



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS-5528-IFC]

RIN 0938-AT91

Most Favored Nation (MFN) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) implements the Most Favored Nation (MFN) Model, a new Medicare payment model under section 1115A of the Social Security Act (the Act). The MFN Model will test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as “drugs”) with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

DATES: Effective date: These regulations are effective on [Insert the date of publication in the **Federal Register**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-5528-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5528-IFC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5528-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Andrew York, 410-786-7400.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments

received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

I. Executive Summary

A. Purpose

High drug prices are impacting the wallets of Medicare beneficiaries, especially during the Coronavirus disease 2019 Public Health Emergency (PHE). Increases in drug prices are accelerating at a rate that significantly outpaces the growth in spending on other Medicare Part B services, and prices in the United States (U.S.) for most Medicare Part B drugs with the highest Medicare spending far exceed prices in other countries. Specifically, drugs have consistently been a major contributor to the overall Medicare Part B spending trend. Medicare Part B Fee-For-Service (FFS) spending for separately payable physician-administered drugs and drugs furnished in a hospital outpatient department represented about 11 percent of Medicare Part B FFS benefit spending in 2015, but accounted for about 37 percent of the change in Medicare Part B FFS benefit spending from 2015 to 2020, and spending on these Medicare Part B FFS drugs increased to represent roughly 14 percent of Medicare Part B FFS benefit spending in 2019.¹ In addition to the continued growth in spending, the U.S. already pays almost twice as much on average as other developed countries pay. In one analysis of 27 drugs, acquisition costs in the U.S. were 1.8 times higher than in comparator countries.² A more recent analysis using the prescription drugs and countries in the MFN Model suggests Medicare Part B paid at least 2.05 times as much as other higher-income countries in 2018.³ The

¹ 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Accessed via: <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>

² "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

³ El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices>).

Centers for Medicare & Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is taking action on President Trump's goal to lower drug costs and seeking to realign financial incentives by implementing the Most Favored Nation (MFN) Model as described in this IFC.

Medicare pays substantially more than other countries for many of the highest-cost Medicare Part B drugs that beneficiaries receive in an outpatient setting for which Medicare Part B allows separate payment.⁴ In many instances, Medicare pays more than twice as much for certain drugs as other countries do.^{5,6} This is because Medicare generally establishes the payment for separately payable Medicare Part B drugs using the methodology in section 1847A of the Act. In most cases, this means payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, the Medicare program does not get the benefit of the substantial discounts provided in other countries, because ASP is calculated using only the prices that manufacturers charge to certain U.S.-based purchasers. ASP-based payments may encourage the use of more expensive drugs because the dollar amount of the 6 percent add-on portion is larger for drugs with higher ASPs.⁷ As MedPAC noted in its June 2017 Report, "Although, in some cases, drugs with patent protection may face competition from other brand drugs in the same therapeutic class, price competition between such

⁴ "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>; El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices>).

⁵ "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>; El-Kilani Z, Finegold K, Mulcahy A, Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices>).

⁶ Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug prices in the MFN Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

⁷ MedPAC, June 2017, "Medicare Part B Drug Payment Policy Issues," accessed via http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf

products may be limited because the [Medicare] Part B drug payment system is not structured to facilitate competition among brand products with similar health effects.”⁸ Thus, the ASP-based payment approach currently used in Medicare Part B may not promote price competition or provide sufficient incentive to minimize avoidable costs.

The MFN Model aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that takes into account the discounts that other countries enjoy, and pays providers and suppliers with a fixed add-on amount that does not reward the use of higher-cost drugs. We expect that this model will reduce Medicare program expenditures while preserving or enhancing quality of care furnished to Medicare beneficiaries, and will lower beneficiary cost-sharing through lower drug payment amounts. The MFN Model will be tested in all states and U.S. territories by the CMS Innovation Center for 7 performance years, from January 1, 2021 to December 30, 2027.

B. Summary of the Major Provisions

The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending. The MFN Model will require mandatory participation. Participants in the MFN Model will include all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN Model drug with limited exceptions, such as providers and suppliers that are paid for separately payable Medicare Part B drugs based on reasonable costs. The vast majority of providers and suppliers that furnish separately payable Medicare Part B drugs are physicians and non-physician practitioners, supplier groups (such as a group of physicians or other

⁸ MedPAC, June 2017, “Medicare Part B Drug Payment Policy Issues,” accessed via: http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf

practitioners), hospital outpatient departments (HOPDs), including on- or off-campus provider-based departments (PBDs), whether paid under the outpatient prospective payment system (OPPS) or the physician fee schedule (PFS), and ambulatory surgical centers (ASCs) paid under the ASC Payment System. Claims from these providers and suppliers will encompass approximately 88 percent of the annual Medicare Part B spending on the drugs we selected for inclusion in the MFN Model beginning in performance year 1. Other types of providers and suppliers that furnish separately payable selected drugs will also be required to participate in the MFN Model, but they may not often furnish the selected drugs or may not typically receive separate payment for Medicare Part B drugs.

The MFN Model will—

- Calculate the payment amount for MFN Model drugs based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organisation for Economic Co-operation and Development (OECD) with a GDP per capita⁹ that is at least sixty percent of the U.S. GDP per capita, based on available data;

- Make an alternative add-on payment for MFN Model drugs that will remove or reduce the financial incentive to prescribe higher-cost drugs more frequently; and

- Reduce beneficiary cost sharing on MFN Model drugs.

C. Summary of Costs and Benefits

We believe the MFN Model will substantially lower drug payment amounts for the most costly Medicare Part B drugs, thereby lowering program expenditures and out-of-pocket costs for beneficiaries. As discussed in more detail in section VI. of this IFC, we estimate that the MFN Model will result in substantial overall Medicare savings

⁹ For the purposes of this IFC, GDP means GDP based on purchasing power parity (PPP), rather than nominal GDP. A nation's GDP at purchasing power parity (PPP) exchange rate is the sum value of all goods and services produced in the country valued at prices prevailing in the U. S.

during the 7-year model performance period (that is, 28 calendar quarters). In the CMS Office of the Actuary (OACT) estimate, OACT estimates savings of roughly \$64.4 billion in Medicare FFS benefits, \$49.6 billion in Medicare Advantage (MA) payments, and \$9.9 billion in Medicaid¹⁰ spending (\$5.7 billion in federal payments and \$4.3 billion in state payments). Overall, OACT estimates that the MFN Model will result in savings of \$85.5 billion, net of the associated change in the Part B premium, in Medicare Part B spending. In addition, OACT estimates that all beneficiaries will save a total of \$28.5 billion from a reduction in the Medicare Part B premium as a result of the MFN Model, and will also see their coinsurance reduced. In the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimate, ASPE estimates roughly a net reduction of \$87.8 billion in spending on MFN Model drugs by the federal government, state governments, and beneficiaries over the 7 years of the model. We note that there is much uncertainty around the assumptions for both the OACT and ASPE estimates and refer readers to section VI. of this IFC for a more complete discussion of potential impacts of the MFN Model.

II. Background on Need for Regulatory Action

On May 11, 2018, President Trump released his Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,¹¹ which outlined the steps his administration is taking to combat high drug prices, end foreign freeloading, and spur biomedical innovation.¹²

On October 25, 2018, CMS released an advance notice of proposed rulemaking (ANPRM) (83 FR 54546)¹³ (hereafter called the October 2018 ANPRM) describing a

¹⁰ Medicaid savings estimates do not include impacts of changes in Average Manufacturer Price (AMP) and Best Price on manufacturer rebates under the Medicaid Drug Rebate Program.

¹¹American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Available at: <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf?language=es>

¹² “President Donald J. Trump’s Blueprint To Lower Drug Prices,” accessed via: <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/>

¹³International Pricing Index Model for Medicare Part B Drugs; Medicare Program, 83 Fed. Reg (210) 54246 (Oct 30, 2018) available at: <https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf>

potential model, referred to in the October 2018 ANPRM as the International Pricing Index Model (IPI), that would test whether changing the payment amount for selected Medicare Part B drugs would reduce Medicare expenditures and preserve or enhance quality of care. In the October 2018 ANPRM, we sought comment on a model test that would—

- Calculate the Medicare payment amount for selected Medicare Part B drugs to be phased down to more closely align with international prices;
 - Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business;
 - Increase the drug add-on payment to reflect 6 percent of historical drug costs;
- and
- Pay physicians and hospitals the add-on based on a set payment amount structure.

We considered the comments that we received in response to the October 2018 ANPRM in developing the MFN Model described in this IFC. In addition to considering these comments, we considered feedback and suggestions from a broad set of stakeholders gathered through comments on the President’s Blueprint and through numerous meetings with stakeholders.

President Trump discussed an Executive Order (EO) regarding an MFN payment model for Medicare Part B drugs on July 24, 2020, and subsequently published a superseding Executive Order on Lowering Drug Prices by Putting America First on September 13, 2020.¹⁴ In response to the September 13, 2020 Executive Order, we will implement the MFN Model described in this IFC.

A. Medicare Part B Drug Benefit and ASP Payment Methodology

¹⁴ Executive Order 13948, <https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-21129.pdf>.

Medicare Part B includes a limited drug benefit for drugs and biologicals described in section 1861(t) of the Act. The majority of drugs paid under Medicare Part B generally fall into three categories: drugs furnished incident to a physician's service in the physician office, HOPD, or other outpatient setting; drugs administered via a covered item of durable medical equipment (DME); and other categories of drugs specified by statute (generally in section 1861(s)(2) of the Act).

Many drugs covered under Medicare Part B are administered via injection or infusion in a physician's office, an HOPD, and certain other outpatient settings, such as ASCs, and, when Medicare allows separate payment for these drugs, the payment limit is typically based on the methodology described in section 1847A of the Act. The payment amount for these drugs does not include payment for administering the drug to a beneficiary; payment for drug administration services is made in accordance with the applicable payment policy for the setting in which the drug was furnished, such as the Physician Fee Schedule (PFS) (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>), the Hospital Outpatient Prospective Payment System (OPPS) (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>), or the Ambulatory Surgical Center Payment System (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html>). Medicare Part B also allows separate payment for drugs in less common situations such as osteoporosis drugs furnished by a home health agency, and when a beneficiary does not have benefits available under the Part A program.

The payment methodology for drugs described in section 1847A of the Act is generally based on the volume-weighted ASP for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) code for the drug plus a 6 percent add-on. The volume-weighted ASP for a HCPCS code is calculated

quarterly using manufacturer-submitted data¹⁵ on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as sales at nominal charge and sales exempt from Medicaid best price¹⁶) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation (that is, the sales price is net of these rebates, discounts, and price concessions). The ASP+6 percent payment amount that Medicare pays for an individual Medicare Part B drug claim generally does not vary based on the exact price an individual provider or supplier pays to acquire the drug. In the case of multiple source drugs, the price of a brand name drug and its generic equivalent(s) included in the same billing code are averaged together to determine the payment allowance.¹⁷ As noted earlier, this payment methodology may create an incentive for the use of more expensive drugs, but, as noted in the MedPAC report (and by sources cited in the report; pages 68 and 79), an add-on may be needed to account for handling and overhead costs and additional mark-up in distribution channels that are not captured in the manufacturer-reported ASP.

Currently, under Medicare Part B, beneficiaries' cost-sharing¹⁸ is generally 20 percent of the Medicare-allowed amount. The term "Medicare-allowed amount" means the maximum amount that a provider or supplier will be paid for a covered health care service or drug. However, for items and services paid under the OPPS, beneficiaries are only financially responsible for a copayment amount up to the amount of the inpatient hospital deductible.¹⁹ Medicare pays for the remaining portion of the Medicare-allowed amount.²⁰

¹⁵ OMB Control Number 0938-0921.

¹⁶ Best price is defined in section 1927(c)(1)(C) of the Act.

¹⁷ Under section 3139 of the Affordable Care Act (Pub. L. 111-148) the add-on amount for a biosimilar is based on the ASP of the reference product. Biosimilars are not grouped together with one another or the reference product for payment purposes.

