain prices at those levels. The MFN Model places no limits on the prices set by pharmaceutical

manufacturers, who ultimately have exclusive control over their products' pricing. As reflected in the OACT estimate, it is possible that some manufacturers will be unwilling to change their current pricing strategies (because of their marketing strategy as discussed in the prior section) and that providers will face a choice of whether to provide the treatment when Medicare's payment for the drug could be less than the cost to acquire the product.

To deter manufacturers from making up for any price concessions under the model by increasing drug prices for U.S. patients outside the model, CMS created policies that will accelerate the phase-in of the model, or if already fully implemented, reduce the MFN payment rate under certain circumstances. CMS has stated that the prices obtained for drugs furnished to beneficiaries included in the MFN Model will be excluded from ASP, so ASP will reflect only prices for units furnished to U.S. patients outside the model. If ASP for a product increases faster than both the Consumer Price Index For All Urban Consumers (CPI-U) and the MFN price, CMS will adjust the phase-in or reduce the MFN payment rate. For example, for 2nd quarter 2021, if a drug's ASP increases at a faster rate than CPI-U and the MFN price for the relevant period, the phase-in formula will be 30 percent MFN price and 70 percent ASP for that quarter and subsequent quarters of that year (instead of 25 percent and 75 percent, respectively).⁶ Further, after the full phase-in of the MFN prices is reached in the fourth year, if ASP's cumulative rate of growth exceeds that of CPI-U and the MFN price, CMS will reduce the MFN Model payment rate by the difference in the growth rate.

The model includes a financial hardship exemption for providers. To qualify, the provider must: (1) show that they exhausted all reasonable methods to obtain drugs at the MFN payment rate, (2) furnish data on their average net acquisition cost for MFN drugs separately for drugs furnished to model participants and to other patients, and (3) explain any additional remuneration they received from drug manufacturers or supply chain entities that do not constitute price concessions. In addition, the provider must have experienced a reduction in their per beneficiary Medicare fee-for-service payments for separately payable Part B drugs that is greater than 25 percent of the provider's per beneficiary total Medicare Part A and Part B fee-for-service payments during the previous year. Providers that meet these criteria will receive a reconciliation payment that is equivalent to the amount that the Part B drug spending per beneficiary exceeded the aforementioned 25 percent threshold.

Comment

The Commission is concerned that the MFN Model places excessive financial risk on providers, potentially risking their patients' access to needed pharmaceutical therapies while placing minimal financial risk on drug manufacturers, the entities exclusively and wholly responsible for setting drug prices. Under Medicare Part B, manufacturers are solely responsible for setting the price of new drugs, and for increasing the price of existing drugs.

⁶ If phase-in could be further accelerated if ASP growth exceeds the growth in CPI-U and the MFN price in subsequent quarters.

The MFN Model does not include any tools to increase providers' leverage with manufacturers, other than the prospect that providers may choose not to purchase the product if the price is greater than Medicare's payment amount. While this approach may work for products with therapeutic alternatives where manufacturers may be concerned about losing volume to other products or products with large Medicare market share, it is less clear it would work well for products with limited alternatives or products with low Medicare market share. In the Commission's June 2017 recommendation on the drug value program (a vendor model), the Commission contemplated placing requirements on manufacturers, as a condition of their products' Medicare coverage, that they offer products to Medicare providers at prices no higher than certain pricing benchmarks. These type of manufacturer requirements could help put some of the financial risk on manufacturers rather than on the provider.