¹⁸ Not including the annual deductible.

¹⁹ Section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year. This limit is \$1,408 in 2020.

²⁰2020 Medicare Parts A & B Premiums and Deductibles: Fact Sheet, available at: <https://www.cms.gov/newsroom/fact-sheets/2020-medicare-parts-b-premiums-and-deductibles>

B. Medicare and Beneficiary Spending

Medicare Part B spending for separately payable physician-administered drugs and drugs furnished in hospital outpatient departments represented about 11 percent of Medicare Part B FFS spending in 2015 but increased to represent roughly 14 percent of Medicare Part B FFS spending in 2019; spending on these Medicare Part B separately payable drugs accounted for about 37 percent of the change in Medicare Part B FFS spending from 2015 to 2019. Furthermore, Medicare Part B FFS spending per capita for separately payable drugs has increased at an average annual rate of 11.5 percent over this same period while Medicare Part B FFS spending per capita has increased by 3.8 percent. From 2015 to 2019, Medicare Part B spending for separately payable drugs increased from \$19.4 billion to \$29.8 billion (a nearly 55-percent increase) with per capita spending increasing from \$583 to \$900. This increase in Medicare Part B FFS spending for separately payable drugs during this period reflects increases in the prices of drugs, introduction of new drugs, changes in utilization of these drugs, changes in Medicare Part B FFS enrollment, and changes in the mix of drugs for those beneficiaries who received them.²¹ Since beneficiaries without supplemental insurance typically pay 20 percent of the Medicare-allowed amount, as described in section II.A. of this IFC, they have faced similar increases in spending on Medicare Part B drugs as has Medicare.²²

A new Issue Brief from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) provides additional evidence of the need for the rule. Between 2006

²¹ The average annual growth in number of Medicare Part B FFS beneficiaries was less than 0 percent from 2015 to 2019, so the change in Medicare Part B beneficiaries does not fully account for the average annual growth (11.4 percent) in Medicare Part B spending for physician-administered payable drugs. Instead, the increase during this period is more fully explained by increases in the prices of drugs, introduction of new drugs, changes in drug utilization, and changes in the mix of drugs than by increases in Medicare enrollment.

²² In 2016, 8 in 10 beneficiaries in traditional Medicare (81 percent) had some type of supplemental insurance (which typically covers some or all of Medicare Part A and Medicare Part B cost-sharing), including employer-sponsored insurance (30 percent), Medigap (29 percent), and Medicaid (22 percent). Nearly 1 in 5 beneficiaries in traditional Medicare (19 percent)—6.1 million beneficiaries overall—had no source of supplemental coverage in 2016. <https://www.kff.org/medicare/issue-brief/sources-of-supplemental-coverage-among-medicare-beneficiaries-in-2016/>

and 2017, Medicare Part B FFS drug spending per enrollee grew at 8.1 percent, more than twice as high as per capita spending on Medicare Part D (3.4 percent) and nearly three times as high as overall retail prescription per capita drug spending (2.9 percent). Spending and enrollment projections by OACT for the 2021 President’s Budget suggest that per capita spending on Medicare Part B physician-administered drugs and separately payable hospital outpatient drugs will grow at a very similar annual rate of 8 percent between 2020 and 2027, before consideration of any COVID-19 pandemic impacts.²³ Because biologics account for about 77 percent of Medicare Part B FFS prescription drug spending, there has been little opportunity to reduce Medicare Part B spending growth through generic substitution, as has occurred in Medicare Part D and in retail pharmacy overall.²⁴

C. Relative High Price of Medicare Part B Drugs

Drug acquisition costs in the U.S. exceed those in Europe, Canada, and Japan, according to an October 2018 ASPE analysis²⁵ of Medicare Part B physician-administered drugs. This finding was generally consistent with the existing evidence base as described in the HHS analysis’s background section, which found peer-reviewed literature on this topic to be relatively limited and dated, but with similar findings of higher drug prices in the U.S. compared to other countries.²⁶ The HHS analysis compared U.S. drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16 other developed economies—Austria, Belgium, Canada, Czechia, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia,

²³ ASPE analysis of OACT spending and enrollment projections.

²⁴ Nguyen X. Nguyen and Steve Sheingold. Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-spending-and-utilization>).

²⁵ Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

²⁶ “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

Spain, Sweden, and the United Kingdom (UK).²⁷ The main analysis in the HHS report focused on 27 drugs accounting for 64 percent of total Medicare Part B drug spending in 2016.²⁸ Among the 27 drugs included in the analysis, acquisition costs in the U.S. were 1.8 times higher than in comparator countries. Acquisition cost ratios ranged from U.S. prices being on par with international prices for one of the 27 drugs, to U.S. prices being up to 7 times higher than the international prices for others. There was variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. had the highest drug prices for 19 of the 27 products.²⁹

A new ASPE Issue Brief updates the earlier analysis for the set of Medicare Part B drugs and the set of countries in the MFN Model. In 2018, based on available data, ASP rates were at least 2.05 times the value-weighted average price for these drugs in OECD countries with per capita GDP at least 60 percent of that in the U.S.³⁰

The results of these reports demonstrate that, save for a few outlier cases, the U.S. prices used to calculate ASP rates are significantly higher than the prices in international comparator countries.³¹ Based on this significant difference, which aligns with the analysis we present in this IFC, we will test the impact of more closely aligning payment for Medicare Part B drugs and biologicals with international prices in the MFN Model.

III. Provisions of the Interim Final Rule with Comment Period

A. Model Performance Period

²⁷ Please refer to the HHS report (“Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>) for more information on the countries selected for analysis.

²⁸ “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

²⁹ The ASPE report utilized ex-manufacturer prices (sometimes called the ex-factory price) stated in U.S. currency on the transaction date. The report defines ex-manufacturer prices as the price received by manufacturers of a product, including discounts applied at the point of sale.

³⁰ El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices>).

³¹ ASP is defined in statute, and based on sales in the U.S.

In part 513, we codify the MFN Model that will be tested for 7 performance years. We define “model performance period” to mean January 1, 2021, the date the model will begin, through December 31, 2027. We are testing a 7-year performance period because it will allow a smooth transition to the MFN Price (described in section III.E.5. of this IFC) by performance year 4 and adequate duration to understand the impact of the MFN Model. As discussed in section III.N. of this IFC, we will assess for potential impacts of the MFN Model across quarterly time periods throughout the performance period. Further, we will assess initial impacts of the MFN Model on quality of care, including access to drugs, prior to beginning performance year 5.

B. Defined Population

Our goal is to include all beneficiaries who are furnished an MFN Model drug by an MFN participant and who, on the date of service, are enrolled in Medicare Part B, have Medicare as the primary payer, and are not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan, hereafter called MFN beneficiaries. Thus, the defined population for the MFN Model will be Medicare FFS beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model. We define the term “MFN beneficiary” in § 513.2.

Testing the model in the population of beneficiaries who receive drugs with high annual Medicare Part B spending allows the MFN Model payment to apply to a broad set of conditions, drugs, medical specialties, clinical settings, and localities rather than having MFN Model payment focused on a particular clinical presentation, course of treatment or single type of care setting. Defining the population in this manner allows CMS to observe the implications of a global approach to calculating Medicare Part B drug payment amounts and an alternative add-on approach across a broad set of providers and suppliers and beneficiaries, as well as a large set of manufacturers. Learnings from

the MFN Model will inform CMS and other stakeholders about the effect of applying the innovative payment model to a broad set of drugs on a diverse set of beneficiaries and to the Medicare program.

C. MFN Participants

1. Eligible Providers and Suppliers

A majority of Medicare spending on separately payable Medicare Part B drugs is for drugs that are furnished incident to a physician's service (see section 1861(s)(2)(A) of the Act), in a HOPD (see section 1861(s)(2)(B) of the Act), including in an on- or off-campus PBD (regardless of whether those PBDs are excepted or nonexcepted),³² or in an ASC (see section 1832(a)(2)(F)(i) of the Act). Depending upon the circumstances, Medicare Part B allows separate payment for drugs to other providers and suppliers, such as pharmacies, home health agencies, hospices, radiation therapy centers, independent diagnostic testing facilities, ambulance suppliers, durable medical equipment (DME) suppliers, mass immunization suppliers, inpatient hospitals (when Part A payment is not permitted), and other types of providers and suppliers. Our goal is to broadly include providers and suppliers that receive separate payment for MFN Model drugs as MFN participants, with limited exceptions. MFN participants will consist of Medicare participating providers and suppliers that submit a claim for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary, unless otherwise excluded.³³ Because separately payable Medicare Part B drugs (that is, potential MFN Model drugs) are most often furnished by physicians, non-physician practitioners, supplier groups (such as group practices), hospitals that are paid under the OPPS as defined in 42 CFR 419.20 (including off-campus PBDs paid under the PFS), and ASCs,

³² That is, regardless of whether those PBDs are excepted or nonexcepted under section 1833(t)(21)(B)(ii) of the Act, as added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74).

³³ These providers and suppliers will be included as participants in the MFN Model only if they participate in Medicare; this means that nonparticipating physicians and non-physician practitioners will not be MFN participants and will continue to be paid in accordance with current program policies.

these providers and suppliers will represent the vast majority of MFN participants. Other types of providers and suppliers (that are not excluded) also will be MFN participants to the extent that they submit a claim for an MFN Model drug furnished to an MFN beneficiary. For example, a home health agency that receives separate payment for an osteoporosis drug (defined in section 1861(kk) of the Act) will be an MFN participant if such drug is an MFN Model drug and the home health agency furnishes such drug to an included beneficiary and a claim is submitted.

We will exclude certain types of providers and suppliers that are ultimately not paid for drugs based on ASP as well as those who are subject to the hold harmless provision in section 1833(t)(7)(D)(ii) of the Act. Thus, in § 513.100(c), we exclude from the MFN Model the following providers and suppliers: Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act); PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act); critical access hospitals (CAHs) (defined under section 1820 of the Act); Indian Health Service (IHS) facilities (described in section 1880 of the Act), except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act; Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act); Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act); hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act; and extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act). In addition, for the first quarter and second quarter of performance year 1, we will exclude acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis in accordance with a waiver under such model of section 1833(t) of the Act. This exclusion, codified at

§ 513.100(c)(9), will apply during the first quarter and second quarter of performance year 1, and only if the hospital participates in a CMS Innovation Center model under which it is paid on a fully capitated or global budget basis. As codified at § 513.100(c)(10), for the third quarter of performance year 1 (that is, beginning July 1, 2021) and beyond, acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis in accordance with a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model if the parameters of the other CMS Innovation Center model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model. Thus, acute care hospitals that are participating in the Maryland Total Cost of Care Model will not be MFN participants during the first two calendar quarters of 2021 while they are paid on a fully capitated or global budget basis. Further, if the parameters of the Maryland Total Cost of Care Model have been updated to adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the parameters for the Maryland Total Cost of Care Model (for example, the annual global budget) for the duration of the MFN Model, then these acute care hospitals will remain excluded from the MFN Model beginning with the third quarter of performance year 1 and beyond. However, if the parameters of the Maryland Total Cost of Care Model change such that the participating acute care hospitals are no longer paid on a fully capitated or global budget basis or if a participating acute care hospital leaves the Maryland Total Cost of Care Model such that they are paid under section 1833(t) of the Act, then such hospitals would no longer fall under this exclusion.

This exclusion also applies on the same terms to acute care hospitals participating in the Pennsylvania Rural Health Model that otherwise meet the definition of MFN participant, unless the parameters of the Pennsylvania Rural Health Model change such that the participating acute care hospitals are no longer paid on a fully capitated or global budget basis or if a participating acute care hospital leaves the Pennsylvania Rural Health Model such that they are paid under section 1833(t) of the Act. We expect that the CMS Innovation Center will adjust the parameters of the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model such that the participants in these CMS Innovation Center models will remain excluded from the MFN Model for the duration of the MFN Model. Further, as discussed in section III.J.1. of this IFC, the CMS Innovation Center intends to address model overlaps with other CMS Innovation Center models whether or not the participants in other models are MFN participants, for example we will account for changes in Medicare Part B drug payments that impact other models' financial calculations.

We note that community mental health centers, comprehensive outpatient rehabilitation facilities (CORF), outpatient rehabilitation facilities (ORF), and certain other providers and suppliers do not submit claims for Medicare Part B drugs or are not paid separately for Medicare Part B drugs; thus, an express exclusion for these providers and suppliers is not necessary. We also note that including these providers and suppliers in the MFN Model would complicate the model design and make it challenging to test the impact of the MFN Model on these types of providers and suppliers because of the varied payment structures among these providers and suppliers.

Table 1 shows the distribution of 2019 Medicare Part B allowed charges for separately payable Medicare Part B drugs by provider and supplier type using available final action claims where Medicare was the primary payer, with limited exclusions as noted. This table shows the distribution of Part B drug claims among provider and

supplier types. To assign claims to a provider or supplier type, we considered the type of Medicare Administrative Contractor (MAC) that processed the claim, type of bill, provider number, revenue center, line place of service code, and specialty of the health care practitioner associated with the drug claim line.

TABLE 1 – DISTRIBUTION OF 2019 MEDICARE PART B ALLOWED CHARGES FOR SEPARATELY PAYABLE DRUGS* BY PROVIDER AND SUPPLIER TYPE

Provider/Supplier Type	Number of Entities (CCNs/TINs)	2019 Total Allowed Charges for Medicare Part B Drugs (All Part B drugs)	Percent of 2019 Total Allowed Charges for Medicare Part B Drugs	2019 Average Allowed Charges for Medicare Part B Drugs Per Entity	90th Percentile	75th Percentile	50th Percentile (Median)	25th Percentile	10th Percentile
OFFICE**	74,479	\$20,847,712,641	51.10%	\$279,914	\$122,388	\$16,581	\$2,291	\$225	\$23
OPPS HOSPITAL	3,230	\$13,896,570,373	34.06%	\$4,302,344	\$12,152,596	\$4,422,271	\$660,230	\$52,065	\$5,371
DME MAC CLAIMS***†	8,523	\$1,999,151,286	4.90%	\$234,560	\$44,066	\$10,363	\$2,477	\$325	\$91
CANCER HOSPITAL†	11	\$1,143,173,710	2.80%	\$103,924,883	\$191,145,257	\$154,558,561	\$78,485,411	\$41,929,846	\$40,509,378
CRITICAL ACCESS HOSPITAL†	1,339	\$1,038,650,020	2.55%	\$775,691	\$2,026,327	\$934,738	\$312,662	\$94,975	\$23,730
MASS IMMUNIZATION (ROSTER BILLER)	5,616	\$588,486,793	1.44%	\$104,788	\$21,038	\$9,843	\$4,099	\$1,569	\$467
PHARMACY	1,273	\$587,394,274	1.44%	\$461,425	\$113,876	\$10,264	\$3,021	\$829	\$216
MARYLAND TCOC MODEL ****††	45	\$414,242,305	1.02%	\$9,205,385	\$27,620,924	\$10,748,035	\$2,418,260	\$973,704	\$439,801
AMBULATORY SURGICAL CENTER	1,984	\$111,196,719	0.27%	\$56,047	\$140,658	\$20,601	\$2,780	\$325	\$13
ESRD FACILITY†	15,175	\$67,981,421	0.17%	\$4,480	\$10,413	\$6,064	\$2,656	\$887	\$308
CHILDRENS HOSPITAL†	56	\$51,989,815	0.13%	\$928,390	\$1,230,460	\$405,272	\$78,414	\$23,304	\$3,492
INPATIENT HOSPITAL PART B ONLY†	3,725	\$37,108,693	0.09%	\$9,962	\$26,399	\$8,573	\$1,905	\$353	\$90
HOME HEALTH AGENCIES	609	\$6,437,758	0.02%	\$10,571	\$8,232	\$2,732	\$745	\$171	\$49
PENNSYLVANIA RURAL HEALTH MODEL††	5	\$4,083,536	0.01%	\$816,707	\$3,148,242	\$388,659	\$326,307	\$214,758	\$5,570
PUBLIC HEALTH OR WELFARE AGENCY	215	\$1,783,090	0.00%	\$8,293	\$19,683	\$8,792	\$2,786	\$275	\$56
SKILLED NURSING FACILITY	1,078	\$1,593,255	0.00%	\$1,478	\$3,642	\$1,629	\$615	\$202	\$65
INDEPENDENT CLINICAL LABORATORY	5	\$1,495,285	0.00%	\$299,057	\$1,492,110	\$1,897	\$1,128	\$112	\$38
INDEPENDENT DIAGNOSTIC TESTING FACILITY	184	\$1,480,862	0.00%	\$8,048	\$20,711	\$7,246	\$1,929	\$388	\$49
FQHC/RHC*****†	26	\$6,580	0.00%	\$253	\$291	\$153	\$108	\$80	\$69
TOTAL	117,578	\$40,800,538,415	100.00%	\$121,432,274	\$239,347,312	\$171,562,275	\$82,307,825	\$43,294,594	\$40,988,875

*Claims where Medicare was not the primary payer and claims for radiopharmaceuticals were excluded for this analysis.

**Office includes suppliers such as physicians, non-physician practitioners, and supplier groups, such as group practices. Note that we exclude claims submitted by non-participating physicians from the MFN Model.

***DME Supplier includes all claims processed by the DME MAC, which include claims for drugs furnished by DME suppliers and other suppliers.

****Maryland Total Cost of Care (MD TCOC) Model Participants, acute care hospitals located in Maryland.

*****FQHC means federally qualified health center; RHC means rural health clinic.

† Indicates provider and supplier types that we exclude from the MFN Model or indicates that we exclude claims of this type from the MFN Model. Note that claims billed by ESRD Facilities that are not paid under the ESRD PPS will be subject to the MFN Model payment.

††CMS Innovation Center models that we are excluding for the first two calendar quarters of performance year 1 and then thereafter if conditions are met.

To minimize the complexity of the MFN Model, we are not including in the MFN Model Medicare Part B drugs that are furnished in the inpatient setting, administered through covered DME, orally administered, or paid under the End-Stage Renal Disease Prospective Payment System (ESRD PPS). Therefore, in § 513.100(d), we provide an exception for claims submitted by acute care hospitals for separately payable Medicare Part B drugs that were administered during an inpatient stay or included on an inpatient claim, such as when a beneficiary has exhausted their Part A benefit days, claims administered by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) as described in 42 CFR 421.404(c)(2), and claims paid under the ESRD PPS, including claims for drugs that are paid using the transitional drug add-on payment adjustment.

Under the approach set forth in § 513.100(b), all Medicare participating providers and suppliers that submit a claim for an MFN Model drug (excluding claims specified in § 513.100(d)) furnished to an MFN beneficiary will be included as MFN participants unless otherwise excluded (as specified in § 513.100(c)), regardless of the volume of MFN Model drugs for which they submit claims. As Table 1 shows, a significant proportion of suppliers bill for a relatively lower volume of MFN Model drugs, such as less than \$2,000 in total annual allowed charges, and will likely have limited claims paid under the MFN Model. We considered whether to make specific payment adjustments under the MFN Model for MFN participants that bill for a low volume of MFN Model drugs during a historical period or whether low-volume providers and suppliers could have the option to opt into or out of the MFN Model. However, we believe that requiring participation in the model only of providers and suppliers that bill for a higher volume of MFN Model drugs would not allow us to observe the impact of the MFN Model on a full range of providers and suppliers and would create opportunities for shifting sites of care and gaming. As such, we are including a broad set of providers and suppliers as MFN

participants, regardless of their volume of billing for MFN Model drugs. As described in section III.I.2. of this IFC, the MFN Model includes a financial hardship exemption in the form of a potential reconciliation amount for MFN participants that are significantly affected by their participation in the MFN Model.

We note that MFN Model drugs could be furnished to a beneficiary in an HOPD who is subsequently admitted to an inpatient hospital stay. When a beneficiary receives outpatient hospital services, including MFN Model drugs, during the 3 days immediately preceding admission to a hospital defined under section 1886(d) of the Act, the outpatient hospital services are treated as inpatient services if the beneficiary has Medicare Part A coverage and such services are not separately payable under Medicare Part B. We will apply this policy consistently under the MFN Model such that if a beneficiary receives an MFN Model drug in an HOPD that is an MFN participant and is admitted to this hospital within 3 days, then those services, including drugs, will be treated as inpatient services (in accordance with Medicare inpatient payment policies) and will not be separately payable under the MFN Model. We note that when a beneficiary receives outpatient hospital services during the day immediately preceding a hospital admission to a hospital not paid under the Inpatient Prospective Payment System (IPPS), such as psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals, the statutory payment window is one day preceding the date of the patient's admission; but because these categories of hospitals will be excluded from the MFN Model, as discussed previously, the payment window policy will not be applicable for this model.

We are codifying these provisions in §§ 513.100(a) through (d).

We note that we include a limitation on the MFN Drug Payment Amount in § 513.210(d)(5) that will apply to certain claims submitted by 340B covered entities as described in section III.E.10. of this IFC to ensure that beneficiaries who are furnished

MFN Model drugs by a 340B covered entity do not face increased cost-sharing under the MFN Model than would otherwise apply.

2. Mandatory Participation and Requirements

Model participation will be mandatory for Medicare participating providers and suppliers that satisfy the MFN participant definition. There will be no specific enrollment activities for MFN participants; rather, their participation will be effectuated by the submission of a claim for an MFN Model drug furnished to an MFN beneficiary, and we will apply the MFN Model payment to such a claim.

As we have described in previous rules implementing models with required provider or supplier participation, such as the Comprehensive Care for Joint Replacement (CJR) Model, mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model. Requiring participation in the MFN Model will allow us to observe the experiences of providers and suppliers with diverse characteristics, such as geographies, patient populations, and specialty mixes. Mandatory participation (with specified exceptions) by providers and suppliers submitting claims for MFN Model drugs in a nationwide model, as further discussed in section III.C.3. of this IFC, will minimize administrative complexity and risk to the integrity of the MFN Model.

In § 513.100(e) and § 513.100(f), we are codifying MFN participant requirements during and after the MFN Model. During the MFN Model performance period described in § 513.1(c), MFN participants must--

- Adhere to the beneficiary protections requirements in § 513.410 to ensure beneficiaries' access to care is not adversely impacted;
- Adhere to the MFN Model-specific billing instructions established by CMS and the MAC responsible for processing the MFN participant's claims, including without

limitation those described in § 513.200, to ensure appropriate and accurate Medicare payments; and

- Participate in MFN Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary of Health and Human Services (the Secretary) determines is necessary to monitor and evaluate the MFN Model, including without limitation “protected health information” as that term is defined at 45 CFR 160.103.

For 2 years after termination of the MFN Model, MFN participants must participate in MFN monitoring activities as described in § 513.420.

MFN participants will continue to bill Medicare for separately payable MFN Model drugs furnished to MFN beneficiaries and be responsible for collecting beneficiary cost sharing amounts for MFN Drug Payment Amounts. As such, we anticipate MFN participants will have the same administrative requirements for collection of beneficiary cost-sharing amounts under the MFN Model as apply to collection of beneficiary cost-sharing outside the MFN Model.

As discussed in section III.L. of this IFC, manufacturers will exclude from their calculation of ASP all units of MFN Model drugs that are furnished to MFN beneficiaries and for which payment under § 513.210 is allowed. Manufacturers will need to determine the number of units to exclude and may adjust purchasing arrangements with MFN participants in order to obtain information about such units. While MFN participants are not required to provide data to manufacturers related to the number of units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed, we anticipate that manufacturers may establish mechanisms to obtain such information, which also may create administrative burden for MFN participants related to the MFN Model. For example, manufacturers could require use of separate purchasing accounts, or reporting of information about units of MFN

Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed in order to receive a more favorable purchase price.