The Commission is very concerned that the MFN Model explicitly sets criteria where Medicare's payment rate to providers for a Part B drug furnished in the model is reduced if the manufacturer increases U.S. prices outside the model faster than certain inflation benchmarks. This linkage is concerning for two reasons. First, it is unclear why Medicare payments inside the model should be reduced if manufacturers increase prices for drugs furnished to patients outside the model (many of whom are not Medicare beneficiaries and are covered by other insurers). Second, the Commission contends that manufacturers, not providers, should bear the financial risk for drug price inflation over time. In the Commission's 2017 recommendation for an ASP inflation rebate, the Commission structured the policy to put financial risk for price growth on the manufacturer, requiring the manufacturer to pay a rebate if ASP increases faster than an inflation benchmark. The Commission views the manufacturer rebate as a more desirable approach than the payment rate limits that would be imposed under the MFN Model, because it would place the risk on manufacturers instead of providers.

To address the financial risk on providers from the MFN Model, CMS has included a hardship exemption policy; however, that policy is unlikely to provide meaningful assistance to providers. Applying for such an exemption will require significant effort from providers. In addition, the threshold for meeting the policy is substantial, and financial assistance would become available to a provider only after the year has ended and they have applied for assistance and been found to qualify. According to OACT's estimate: "We expect that few, if any, providers will have annual losses above this level, and that those who do may be insolvent and therefore unable to obtain retrospective hardship payments. We note in this regard that a hypothetical provider could experience revenue losses of 24.9 percent per year in each of the model's seven years, resulting in an 86.5 percent loss of revenue in Performance Year 7."⁷

Publicly available data sources may not provide consistent and accurate sales data to set the payment rate of MFN drugs

CMS will use publicly available data sources that contain international drug pricing information stated in U.S. currency. Although the IFC does not include names of the specific data sources from

⁷ Centers for Medicare & Medicaid Services. 2020, op. cit.

which CMS will draw international drug prices to determine MFN drug prices,⁸ it does indicate that the agency will use the following hierarchy to determine which source to use:

- The first preference will be a data source that includes sales and volume data for the applicable ASP calendar quarter from at least one relevant country. The relevant countries are non-U.S. OECD member countries with GDPs per capita that are at least 60 percent of the U.S. GDP per capita. CMS has identified 22 relevant countries, using the CIA World Factbook to determine the per capita GDP for each OECD country.⁹
- The second preference will be a data source that does not have sales and volume data for the applicable ASP calendar quarter but contains sales and volume data for any prior calendar quarter beginning on or after October 1, 2019, from at least one relevant country.
- The third preference will be the data used by CMS to determine the most recent MFN drug price used to calculate an MFN drug payment amount posted on the model's website.
- The fourth preference will be a data source with ex-manufacturer price data (which represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof) for the applicable ASP calendar quarter from at least one relevant country.¹⁰
- The fifth preference will be a data source with list price data for the applicable ASP calendar quarter from at least one included country.

Comment

If designed effectively, a model that benchmarks a drug's payment rate to international prices that are lower (on average) may initially result in lower drug spending.¹¹ Such a model could use data from publicly available sources. However, the Commission is concerned that, over time, manufacturers and their purchasers in other countries are likely to implement pricing and marketing strategies to counteract the effects of the MFN Model relying on existing sources for international pricing data.¹²

For example, manufacturers can list high prices in reference countries while providing those countries with confidential rebates or discounts. According to researchers, accurate measurement

⁸ The IFR names one potential data source—IQVIA's proprietary MIDAS dataset—in an illustrative example.

⁹ The 22 relevant countries identified by CMS are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, the Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

¹⁰ The ex-manufacturer price is similar to Medicare's payment based on wholesale acquisition cost, which is the manufacturer's list price for a drug paid by wholesalers or direct purchasers in the U.S.

¹¹ Persson, U. and B. Jonsson. 2016. The end of the international reference pricing system? *Applied Health Economics and Health Policy* 14, vol. 1: 1–8.