3. Model Geographic Area

In the October 2018 ANPRM, CMS anticipated the geographic area included in a potential IPI Model would encompass 50 percent of Medicare Part B drug spending. Several commenters expressed concern that having model participants subjected to multiple payment methodologies for included drugs based on having some but not all of their locations within the model's geographic area would be administratively burdensome. Additionally, some commenters expressed concern at the idea of requiring participation in some geographic areas but not others, noting that this approach would disproportionately affect some providers and suppliers and not others. Multiple commenters noted that reduced cost-sharing for patients in the model compared to those outside of the model would create potential differences in access for beneficiaries. One commenter noted that there would be a risk of patient steering if the model created a financial incentive for providers and suppliers to provide care at sites outside of the model geographic area rather than at sites in the model geographic area.

Due to the administrative complexity and risk to model integrity associated with a limited scope, CMS believes that the MFN Model cannot realize its full potential in spending reductions for Medicare and its beneficiaries and improvement in quality of care without broad participation of Medicare participating providers and suppliers through a nationwide scope. Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the scope of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. It follows that the Secretary could similarly elect not to limit testing to certain geographic areas, and instead test a nationwide model.

The MFN Model requires mandatory, nationwide participation of Medicare participating providers and suppliers (with limited exclusions) to be able to successfully test the model for the reasons described later in this section. First, a nationwide scope avoids additional administrative burden on MFN participants with some service locations inside the MFN Model geographic area and others outside of the MFN Model geographic area, which could lead to such MFN participants needing to track and follow separate requirements for how drugs are acquired, furnished, and billed, depending on the service location. Second, a nationwide model geographic area eliminates the potential for MFN participants with service locations both inside and outside the MFN Model's geographic area to seek to influence beneficiaries' choice of treatment location in response to the differences between non-model payments and the MFN Model payments. This potential issue is of particular concern for the MFN Model given the broad use of MFN Model drugs and the ambulatory settings in which these drugs may be furnished, which can be geographically distributed over wide areas. Third, CMS also believes that a nationwide model geographic area maintains continuity with current treatment patterns by limiting disruption to beneficiary and health care provider treatment plans that may arise due to potential changes in the site of care. Fourth, a nationwide model geographic area allows all eligible beneficiaries who receive an MFN Model drug from an MFN participant where separate payment is allowed to benefit from the cost-sharing reductions under the MFN Model. Finally, CMS believes that a nationwide model geographic area along with mandatory participation creates the necessary market participation to increase the likelihood of MFN participants being able to acquire MFN Model drugs at lower prices as discussed in section VI. of this IFC. CMS notes that several of these points were commented on by several respondents to the October 2018 ANPRM. These points highlight the challenges that accompany a limited scope (non-nationwide) model geographic area. CMS therefore believes a nationwide scope is the most appropriate for

the MFN Model. Thus, we are codifying in § 513.120 that the MFN Model geographic area includes all states and U.S. territories.

As described in section VI. of this IFC, we anticipate that there could be potential challenges associated with a mandatory, nationwide model, namely greater impacts on manufacturers, a greater number of MFN participants that potentially receive lower payments for drugs under the model, and fewer non-participants who potentially increase their patient volume should beneficiaries need to locate alternative sites of care. We have designed the model to mitigate these potential challenges where possible.

D. MFN Model Drugs

We will begin the MFN Model with 50 Medicare Part B drugs, identified by Healthcare Common Procedure Coding System (HCPCS) codes with high annual spending during 2019 (based on dates of service and after applying certain exclusions), that will be included on the MFN Model Drug HCPCS Codes List (described later in this section), and maintain approximately 50 Medicare Part B drugs on the MFN Model Drug HCPCS Codes List during the 7-year model performance period. We will focus the model on the separately payable, physician-administered Medicare Part B drugs with the highest annual spending which make up a portion of the roughly 550 HCPCS codes listed on the quarterly ASP pricing files, but encompass approximately three-quarters of annual Medicare Part B drug spending³⁴, and are furnished by the types of providers and suppliers that frequently bill under Medicare Part B. The MFN Model payments will apply only to MFN Model drugs when these drugs are administered by MFN participants to MFN beneficiaries and Medicare Part B allows separate payment as the primary payer.

³⁴ CMS publishes a Medicare Part B Drug Dashboard which can be used to view annual spending on drugs by HCPCS code. The downloadable file can be used to examine the proportion of annual spending for the included drugs. See: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>

In § 513.130(b), we exclude some categories of Medicare Part B drugs from the model, such as certain vaccines, radiopharmaceuticals, oral drugs, compounded drugs, and intravenous immune globulin products. We also exclude drugs that are billed with HCPCS codes to which any generic drugs are assigned, including in applicable instances where single source drugs or biologicals were within the same billing and payment code as of October 1, 2003. For purposes of the MFN Model, we consider a drug to be a generic drug if it is approved under an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act. In accordance with President Trump's Blueprint to Lower Drug Prices, we are excluding such drugs because these drugs are already subject to competitive market forces and because the Medicare Part B payment allowances for these drugs already reflect price competition from generic products. In addition, we are excluding drugs for which there is an Emergency Use Authorization (EUA) or approval by the Food and Drug Administration (FDA) to treat patients with suspected or confirmed coronavirus disease 2019 (COVID-19). Since there may likely be urgent, high demand for such drugs and available supply may be targeted to certain populations, this exclusion allows maximum flexibility for potential changes in drug distribution for such drugs.

To encourage introduction and use of biosimilars, the Trump Administration has taken several actions, including establishing separate HCPCS codes for Medicare Part B biosimilar biological products. We are not excluding biosimilar biological products from the MFN Model, however, given the relative lower annual Medicare Part B spending for HCPCS codes for separately payable biosimilar biological products through 2019, only one biosimilar biological product is included among the performance year 1 MFN Model Drug HCPCS Codes List in Table 2.

We further discuss the drugs that will be included in or excluded from the MFN Model in the following four subsections.

1. MFN Model Drug HCPCS Codes List

We will use an approach for including drugs in the MFN Model that is similar to what we described in the October 2018 ANPRM. However, rather than beginning with approximately 27 drugs, as discussed in the October 2018 ANPRM, and adding drugs annually, we will include approximately 50 Medicare Part B drugs in the MFN Model for each performance year. We will identify the top 50 Medicare Part B separately payable drugs with the highest aggregated Medicare Part B total allowed charges in the baseline period, after excluding certain claims, to result in an initial set of drugs that will be included in the model beginning in performance year 1. Thereafter, annual additions will follow a similar process using claims data for the subsequent year.

Compared to beginning with a smaller number of drugs and phasing in additional drugs in each subsequent performance year, beginning with 50 Medicare Part B drugs simplifies the model design and reduces complexity for MFN participants. Based on spending patterns over time for high spend Medicare Part B drugs,³⁵ we expect the set of included Medicare Part B drugs to remain relatively stable over the model's 7-year performance period, and we believe that a generally stable set of MFN Model drugs will help MFN participants plan their drug acquisition strategies. We believe the benefits of this stability outweigh the incremental challenge of beginning the MFN Model with a longer drug list than envisioned in the October 2018 ANPRM, and allows Medicare and its beneficiaries to benefit from the model payment methodology sooner for more of the highest spend Medicare Part B drugs, if anticipated savings are realized.

By focusing the MFN Model on separately payable Medicare Part B drugs, payments for products that are bundled or otherwise included in payment for a procedure or other services will not be affected by the MFN Model and payments for such bundled

³⁵ CMS publishes a Medicare Part B Drug Dashboard, which can be used to view annual spending on drugs by HCPCS code. See: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html>

services will not have to be separated or adjusted. This approach does not exclude drugs that are packaged under a Medicare payment system in certain settings and separately payable in other settings. However, the MFN Model payment only applies to such drugs in settings where separate payment is allowed.

In § 513.130, we describe the creation and periodic updates of an MFN Model Drug HCPCS Codes List, which designates the MFN Model drugs that are subject to the MFN Model payments specified in § 513 subpart C. Specifically, to select the list of drugs included in the MFN Model for the beginning of performance year 1 (that is, beginning January 1, 2021), the regulation text at § 513.130(a)(1) codifies that, after making the exclusions specified in § 513.130(b)(1) and (b)(2), CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges, and adds those HCPCS codes to the MFN Model Drug HCPCS Codes List, after updating such HCPCS codes for any applicable changes. We will use HCPCS codes to identify drugs because they are an established way to identify, bill, and pay for separately payable Medicare Part B drugs in the Medicare claims processing system, and they are commonly used in other Medicare Part B drug payment resources like the ASP drug pricing files. For this process, we will use final action Medicare Part B claims for separately paid drugs with dates of service within calendar year 2019 and allowed charges greater than \$0 where Medicare was the primary payer from all Medicare providers and suppliers as the baseline period. This period is the most recent full calendar year of claims data that was sufficiently available prior to the model performance period start on January 1, 2021. Accordingly, we arrayed drugs, using HCPCS codes, in descending order based on the aggregate Medicare Part B total allowed charges in the 2019 baseline period, after making the exclusions specified in § 513.130(b)(1) and (b)(2), and identified the 50 Medicare Part B drugs (identified by HCPCS codes) with the highest total Medicare Part B allowed charges. These HCPCS

codes are included on the MFN Model Drug HCPCS Codes List for the beginning of performance year 1 as shown in Table 2 of this IFC.

The MFN Model uses an annual calendar year baseline period for purposes of identifying the drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 1 (and annually thereafter, using the next subsequent calendar year as the baseline) because: the vast majority of HCPCS Code updates occur annually in the January HCPCS update; the model will use an annual baseline period to calculate the alternative add-on payment amount described in section III.F. of this IFC; and these baseline periods will be aligned for consistency in the model design.

This approach for identifying the drugs that are included in the MFN Model at the beginning of performance year 1 captures most of the drugs listed in the October 2018 ASPE report,³⁶ which used the Medicare Part B National Summary Drug file from 2016 to identify approximately 27 HCPCS codes associated with high amounts of spending, and nearly all the drugs listed in the November 20, 2020 ASPE report, which applied the criteria in the MFN Model to Medicare Part B claims data for 2018.³⁷ This approach also results in the inclusion of a variety of drugs and biologicals (including biosimilar biological products) that are used to treat common conditions in the Medicare Part B beneficiary population. These drugs and biologicals with high annual Medicare allowed charges are frequently prescribed and administered by various physician specialties to beneficiaries with various medical conditions. Examples of uses of the drugs included in the MFN Model are: drugs and biologicals used to treat cancer and related conditions, biologicals used for the treatment of rheumatoid arthritis and other immune mediated

³⁶ “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

³⁷ El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (<https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices>).

conditions, and biologicals used to treat macular degeneration. Beneficiaries who receive such drugs, often on a recurring basis, face substantial cost-sharing liability directly or through their supplemental insurance, and such costs may be partly avoidable (that is, reduced) if Medicare payment for these drugs were not based on the current ASP methodology.

Beginning with 50 of the highest spend HCPCS codes based on annual Medicare Part B allowed charges during 2019, after taking into account certain exclusions, focuses the MFN Model on a wide variety of frequently utilized Medicare Part B drugs and specialties that administer such drugs to Medicare FFS beneficiaries, and allows CMS to test the MFN Model payment on a broad set of drugs and biologicals that are furnished to many beneficiaries. We believe that including single source drugs and biologicals (including biosimilar biological products) that move into the top 50 HCPCS codes on an annual basis will capture potential shifts in utilization to drugs that had not yet been included in the MFN Model, if such shifting were to occur, and will mitigate the potential for medically unnecessary shifts in utilization.

In developing this approach, we also considered comments we received in response to the October 2018 ANPRM on using drug classes to help inform which drugs to include in the MFN Model, as well as requests to consider how access to Medicare Part B drugs (as a whole and for specific subsets of drugs) might be affected by inclusion in the model. We considered these suggestions and believe that using annual Medicare Part B allowed charges as a primary factor is a more transparent, consistent, and clear approach because attempting to identify drugs for inclusion in the MFN Model based on groups or classes of drugs could become complicated and confusing for MFN participants. There are numerous drug classification approaches available; for example, drug classification can be based on a chemical class, site of action, mechanism of action, as well as other factors. These approaches can become difficult to apply consistently

when drugs from different chemical classes are used to treat the same condition, when a drug has more than one mechanism of action, or when conditions are treated with drugs having more than one mechanism of action. For example, the Medicare Part B biological products commonly used to treat rheumatoid arthritis include a variety of monoclonal antibodies. Using broad terms such as monoclonal antibodies to identify a “group” of MFN Model drugs would include a variety of biologicals that are commonly also used in treating other conditions, such as Crohn’s disease, ulcerative colitis, cancer, and multiple sclerosis. Attempting to select MFN Model drugs using more narrow terms, for example by specifying agents that exert effects on more specific inflammatory pathways, such as tumor necrosis factor and interleukins, would miss biologicals that affect other pathways, like T cell stimulation. These approaches may also miss products that are primarily used to treat other diseases, but may be used less frequently in rheumatoid arthritis, and these approaches may not be readily adaptable for novel products that may be introduced over the 7-year performance period of the model.

In § 513.130(a)(2), we are codifying the process for annual updates of the MFN Model Drug HCPCS Codes List to update the list of drugs that will be included in the MFN Model for the subsequent performance year, as further described in section III.D.3. of this IFC.

2. Exclusion of Certain HCPCS Codes and Claims

In the October 2018 ANPRM, we discussed the potential exclusion of several groups of drugs from the potential IPI Model (83 FR 54555). Commenters generally agreed that these drugs should be excluded. As codified in § 513.130(b)(1), the MFN Model excludes the following types of drugs, by excluding claims at the HCPCS code level, before identifying the top 50 drugs with the highest aggregate annual Medicare Part B total allowed charges:

- Medicare Part B vaccines specified in section 1861(s)(10) of the Act (that is, influenza, pneumococcal pneumonia, and Hepatitis B vaccines, and any future vaccine for COVID-19). These preventive products are paid under section 1842(o)(1)(A)(iv) based on average wholesale price (AWP), a price that does not include discounts or rebates. Including such drugs in the MFN Model also would not comport with our test of an alternative add-on payment amount (described in section III.F. of this IFC) because the statutory add-on percentage under section 1847A of the Act does not apply to these drugs.

- Radiopharmaceuticals. Many radiopharmaceuticals are typically acquired outside of the traditional drug supply chain. Nuclear pharmacies are frequently involved in the preparation of patient-ready doses of these drugs, and Medicare Part B payment is frequently based on contractor pricing. We are excluding radiopharmaceuticals from the MFN Model because it is unlikely that we will be able to obtain reliable international drug pricing information for radiopharmaceuticals.

- Oral Medicare Part B drugs, including oral anticancer drugs described in section 1861(s)(2)(Q) of the Act, oral antiemetic drugs described in section 1861(s)(2)(T) of the Act and immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Oral anticancer, antiemetic, and many immunosuppressive drugs are often used outside of the provider and supplier settings (for example, these drugs are often used at home); therefore, we are excluding these oral drugs from the MFN Model.

- Compounded drugs including products prepared by outsourcing facilities.³⁸ Although subject to certain FDA requirements, these products are not approved by FDA per se, and with one exception under the OPPIs³⁹ are not billed under drug-specific HCPCS codes; they are typically billed using under “not otherwise classified” (NOC)

³⁸ See section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) with respect to the definition of outsourcing facilities and their regulation by FDA.

³⁹ C9257 Injection, bevacizumab, 0.25 mg.

codes. Also, compounded drugs are typically acquired outside of the traditional drug supply chain, and Medicare Part B payment for compounded drugs is generally based on contractor pricing, such as invoice pricing. We are excluding these drugs because it is unlikely that we will be able to obtain reliable international drug pricing information for compounded drugs.

- Intravenous immune globulin products. In response to the October 2018 ANPRM, a commenter suggested that CMS exclude plasma-derived products and stated such products have potential unique sourcing and distribution, and past supply shortages. We note that FDA has identified a current shortage related to one of the HCPCS codes that is among the top drugs with high aggregate 2019 Medicare Part B total allowed charges (J1569, Gammagard liquid infusion). Three other immune globulin products are also among the top drugs in 2019, J1459 (Inj ivig privigen 500 mg), J1561 (Gamunex-c/gammaked), and J1568 (Octagam injection). After considering this concern, we are excluding intravenous immune globulin products from the MFN Model because these products are at higher risk of shortage based on their complex sourcing and production, and we are aware of the ongoing exploration of the potential benefit of plasma in the treatment of patients with COVID-19.

- Drugs that are subject to an EUA or receive FDA approval to treat patients with suspected or confirmed COVID-19. The exclusion of these drugs will minimize any potential for the MFN Model to impact rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID-19.

- Drugs without drug-specific HCPCS codes, that is, those billed under “not otherwise classified” (NOC) codes, such as J3490. NOC codes are used to bill for drugs not assigned to a particular HCPCS code. NOC codes typically include a variety of unrelated drugs that cannot be easily separated for the purpose of ranking allowed charges of the individual drugs. Also, significantly greater claims processing complexity

for Medicare and MFN participants would result if we had to identify whether an MFN Model drug was billed under a NOC code during MFN Model operations. By excluding HCPCS codes for these types of drugs, these drugs will be fully excluded from the MFN Model.

While we intend that the MFN Model drugs will encompass a wide variety of frequently utilized Medicare Part B drugs, we also intend that drugs will not be included on the basis of substantial use at home. Thus, in § 513.130(b)(2), we codify the exclusion of claims that were processed and paid by the DME MACs as described in 42 CFR 421.404(c)(2), and professional claims with a place of service code that indicates the drug was used in a home, including home-like settings, prior to identifying the top 50 drugs (by HCPCS code).⁴⁰ The place of service exclusion applies only to professional claims because place of service codes are not used on institutional claims to identify home use. Specifically, professional claims with place of service codes 04 – homeless shelter, 12 – home, 13 – assisted living facility, 14 – group home, 16 – temporary lodging, and 33 – custodial care facility will be excluded prior to identifying the top 50 drugs (by HCPCS code).

For future years of model implementation, we seek comment on whether all blood related, plasma derived, and human tissue products should be included in or excluded from the MFN Model. We also seek comment on how CMS should define such products and what would be the supporting rationale for such an exclusion and how to address such considerations in the future. We note that we are also considering as a potential addition to the model design whether certain drugs, such as certain gene and cell therapies (for example, chimeric antigen receptor T-cell (CAR-T) products) and drugs approved by FDA after the start of the MFN Model that are indicated for and used to treat

⁴⁰ The DME MACs process Medicare Durable Medical Equipment, Orthotics, and Prosthetics (DMEPOS) claims for a defined geographic area or "jurisdiction," servicing suppliers of DMEPOS. Professional claims must comply with the ASC X12 837 Professional guide (005010X222A1).

rare diseases or conditions, should be excluded from the MFN Model for all performance years, or for several years after the drug is first sold in the U.S. We note that under the MFN Model, annual Medicare Part B allowed charges would have to exceed tens of millions of dollars for such drugs to reach the top 50 and be added to the MFN Model. We also note that many of the top 50 drugs in 2019 are used to treat conditions with limited populations and were first approved within the last 5 years. In addition, we note that while drugs may initially be approved for one or a few very narrow indications, subsequently approved indications can quickly expand the use of the drug to a much larger patient population. We are considering whether we should exclude certain gene and cell therapies based on supply chain criteria, similar to our policy to exclude vaccines and compounded drugs. For future years, we seek comment on whether we should exclude certain gene and cell therapies or new drugs for the treatment of rare diseases and conditions from the MFN Model, and how CMS would identify such drugs for exclusion, particularly how we would define such drugs, identify rare diseases and conditions for purposes of the MFN Model, and determine the appropriate length of such exclusion (for example, all performance years or several years after the drug is first sold in the U.S.).

Some commenters have suggested that drugs in short supply (based on inclusion on the FDA drug shortages list) should be excluded from drug payment models. As discussed previously, we are excluding intravenous immune globulin products from inclusion on the MFN Model Drug HCPCS Codes List, because these products are at higher risk of shortage based on their complex sourcing and production. Otherwise, based on our experience with ASP pricing, shortages of high cost single source drugs and biologicals are uncommon, of short duration, and generally apply to some but not all package sizes of a drug. As described in section III.E.12. of this IFC and codified in § 513.210(d)(2), we include a quarterly payment exception for MFN drugs that are in short supply (based on inclusion on the FDA drug shortages list). We believe it will be less

disruptive to the MFN Model to include a quarterly payment exception for MFN Model drugs during the time they are in short supply than to exclude such drugs from the MFN Model altogether because a quarterly payment exception approach will avoid changing the inclusion status of drugs should a shortage occur and again when the shortage is resolved, eliminate the need to consider developing a process to add and remove replacement drugs to maintain the number of MFN Model drugs, and avoid manufacturers having to change processes for capturing sales of such drugs in their ASP calculations as discussed in section III.L. of this IFC (under this policy, manufacturers will not include in their calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants where the MFN Drug Payment Amount is paid by Medicare as the primary payer).

Finally, we considered whether an exception to inclusion on the MFN Model Drug HCPCS Codes List might be appropriate for MFN Model drugs in cases where pharmaceutical manufacturers that distribute the drug in the U.S. do not own the rights to the drug product for distribution outside the U.S. and therefore do not control ex-U.S. pricing for the drug product. To avoid a gaming opportunity whereby manufacturers' new or recent business arrangements create such cases, this type of exception could be defined such that only ownership rights that were transferred prior to the October 2018 ANPRM, when CMS announced a new Medicare Part B drug payment model was being developed, would qualify. To avoid an exception being too broad, we are concerned that additional criteria should be required to qualify for it, such as whether the increase in the MFN Model drug's applicable ASP (a measure of U.S. prices) based on sales since October 2018 has been slower than inflation (that is, the change in the CPI-U from the end of October 2018 through the ASP calendar quarter for the first calendar quarter of the model), and whether the U.S. manufacturer makes a legally enforceable commitment to future U.S. price increases being slower than inflation moving forward, if such an

exception were to be granted. In addition, to maintain the exception for the remainder of the model, the increase in the MFN Model drug's applicable ASP since October 2018 would need to be assessed quarterly to determine whether it continues to be slower than inflation. Given the complex and numerous relationships that manufacturers may have across U.S. and international markets, we are not including such an exception for the MFN Model.

We seek comments for future years on our approach to identifying and maintaining the MFN Model Drug HCPCS Codes List and whether there is a need for an exception relating to manufacturers' ownership of drug products internationally, and if so, how such an exception might be defined and operated transparently.

3. Annual Updates to the MFN Model Drug HCPCS Codes List

As discussed in section III.D.1. of this IFC, the MFN Model will begin with 50 drugs and biologicals by HCPCS code on the MFN Model Drug HCPCS Codes List for performance year 1. We will keep approximately 50 drugs by HCPCS code in the MFN Model during the 7-year performance period so that drugs that continue to account for a large portion of Medicare Part B drug spending will continue to be included in the model. However, we believe that some adjustments to the MFN Model Drug HCPCS Codes List will likely be required from time to time as drugs enter and exit the market and as utilization of Medicare Part B drugs (measured by annual total allowed charges) changes. Thus, we will update the MFN Model Drug HCPCS Codes List annually. The annual update process will occur prior to the beginning of each performance year rather than more frequently, such as a quarterly process, because less frequent changes to the MFN Model Drug HCPCS Codes List will decrease the burden associated with participating in the model. We believe that making fewer changes to the MFN Model Drug HCPCS Codes List will result in MFN participants having to make fewer changes to acquisition arrangements, and this in turn will lessen any potential for disruption in workflow and

care delivery compared to a quarterly update process. Additionally, as specified in § 513.130(a)(4), some quarterly changes may be necessary to comport with HCPCS coding updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, such as when a code is terminated and a successor code is established.