¹² Espin, J., J. Rovira, and A. O. de Labry. 2011. *WHO/HAI project on medicine prices and availability*. Working paper 1: External reference pricing. World Health Organization and Health Action International.

of transaction (net) prices obtained through publicly available international reference pricing (IRP) sources may be problematic due to the use of confidential rebates and other risk- and cost-sharing measures between manufacturers and payers/countries. Indeed, such confidential (off-invoice) rebates may be preferred by manufacturers to reductions in list prices, which would spill over to other countries through IRP.¹³ Because off-invoice rebates and other confidential agreements are not reflected in (publicly) available drug prices, payers may ultimately reference inaccurate higher prices.¹⁴ Docteur argues that IRP may inflate manufacturers' list prices.¹⁵

Both OACT's and ASPE's impact analysis in the IFR speak to the challenges of using international reference pricing over a multi-year period. For example, the Medicare actuaries assume that manufacturers will raise their published price in other countries beginning in the second year of the model to limit the size of the discount off of ASP that the model achieves. ASPE also points out that "observed prices" in other countries will likely increase, but this does not "mean that net prices will necessarily increase as countries will try to find ways to prevent spending increases while limiting disruption in their drug markets."¹⁶ In addition, ASPE assumes that for new drugs launched after the model begins, manufacturers will adjust their international pricing so that the price achieved for new products under the model will be the same as ASP absent the model.

CMS has noted other challenges in relying on available data sources including:

- The data sources used to obtain pricing data can vary across drugs within a given calendar quarter and for a given drug over time. For example, CMS acknowledges that: "It is possible that we will use different data sources for different drugs over different quarters. We will use the data as available from the data source, and we will not make adjustments to account for differences between the data sources or for confidential rebates."¹⁷ In addition, in a given calendar quarter, the pricing information across the MFN drugs will vary, representing a mix of list prices, ex-manufacturer prices (sometimes called the ex-factory price) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. The agency also acknowledges that confidential manufacturer rebates will not likely be accounted for within these data; therefore, existing sources for international drug sales data may overstate actual prices realized by manufacturers.

¹³ These include product-specific rebates and broader provisions for price rollbacks or rebates if drug expenditures exceed targets. Danzon, P. M. 2018. Differential pricing of pharmaceuticals: Theory, evidence and emerging issues. *PharmacoEconomics* 36, vol. 12: 1395–1405.

¹⁴ Young, K. E., I. Soussi, and M. Toumi. 2017. The perverse impact of external reference pricing (ERP): A comparison of orphan drugs affordability in 12 European countries. A call for policy change. *Journal of Market Access & Health Policy* 5, vol. 1: 1–11.

¹⁵ Docteur, E. 2008. Value for money and valued innovation: A trade-off or mutually compatible goals? Presented at Organisation for Economic Co-operation and Development high-level symposium on pharmaceutical pricing policy. October 27. <https://www.oecd.org/els/health-systems/41593281.pdf>.

¹⁶ Centers for Medicare & Medicaid Services 2020, op. cit.

¹⁷ Centers for Medicare & Medicaid Services 2020, op. cit.

- Difficulty in identifying the same product across countries. Manufacturers sometimes launch the same products in different countries using different commercial names, pharmaceutical formulations, dosages, and vial and pack sizes.¹⁰ Indeed, marketing nonidentical products may be a technique used by manufacturers to counteract the use of IRP. Thus, IRP may promote minor product differentiation (with no therapeutic advances).¹⁸

Another concern is that prices from existing data sources may not be measured consistently. Toumi and colleagues state that comparing prices across countries is difficult because available pricing data are varied. For example, pricing data could vary depending on whether they reflect the pharmacy's purchasing price, pharmacy's retail price, or the manufacturer's list price. Adjusting heterogeneous prices can be problematic.¹⁹ In its report, ASPE states that some countries' data are collected at the hospital level, while other countries' data are collected at a higher level such as the wholesale level.²⁰

The large magnitude of the fixed add-on payment could create adverse incentives

The MFN Model will replace the 6 percent add-on to ASP in the current Part B drug payment system with a fixed dollar add-on payment amount of \$148.73 for each dose of a drug in the MFN Model. CMS based this add-on amount on 6.1224 percent of the applicable ASPs for 2019 claim lines for the MFN Model drugs that CMS has selected for the first year of the MFN Model. CMS will increase the dollar add-on amount each quarter using the CPI-U. The payment that MFN participants will receive for each MFN drug furnished will be the drug's MFN payment rate plus the fixed add-on payment. Beneficiaries will not be responsible for cost sharing for the fixed add-on portion of the payment.