For each annual update for performance years 2 through 7, as described in § 513.130(a)(2), we will array in descending order all separately payable Medicare Part B drugs, using HCPCS codes, based on total allowed charges after applying the exclusions codified in § 513.130(b)(1) and (b)(2), using the most recent full calendar year's Medicare Part B claims from all providers and suppliers. Those drugs (as identified by HCPCS codes) that have total allowed charges that fall in the top 50 drugs by spending for that calendar year that are not already on the MFN Model Drug HCPCS Codes List will be added to the MFN Model Drug HCPCS Codes List to take effect on the first day of the next performance year and the MFN Drug Payment Amount that will apply will be based on the applicable MFN Price phase-in for that performance year and will follow the annual payment updates thereafter. This process will be used only to add HCPCS codes that are new to the top 50 – to maintain consistency, we will not remove any codes from the MFN Model Drug HCPCS Codes List on the grounds that the HCPCS code dropped out of the top 50. We will keep all HCPCS codes that were included on the MFN Model Drug HCPCS Codes List for the prior performance year on the MFN Model Drug HCPCS Codes List, except in certain circumstances as noted in section III.D.4. of this IFC, in order to have greater stability in the set of drugs that are included in the MFN Model across the performance years. As a result, in performance years 2 through 7, the number of HCPCS codes on the MFN Model Drug HCPCS Codes List may be greater than 50. We believe this approach has the potential to identify drugs that are alternative therapies to MFN Model drugs, such as competitor products, where MFN participants may shift utilization to avoid using drugs subject to the MFN Model payment, and will

provide a mechanism for adding such drugs to the MFN Model. In addition, this approach will serve as a mechanism to identify newer drugs with high annual Medicare Part B spending for inclusion in the MFN Model.

To maintain transparency, when we add HCPCS codes that are new to the top 50 or are replacement codes for HCPCS codes that are listed on the MFN Model Drug HCPCS Codes List, we will list the code's start date for inclusion in the MFN Model. In addition, we will revise HCPCS codes on the MFN Model Drug HCPCS Codes List as necessary to reflect quarterly HCPCS code updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, for example when a permanent code replaces a temporary code, a HCPCS code is terminated and a replacement code is established, or a HCPCS code is established for Medicare use. In such case, we will include an end date on the MFN Model Drug HCPCS Codes List for the terminated code. We will notify MFN participants of updates to the MFN Model Drug HCPCS Codes List no less frequently than quarterly by adding the updated MFN Model Drug HCPCS Codes List to the MFN Model website (<https://innovation.cms.gov/initiatives/most-favored-nation-model>).

4. Approach for Removing Drugs from the MFN Model Drug HCPCS Codes List

We do not anticipate that drugs will be removed from the MFN Model frequently. In accordance with § 513.130(a)(3), we will remove drugs from the MFN Model Drug HCPCS Codes List only under the following limited circumstances, but no more frequent than quarterly, to align with quarterly MFN Model payment updates:

- If they are permanently withdrawn from the U.S. market;
- If a specific HCPCS code included on the MFN Model Drug HCPCS Codes

List is terminated with no replacement code available or planned; or

- The drug is excluded from the MFN Model pursuant to the exclusions in § 513.130(b)(1), for example a HCPCS code describes a generic drug approved under an ANDA or a drug with an EUA or FDA approval to treat patients with suspected or confirmed COVID-19.

To maintain transparency, we will remove HCPCS codes by setting an end date on the MFN Model Drug HCPCS Codes List at the next quarterly update after CMS becomes aware, through environmental scanning activities, that all of the NDCs assigned to a HCPCS code have been withdrawn from the U.S. market and the drug is permanently withdrawn from the U.S. market, or the HCPCS code has been terminated with no replacement code available or planned, or the exclusion in § 513.130(b) applies. HCPCS codes that are removed from the MFN Model Drug HCPCS Codes List will no longer be subject to the MFN Model payment, but rather will be subject to current Medicare payment policies. If the conditions for removal no longer exist, the HCPCS code could again qualify for inclusion on the MFN Model Drug HCPCS Codes List at the next annual update.

5. Performance Year 1 MFN Model Drug HCPCS Codes List

To create the MFN Model Drug HCPCS Codes List for performance year 1, we arrayed drug HCPCS codes by aggregate 2019 Medicare Part B total allowed charges⁴¹ after applying the exclusions in § 513.130(b)(1) and (b)(2). We then identified the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges. This process excluded HCPCS codes for two influenza vaccines (90662 (Iiv no prsv increased ag im) and 90653 (Iiv adjuvant vaccine im)), two pneumococcal

⁴¹ We used 2019 final action claims data that were available in the CMS Chronic Conditions Data Warehouse in September 2020 where Medicare was the primary payer.

pneumonia vaccines (90732 (Ppsv23 vacc 2 yrs+ subq/im) and 90670 (Pcv13 vaccine im)), and a radiopharmaceutical (A9606 (Radium ra223 dichloride ther)) from the MFN Model Drug HCPCS Codes List. The exclusion of intravenous immune globulin products excluded four HCPCS codes: J1459, Inj ivig privigen 500 mg; J1561, Gamunex-c/gammace; J1568, Octagam injection; and J1569, Gammagard liquid injection. Additionally, one HCPCS code that describes a generic drug (J9395, Injection, fulvestrant) was excluded. Excluding claims that were processed and paid by the DME MACs resulted in the following HCPCS codes no longer falling within the top 50 drugs in 2019: J7605 (Arformoterol non-comp unit); J7686 (Treprostinil, non-comp unit); and J3285 (Treprostinil injection). Excluding claims based on the place of service exclusion resulted in one HCPCS code, J7192 (Factor viii recombinant nos), no longer falling within the top 50 drugs in 2019.

Using this approach for selecting MFN Model drugs, the resulting performance year 1 MFN Model Drug HCPCS Codes List includes single source drugs and biologicals that accounted for approximately 75 percent of annual Medicare Part B drug allowed charges for separately payable drugs during 2019. Table 2 displays the list of MFN Model drugs (by HCPCS code) that are included on the MFN Model Drug HCPCS Codes List for the beginning of performance year 1, along with the top billing specialties.

CMS will publish the MFN Model Drug HCPCS Codes List quarterly on the MFN Model website (<https://innovation.cms.gov/initiatives/most-favored-nation-model>), in advance of the calendar quarter, along with MFN Model Payment amounts and other MFN Model information and materials.

TABLE 2: PERFORMANCE YEAR 1 MFN MODEL DRUG HCPCS CODES LIST WITH TOP BILLING SPECIALTIES

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges, after exclusions (in dollars)	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
1	J0178	Aflibercept injection	\$2,982,942,674	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
2	J9271	Inj pembrolizumab	\$2,815,337,226	Hematology/Oncology	Internal Medicine	Medical Oncology
3	J9299	Injection, nivolumab	\$1,878,981,569	Hematology/Oncology	Internal Medicine	Medical Oncology
4	J9312	Inj., rituximab, 10 mg	\$1,865,991,330	Hematology/Oncology	Internal Medicine	Rheumatology
5	J0897	Denosumab injection	\$1,721,580,561	Hematology/Oncology	Internal Medicine	Rheumatology
6	J2778	Ranibizumab injection	\$1,295,341,479	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
7	J2505	Injection, pegfilgrastim 6mg	\$1,242,697,080	Hematology/Oncology	Internal Medicine	Medical Oncology
8	J9035	Bevacizumab injection	\$1,099,476,084	Hematology/Oncology	Internal Medicine	Medical Oncology
9	J1745	Infliximab not biosimil 10mg	\$1,010,328,165	Rheumatology	Gastroenterology	Internal Medicine
10	J0129	Abatacept injection	\$968,556,135	Rheumatology	Internal Medicine	Hematology/Oncology
11	J9355	Inj trastuzumab excl biosimi	\$851,042,669	Hematology/Oncology	Internal Medicine	Medical Oncology
12	J9145	Injection, daratumumab 10 mg	\$843,712,153	Hematology/Oncology	Internal Medicine	Medical Oncology
13	J2350	Injection, ocrelizumab, 1 mg	\$703,104,359	Neurology	Hematology/Oncology	Internal Medicine
14	J1300	Eculizumab injection	\$562,413,430	Neurology	Hematology/Oncology	Internal Medicine
15	J9305	Pemetrexed injection	\$539,680,121	Hematology/Oncology	Internal Medicine	Medical Oncology
16	J9022	Inj, atezolizumab,10 mg	\$486,551,001	Hematology/Oncology	Internal Medicine	Medical Oncology
17	J9173	Inj., durvalumab, 10 mg	\$476,638,073	Hematology/Oncology	Internal Medicine	Medical Oncology
18	J2353	Octreotide injection, depot	\$466,969,222	Hematology/Oncology	Internal Medicine	Medical Oncology
19	J0717	Certolizumab pegol inj 1mg	\$458,757,878	Rheumatology	Internal Medicine	Nurse Practitioner
20	J9041	Inj., velcade 0.1 mg	\$436,302,629	Hematology/Oncology	Internal Medicine	Medical Oncology
21	J2357	Omalizumab injection	\$423,947,996	Allergy/Immunology	Internal Medicine	Pulmonary Disease
22	J0585	Injection,onabotulinumtoxina	\$389,236,097	Neurology	Physical Medicine and Rehabilitation	Ophthalmology
23	J1602	Golimumab for iv use 1mg	\$368,492,761	Rheumatology	Internal Medicine	Nurse Practitioner
24	J3380	Injection, vedolizumab	\$362,050,123	Gastroenterology	Hematology/Oncology	Internal Medicine
25	J9264	Paclitaxel protein bound	\$333,264,824	Hematology/Oncology	Internal Medicine	Medical Oncology
26	J9228	Ipilimumab injection	\$331,065,114	Hematology/Oncology	Internal Medicine	Medical Oncology
27	J9217	Leuprolide acetate suspnsion	\$331,012,840	Urology	Hematology/Oncology	Internal Medicine
28	J9306	Injection, pertuzumab, 1 mg	\$318,023,592	Hematology/Oncology	Internal Medicine	Medical Oncology
29	J9047	Injection, carfilzomib, 1 mg	\$296,821,394	Hematology/Oncology	Internal Medicine	Medical Oncology
30	J3262	Tocilizumab injection	\$279,068,051	Rheumatology	Internal Medicine	Hematology/Oncology
31	J1930	Lanreotide injection	\$278,600,806	Hematology/Oncology	Internal Medicine	Medical Oncology
32	J3357	Ustekinumab sub cu inj, 1 mg	\$264,386,412	Rheumatology	Gastroenterology	Dermatology
33	J0881	Darbepoetin alfa, non-esrd	\$258,409,215	Hematology/Oncology	Internal Medicine	Medical Oncology
34	J2323	Natalizumab injection	\$255,449,074	Neurology	Hematology/Oncology	Internal Medicine
35	J2796	Romiplostim injection	\$248,212,119	Hematology/Oncology	Internal Medicine	Medical Oncology
36	J9034	Inj., bendeka 1 mg	\$219,156,831	Hematology/Oncology	Internal Medicine	Medical Oncology
37	J0885	Epoetin alfa, non-esrd	\$187,518,352	Hematology/Oncology	Internal Medicine	Nephrology
38	Q2043	Sipuleucel-t auto cd54+	\$182,158,187	Urology	Hematology/Oncology	Internal Medicine
39	J2182	Injection, mepolizumab, 1mg	\$177,640,239	Allergy/Immunology	Internal Medicine	Pulmonary Disease
40	J1439	Inj ferric carboxymaltos 1mg	\$173,008,338	Hematology/Oncology	Internal Medicine	Medical Oncology
41	J9042	Brentuximab vedotin inj	\$162,519,904	Hematology/Oncology	Internal Medicine	Medical Oncology
42	J9055	Cetuximab injection	\$162,477,948	Hematology/Oncology	Internal Medicine	Medical Oncology
43	J9354	Inj, ado-trastuzumab emt 1mg	\$157,438,453	Hematology/Oncology	Internal Medicine	Medical Oncology
44	Q5111	Injection, udenyca 0.5 mg	\$155,483,502	Hematology/Oncology	Internal Medicine	Medical Oncology
45	J7324	Orthovisc inj per dose	\$152,408,630	Orthopedic Surgery	Physician Assistant	Sports Medicine
46	J2785	Regadenoson injection	\$150,339,213	Cardiology	Interventional Cardiology	Internal Medicine
47	J0517	Inj., benralizumab, 1 mg	\$136,977,827	Allergy/Immunology	Internal Medicine	Pulmonary Disease
48	J2507	Pegloticase injection	\$123,947,596	Rheumatology	Internal Medicine	Hematology/Oncology

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges, after exclusions (in dollars)	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
49	J9176	Injection, elotuzumab, 1mg	\$123,725,659	Hematology/Oncology	Internal Medicine	Medical Oncology
50	J9311	Inj rituximab, hyaluronidase	\$121,583,613	Hematology/Oncology	Internal Medicine	Medical Oncology

Note: Ambulatory Surgical Center is included as a specialty to show drug utilization in this setting.

*The short description effective as of January 1, 2021.

Table 3 shows the distribution of total 2019 Medicare Part B allowed charges for the drugs identified in Table 2 by provider and supplier type to show the types of providers and suppliers that had claims for these separately payable Medicare Part B drugs in 2019. To assign claims to a provider or supplier type, we considered the type of MAC that processed the claim, type of bill, provider number, revenue center, line place of service code, and specialty of the health care practitioner associated with the drug claim line.

**TABLE 3 – DISTRIBUTION OF 2019 MEDICARE PART B ALLOWED CHARGES* FOR PERFORMANCE YEAR 1
MFN MODEL DRUGS BY PROVIDER AND SUPPLIER TYPE**

Provider/Supplier Type	Number of Entities (CCNs/TINs)	2019 Total Allowed Charges for MFN Model Drugs	Percent of 2019 Total Allowed Charges for MFN Model Drugs	2019 Average Allowed Charges for MFN Model Drugs Per Entity	90th Percentile	75th Percentile	50th Percentile (Median)	25th Percentile	10th Percentile
OFFICE**	18,783	\$16,896,364,008	56.64%	\$899,556	\$1,387,304	\$173,219	\$24,958	\$3,355	\$406
OPPS HOSPITAL	2,579	\$10,970,275,972	36.77%	\$4,253,694	\$11,602,122	\$4,771,715	\$1,147,107	\$79,683	\$3,064
CANCER HOSPITAL†	11	\$954,666,587	3.20%	\$86,787,872	\$157,901,464	\$129,520,505	\$63,472,661	\$37,493,103	\$34,352,282
CRITICAL ACCESS HOSPITAL†	1,146	\$641,638,057	2.15%	\$559,894	\$1,515,002	\$654,881	\$200,902	\$52,168	\$11,697
MARYLAND TCOC MODEL****†	44	\$307,057,157	1.03%	\$6,978,572	\$23,025,921	\$8,433,607	\$1,245,538	\$191,929	\$43,618
CHILDRENS HOSPITAL†	50	\$36,455,923	0.12%	\$729,118	\$462,763	\$172,467	\$31,188	\$4,860	\$904
AMBULATORY SURGICAL CENTER	540	\$17,318,224	0.06%	\$32,071	\$42,570	\$14,649	\$3,675	\$726	\$102
PENNSYLVANIA RURAL HEALTH MODEL††	4	\$2,684,657	0.01%	\$671,164	\$2,306,421	\$1,244,263	\$160,364	\$98,065	\$57,508
INPATIENT HOSPITAL PART B ONLY†	506	\$2,321,456	0.01%	\$4,588	\$11,454	\$4,794	\$804	\$226	\$109
PHARMACY	16	\$1,382,119	0.00%	\$86,382	\$231,186	\$106,502	\$13,640	\$5,489	\$2,278
ESRD FACILITY†	5	\$583,943	0.00%	\$116,789	\$576,224	\$4,529	\$2,443	\$509	\$237
INDEPENDENT DIAGNOSTIC TESTING FACILITY	4	\$78,296	0.00%	\$19,574	\$65,538	\$38,040	\$6,319	\$1,108	\$118
FQHC/RHC****†	1	\$2,151	0.00%	\$2,151	\$2,151	\$2,151	\$2,151	\$2,151	\$2,151
TOTAL	23,689	\$29,830,828,548	100.00%	\$101,141,424	\$199,130,121	\$145,141,324	\$66,311,750	\$37,933,371	\$34,474,473

*Claims where Medicare was not the primary payer and claims for radiopharmaceuticals were excluded for this analysis.

**Office includes suppliers such as physicians, non-physician practitioners, and supplier groups, such as group practices. Note that we are excluding claims submitted by non-participating physicians from the MFN Model.

***Maryland Total Cost of Care (MD TCOC) Model Participants, acute care hospitals located in Maryland.

****FQHC means federally qualified health center; RHC means rural health clinic.

† Indicates provider and supplier types that we are excluding from the MFN Model or indicates that we are excluding claims of this type from the MFN Model. Note that claims billed by ESRD Facilities that are not paid under the ESRD PPS will be subject to the MFN Model payment.

††CMS Innovation Center models that we are excluding for the first two calendar quarters of performance year 1 and then thereafter if conditions are met.

E. Model Payment Methodology for MFN Model Drugs

The MFN Model will test an innovative approach to calculating drug payment through use of a more comprehensive set of drug pricing data to calculate an alternative payment amount for MFN Model drugs, along with an alternative add-on payment, which is described in section III.F. of this IFC. Payment for drug administration services, when applicable, will continue to be separately billed by model participants to Medicare; there will be no change in the payment for drug administration services under the MFN Model. Providers and suppliers will continue to purchase MFN Model drugs, furnish such drugs to beneficiaries, submit claims to Medicare, and collect applicable beneficiary cost-sharing. Under the MFN Model, payments for separately payable Medicare Part B drugs will include the alternative drug payment amount and the alternative add-on payment amount, both subject to sequestration, as applicable.

Similar to the current approach under section 1847A of the Act, the MFN Model alternative payment limit for the “drug portion” of payment for MFN Model drugs (that is, not including the add-on amount) will be calculated by CMS quarterly. This amount is called the MFN Drug Payment Amount. The calculation of the MFN Drug Payment Amounts is codified in § 513.210(b). Beneficiary cost-sharing will apply to the MFN Drug Payment Amount for included drugs.

We will calculate an MFN Drug Payment Amount for each drug on the MFN Model Drug HCPCS Codes List based on an MFN Price, which will be derived from the lowest GDP-adjusted country-level price, based on non-U.S. OECD member countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.⁴² We will use GDP per capita information that is based on purchasing power parity. We are also establishing limits such that the MFN Drug Payment Amount will not exceed non-model payment for the drug (excluding any non-

⁴² Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the MFN Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

model add-on payment amount), will not apply to drugs that are not separately payable, and certain other limitations discussed later in this section.

Section III.E.1. of this IFC identifies the data sources for the MFN Model drugs' international drug pricing information that we will use to calculate the MFN Price for each drug. Section III.E.2. of this IFC outlines the international drug pricing information we will include in these calculations and the included countries. Section III.E.3. of this IFC defines the MFN Drug Payment Amount. Section III.E.4. of this IFC outlines our approach to calculating each drug's MFN Drug Payment Amount. Section III.E.5. of this IFC describes the phase-in of the MFN Price. Section III.E.6. of this IFC describes the alternative calculation for the MFN Drug Payment Amount for situations where no international drug pricing information is available for an MFN Model drug. Section III.E.7. of this IFC provides illustrative MFN Drug Payment Amounts for each drug on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2 using historical data. Section III.E.8. of this IFC describes the timing of data and MFN Drug Payment Amount updates. Section III.E.9. of this IFC describes adjustments to the phase-in formula and incentives for manufacturers to address rising U.S. drug prices. Section III.E.10. of this IFC describes the limitation on the MFN Drug Payment Amount. Section III.E.11. of this IFC describes the method for establishing MFN Drug Payment Amounts for MFN Model drugs added to the model for performance year 2 and subsequent performance years. Section III.E.12. of this IFC describes the quarterly payment exception for MFN Model drugs in short supply. Section III.E.13. of this IFC describes continued payment of the blood clotting factor furnishing fee under the MFN Model.

1. Data Sources on International Drug Pricing Information

We will rely on existing data sources to obtain data that we will use to calculate and update the MFN Drug Payment Amounts. We will use existing data sources that contain international drug pricing information, including list prices, sales and/or volume data (for example, package size and number of packages sold), as available, in order to optimize

operational efficiency. Sales may be based on 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. 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.

In the October 2018 ANPRM, we considered establishing a data collection system for manufacturers to report to CMS their international drug sales data for prices and units sold to support the calculation of the model payment for each drug. In response to the October 2018 ANPRM, we received comments stating that CMS should use existing data sources for international drug pricing information in order not to place burden on manufacturers. Some commenters expressed concerns that new data reporting would greatly increase burdens and costs for manufacturers, further limiting their ability to invest in research and development for innovative therapies, and would be impractical because defining price reporting for foreign markets would be too complex and could not adequately capture fluid pricing policy changes. We appreciate these concerns, and as such, we will rely on existing data sources for purposes of calculating MFN Drug Payment Amounts. We believe that existing data sources are adequate for purposes of calculating country-level prices, GDP-adjusted country-level prices, and the MFN Prices, as described in this IFC, that will be used to calculate the MFN Drug Payment Amount.

Commenters also noted that one potential adverse reaction to the model described in the October 2018 ANPRM may be a shift internationally to a high price and high rebate pricing strategy. Specifically, commenters expressed concern that if the international drug pricing information used to establish payment under a model relied on the list prices in the included countries, then manufacturers would restructure their pricing arrangements to increase the list prices of the model's drugs in those countries, and offer higher rebates to offset the increased list

price. CMS appreciates this concern, and we will prioritize use of available international drug pricing information that incorporate discounts and rebates to the extent possible, rather than just the list prices.

We have assessed several existing data sources to determine the availability and sufficiency of international drug pricing information. In § 513.140(c), we are codifying the use of one or more international drug pricing data sources. Specifically, we will use one or more data sources, available to CMS at least 20 business days prior to the start of a calendar quarter, that utilize a standardized method for identifying drugs across countries within that data source, such as using an internationally recognized method for identifying scientific and nonproprietary names (for example, active ingredient name) and a standard method for identifying drug forms that at a minimum distinguishes among injectable, oral, and other forms of a drug. For example, the data source might use the International Nonproprietary Names (INN), as applicable.⁴³ This process requires mapping between the data source's standardized method for identifying scientific and nonproprietary names and HCPCS codes, as discussed and illustrated in section III.E.7. of this IFC. Further, we will use one or more data sources that contain international drug pricing information stated in U.S. currency, such as list prices, ex-manufacturer prices (sometimes called the ex-factory price) that represents actual or calculated prices paid to the manufacturer by wholesalers and other distributors, actual or calculated sales for retail and other distribution channels, or volume data (for example, number of units sold).

If more than one data source is available for an MFN Model drug, as noted previously, we will prioritize the data sources using a hierarchy that we describe later in this section. Thus, for each MFN Model drug, we will identify and use the most comprehensive data source available, using the hierarchy codified in § 513.140(c)(3). We will use only one data source for an MFN Model drug for a quarter, meaning we will not combine data from different data sources

⁴³ World Health Organization, International Nonproprietary Names accessed via <https://www.who.int/medicines/services/inn/en/>

or time periods to calculate the MFN Drug Payment Amount for an MFN Model drug for a quarter.