CMS states that: "The goals for the model's approach to the alternative add-on payment are to test an innovative way to pay the add-on portion of the drug payment, boost add-on revenue for MFN participants on average based on historical overall add-on revenue, create an incentive to encourage appropriate drug utilization by breaking the link between the manufacturer's drug price and the calculation of the Medicare Part B payment for the add-on amount, and remove or reduce the incentive to furnish higher-cost drugs inherent in the current methodology."²¹

Comment

The Commission has concerns about the magnitude of the fixed add-on payment and the adverse incentives that could be associated with a fixed add-on of this size. To the extent the agency believes an add-on is needed in the MFN model, we urge the agency to carefully consider what

¹⁸ Docteur 2008, op cit.

¹⁹ Toumi, M., C. Remuzat, A-L. Vataire, et al. 2014. External reference pricing of medicinal products: Simulation-based considerations for cross-country coordination. European Union.
https://ec.europa.eu/health/sites/health/files/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf.

²⁰ Assistant Secretary for Planning and Evaluation. 2018. *Comparison of U.S. and international prices for top Medicare Part B drugs by total expenditures*. Washington, DC: ASPE.

²¹ Centers for Medicare & Medicaid Services 2020, op. cit.

magnitude of fixed add-on is appropriate. As discussed in the Commission's June 2016 report, a large fixed add-on could create incentives for dosing regimens that include more frequent administrations and thus more add-on payments.²²

CMS's analysis suggests that, for some specialties, add-on payments will increase substantially. For example, CMS's analysis indicates add-on payments will increase for ophthalmology (140 percent), internal medicine (4 percent), and rheumatology (9 percent). The IFR does not sufficiently explain why the add-on payment should increase substantially for some specialties, nor does it define the purpose of these increased add-on payments. The IFR states that "although the alternative add-on payment was designed to hold MFN participants harmless based on current revenue to the greatest extent possible, . . . some specialties will benefit from a higher aggregate add-on payment amount, while for other specialties some portion of such specialties will have a decrease in aggregate add-on payment."²³ In the Commission's view, creating an add-on payment for the purposes of holding providers harmless is inconsistent with the principle of setting payment rates at a level that reflects actual costs.

Under current policy, Medicare pays providers for the costs associated with furnishing drugs through its payment for drug administration services under the physician fee schedule and outpatient prospective payments system. If the large fixed add-on is meant to compensate for perceived insufficiencies of the payment rates associated with drug administration, those costs would be better addressed through adjustments to Medicare's payment rates for drug administration services under the physician fee schedule and outpatient hospital prospective payment systems. For example, the agency could examine whether the current drug administration payment rates accurately capture the costs associated with drug administration services and make adjustment to those rates if the analysis suggests it is warranted. To extent that the agency believes an add-on payment is needed in the MFN model beyond what is paid for the drug itself and for drug administration services, we would urge the agency to consider a more modest fixed add-on so as to not influence the prescribing patterns of MFN provider participants. CMS should also explain the purpose of a more modest fixed add-on under the MFN Model.

Potentially conflicting incentives for manufacturers and providers because some drugs within a therapeutic drug class will be included in the model while others will not

In the first year of the MFN Model (CY 2021), the list of drugs covered under the MFN Model will include 50 drugs currently covered under Medicare Part B, identified by their Healthcare Common Procedure Coding System (HCPCS) codes. The initial list of 50 MFN Model drugs will include drugs that have the 50 highest aggregated Medicare Part B allowed charges in the baseline period, which is 2019. CMS will update the list of MFN Model drugs annually. For the second year of the MFN Model (2022), CMS will re-evaluate which drugs had the 50 highest aggregated Medicare Part B allowed charges, using data from 2020 claims. If any of the 50 drugs with the highest aggregated allowed charges in 2020 are not on the list of the 50 MFN Model drugs for

²² Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system Medicare*. Washington, DC: MedPAC.

²³ Centers for Medicare & Medicaid Services 2020, op. cit.

2021, CMS will add those drugs to the 50 drugs on the initial list of MFN Model drugs. In each subsequent year, CMS will use the same method to add drugs to the list of MFN Model drugs. However, CMS will not remove any drugs that were already on the list of MFN Model drugs. Therefore, the list of MFN Model drugs will always include at least 50 drugs, and drugs will be added but never removed from this list, with the following exceptions:

- Drugs permanently withdrawn from the U.S. market;
- Drugs that have a HCPCS code that has been terminated and not replaced; and
- Drugs that have a HCPCS code that include a generic drug or a drug with an emergency use authorization or FDA approval for treatment of COVID-19.

Comment

The Commission is very concerned that not all drugs within a given therapeutic class will be included in the model. For example, in the first calendar quarter of the model:

- Among the erythropoiesis-stimulating agents, biologics used to stimulate production of red blood cells, epoetin alfa (reference product) and darbepoetin will be included in the MFN Model while epoetin beta and epoetin alfa (biosimilar product) will not be included in the model.
- Among the more than 10 viscosupplement products in which hyaluronate is used to treat osteoarthritis of the knee, only one product—Orthovisc—is included in the MFN Model, while the rest of the viscosupplement products will not be included in the model.

The Commission contends that Medicare should pay similar rates for similar care. Consistent with this principle, if Medicare is seeking lower prices via the MFN Model for some products in a therapeutic class, it would be appropriate to take the same approach for all products in that class by including them in the model. In addition, having only some drugs within a therapeutic drug class included in the MFN Model could result in conflicting incentives for both manufacturers and providers. For example:

- Manufacturers could alter pricing strategies for non-MFN drugs. Manufacturers may modify pricing to stay just below the top 50 in spending to remain outside the model.
- To the extent clinically possible, providers might switch beneficiaries from MFN drugs to non-MFN drugs with similar health effects, effectively bypassing the model and reducing the potential for savings.

Because there is a 2-year lag in the data CMS uses to identify the top 50 drugs, new drugs will be outside the model for at least the first two years on the market, while existing products in the same therapeutic class may be in the model, creating incentives for providers to move to new, potentially more expensive products. In addition, this could create incentives for manufacturers to

launch new “me-too” products (including drugs approved under the FDA’s 505(b)(2) pathway) that are similar to existing products, as a way to bypass the model.

Conclusion

Reducing the prices Medicare pays for drugs is a crucial priority for the Medicare program. High prices translate into unnecessary added costs borne by beneficiaries and taxpayers, and they contribute to concerns about the financial sustainability of the Medicare program. Although the MFN Model’s goals of lowering Part B drug prices are commendable, the Commission has substantial concerns about the implications of the model for beneficiary access and urges CMS not to proceed.

CMS should instead pursue policies recommended by the Commission that are aimed at achieving our shared goal of obtaining the best value possible in Medicare’s payment systems for drugs:

- Implement an inflation rebate under which the manufacturer bears the financial liability if the price of a drug rises higher than an inflation benchmark, which would protect the Medicare program and beneficiaries from the potential for rapid price increases for individual products.
- Establish consolidated billing codes for reference biologics and biosimilars, which would spur price competition among these products.

While we believe these two policies would be an important step forward, we acknowledge that additional approaches are needed to address high launch prices and to improve the price competition and value for Part B–covered drugs.

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission’s Executive Director, at 202-220-3700.

Sincerely,



Michael E. Chernew, Ph.D.
Chair