Whenever possible, we will use international drug pricing information from two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply since the ASP payment limits that apply to that calendar quarter are based on manufacturers' U.S. sales from two calendar quarters prior such that the U.S. and international drug pricing data will be based on information from the same calendar quarter. We use the term applicable ASP calendar quarter to mean the period that is two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply.

The hierarchy of data sources we will use is as follows:

- A data source with sales and volume data for the applicable ASP calendar quarter from at least one included country, that is, a non-U.S. OECD member country at the end of the applicable ASP calendar quarter with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.
- 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 included country.
- The extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website.
- A data source with ex-manufacturer price data for the applicable ASP calendar quarter from at least one included country.
- A data source with list price data for the applicable ASP calendar from at least one included country.

In each of these cases, if there is more than one data source meeting the requirements in §510.140(c), we will use the data source at the highest level of the hierarchy that contains information from the highest number of included countries, and, if available, incorporates

discounts and rebates into its drug pricing information. 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. We note that, based on the performance year 1 MFN Model Drug HCPCS Codes List shown in Table 2, levels 4 and 5 of the hierarchy will only apply to MFN Model drugs that are added to the MFN Model Drug HCPCS Codes List after performance year 1 and perhaps for Q2043 (Sipuleucel-t auto cd54+)⁴⁴ and J2507 (Pegloticase injection), because for other MFN Model drugs in performance year 1, the first three levels of the hierarchy will always result in an available data source as we consider the data used by CMS to create the illustrative MFN Prices and MFN Drug Payment Amounts in Table 6 of this IFC to satisfy level 3 of our hierarchy. To illustrate: Suppose we identified four data sources meeting the requirements of §510.140(c), where Data Source 1 contains sales and volume data for MFN Model drug X for the applicable ASP calendar quarter from 10 included countries, Data Source 2 contains sales and volume data for MFN Model drug X for the applicable ASP calendar quarter from 15 included countries, Data Source 3 contains sales and volume data from the third calendar quarter of 2020 for MFN Model drug X from 16 included countries, and Data Source 4 contains list price information for the applicable ASP calendar quarter from all included countries. In this scenario, we would use information solely from Data Source 2 to determine the MFN Price for MFN Model drug X by calculating unadjusted country-level prices for each of the 15 countries for which Data Source 2 contains information, and we would not use Data Sources 1, 3, or 4 to calculate the MFN Price for MFN Model drug X for that quarter. For further illustration of how we will apply the hierarchy in calculating MFN Drug Payment Amounts, see section III.E.4.a. of this IFC.

We will use international sales and volume information from as early as the third

⁴⁴ No data on international pricing or sales of Sipuleucel-t auto cd54+ were available in the data source used for Table 6, but international drug pricing information for this drug could be available in other sources.

calendar quarter in 2020 to minimize the possibility of having no international sales and volume information with which to calculate the MFN Price and to mitigate the potential effect of manufacturers' limiting the reporting of international drug pricing information during the model performance period.

In addition, the one or more data sources we will use will have mechanisms in place to maintain, update, and correct, if necessary, the data source on at least a quarterly basis. Further, the data sources we will use will be maintained by organizations that seek to limit the lag inherent in data to no more than 180 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the data source.

We plan to monitor the implementation of a World Health Assembly (WHA) resolution to “improve the transparency of markets for medicines, vaccines, and other health products.” This resolution aims to help Member States make more informed decisions when purchasing health products, negotiate more affordable prices, and ultimately expand access to health products for their populations. In particular, the WHA resolution⁴⁵-

- Urges Member States to publicly share information on net prices paid for health products, to promote greater transparency on pharmaceutical patents and clinical trial results and to improve suppliers' reporting of information such as sales revenues and units sold; and,
- Requests the WHO secretariat to support the development and implementation of national policies relevant to transparency and to monitor the impact of transparency on affordability and availability of health products, including the effect of differential pricing.

We will monitor developments related to this WHA resolution and assess its impact on

⁴⁵ World Health Assembly Update, 28 May 2019, accessed via: https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

the availability of data we will use to calculate and update MFN Drug Payment Amounts.

As discussed previously, we will use a hierarchy when selecting from available data sources and start by using data sources that incorporate discounts and rebates to the extent possible in order to address commenters' concerns about a shift internationally to a high price and high rebate pricing strategy. We believe that using one or more data sources will help to ensure that we will capture sufficient information to monitor the international drug pricing landscape and to calculate and update MFN Drug Payment Amounts. Data sources that include the information described previously, as determined by CMS, will be considered sufficient, and as such, we will calculate MFN Drug Payment Amounts for MFN Model drugs using information extracted from such data sources. Specifically, as necessary, for each MFN Model drug, we will extract and use data that align with the data sources' standardized method for identifying scientific and nonproprietary names and dosage forms (for example, injectable forms), and with the HCPCS code's long descriptor, including dosage form, for the HCPCS codes on the MFN Model Drug HCPCS Codes List, as applicable. Further, we will only use the extracted data for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor as determined by CMS when such limitation is not feasible prior to extracting the data. For example, for a drug, one HCPCS code may include drug products that are a certain type of formulation, such as short-acting, intravenously administered drug products, and another HCPCS code may include drug products with the same scientific and nonproprietary name but a different formulation (such as a long-acting suspension for intramuscular injection), and the extracted data contains international drug pricing information for both formulations. In such case, we will align the extracted data in accordance with the HCPCS code descriptor for the MFN Model drug. In order to align with our existing policies for how we utilize manufacturer-reported ASP data to calculate payment limits, we may find it necessary to make adjustments to the data that we extract from international drug pricing information data sources. For example, in calculating payment amounts based on ASP we do not adjust the volume or units of a drug

(that is, the amount of a drug in a package) for intentional overfill (see 75 FR 73466). If we find that a data source from which we obtain international drug pricing information makes adjustments for overfill, we will make adjustments to the data that we extract from such source so that the extracted data is comparable to ASP data. There could be other cases where we will have to examine the extracted data and make adjustments to align the data with a HCPCS code descriptor for an MFN Model drug. Specifically, we will adjust the extracted international drug pricing information for MFN Model drugs when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product as determined by CMS. In such cases where we confirm a difference, we will make adjustments to the pricing, sales and volume data as necessary before calculating the unadjusted country-level price for the drug at the HCPCS code level. We believe that such cases will be rare. However, we identified the need to make such adjustment to the international drug pricing information we used to illustrate the MFN Drug Payment Amounts for J9311 (Inj rituximab, hyaluronidase) shown in Table 6 to align the package size volume with manufacturer labeling and the HCPCS code dosage descriptor. We note that there could be additional cases if international drug pricing data sources that we will select show prices, sales or volume data that are adjusted for intentional overfill, include multiple ingredients for a single drug product, or are in error (for example, the package size represents the maximum volume of a vial instead of the volume of drug in a package).

We will only use the extracted data that have complete package size information. As discussed previously, we will use a hierarchy to determine which data source to use for each MFN Model drug for a quarter, in which we will select a data source that includes sales and volume data first. Data without both sales and volume data will not be able to be combined with other data, therefore we will exclude such observations. For data sources with international sales and volume data for a given MFN Model drug, we will exclude from the calculation of the unadjusted country-level price data that fall below a minimum threshold or are incomplete, that

is, international pricing data with less than \$1,000 in quarterly sales, with less than 1,000 units in quarterly volume, or where both sales and volume data are not present. We believe that \$1,000 in quarterly sales and 1,000 units in quarterly volume for a package size is an appropriate minimum necessary to establish sufficient sales and volume for data to be included in the calculation of a meaningful and reliable unadjusted country-level price for an MFN Model drug and will minimize inclusion of potential outlier data. We will exclude presentations with low volume or low sales to prevent outlier presentations from exerting undue influence.

In developing the illustrative MFN Prices shown in Table 6, we applied these exclusions. Minimal sales and volume across all countries were excluded because of the low volume or sales exclusion criteria. We explored the impact of different volume and expenditure thresholds, and determined that \$1,000 in quarterly sales and 1,000 units are a reasonable threshold to reduce risk associated with extremely low values. We found that data with potential outlier sales remained relatively common with lower thresholds (that is, below \$1,000 in quarterly sales). While using higher thresholds may further reduce potential inclusion of outlier sales data, doing so would result in having less data to calculate unadjusted country-level prices.

The exclusion of international pricing data with less than \$1,000 in quarterly sales or with less than 1,000 units in quarterly volume from the calculation of the unadjusted country-level price will greatly minimize the potential risk for including possible outlier or errant data. To better understand this potential issue, we considered the impact of including or excluding data with less than \$1,000 in quarterly sales or less than 1,000 units in quarterly volume in the calculation of the unadjusted country-level price. There was little impact from including these data but, as a potential safeguard to prevent inclusion of inappropriately low or high international drug pricing information in our calculations for the MFN Model, we will exclude such data from the calculation of the unadjusted country-level price. Overall, where this approach had more than a 1 percent impact, there tended to be an increase in the MFN Prices.

We also considered whether pricing information that is greater than or less than 95

percent of the mean across all data for the drug at the equivalent of the HCPCS code billing unit level should be considered a possible outlier or error and whether trimming such data or removing such data would be warranted. In our experience with international drug pricing information data sources, outlier or potentially erroneous data appear only in isolated instances and are often suggestive of unintended differences in the unit at which data is shown. For example, the pricing data for a product with a standard unit of one gram in one country could appear to be 1,000 times lower than the pricing data for that same product from other countries in the data source; in such a case, it seems likely that the data for the one country with a very low relative price represents the price per milligram not per gram and such data would likely be corrected over time by the data source. We believe international drug pricing data sources have mechanisms to correct such discrepancies based on market research of currently available international drug pricing information data sources. Further, as codified in § 513.140(c), the international drug pricing information data sources that we will obtain will have mechanisms in place to maintain, update, and correct, if necessary, the information on international drug pricing in the database on at least a quarterly basis. As such, because we will revise the MFN Drug Payment Amounts quarterly, we will recalculate the MFN Drug Payment Amounts for up to four prior quarters when revised international drug pricing information is available in the data source that we used to calculate the MFN Model drug's MFN Price for the relevant quarter or ASP updates for the relevant quarter are available.⁴⁶ In cases where an MFN Drug Payment Amount for a prior quarter is recalculated by CMS, CMS will prospectively apply the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates, and will not automatically reprocess claims to apply the recalculation, but reserves the right to do so. To the extent that MFN Model claims are reprocessed due to revisions to the international drug pricing information, the Medicare payment amount and

⁴⁶ We will apply the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates.

beneficiary cost sharing will be recalculated to reflect the revised prices. If prior to calculating the unadjusted-country level prices for a quarter, the data source confirms that there is an error that they plan to correct in a future version of the dataset and we have the corrected information, we will make the correction to avoid the need to reprocess claims later. Therefore, we do not believe it is necessary to take further steps to trim or remove potential outlier or erroneous international drug pricing information before calculating the unadjusted country-level prices. We note that CMS does not make outlier adjustments to ASP data.

In addition, for future years, we seek comment on whether a threshold should be applied to determine whether the MFN Drug Payment Amount should be recalculated for a prior quarter. Specifically, we are interested in comments on whether recalculations should only occur when the international drug pricing information data source used corrects its data and the impact on the MFN Price is more than a nominal amount. We seek comment on the appropriate amount of such threshold and how a nominal amount should be defined. Finally, in the event that the international drug pricing information data source that we used to calculate the MFN Drug Payment Amount for an MFN Model drug for a quarter identifies an error in their data and does not correct such error within 180 days after the applicable ASP calendar quarter, we seek comment on whether CMS should recalculate the MFN Drug Payment Amount for such MFN Model drug and quarter using international drug pricing information in accordance with the hierarchy in § 513.140(c)(3) after excluding the data source we initially used. We also seek comment on whether CMS should adopt an alternative approach to remediating such data errors.

2. International Data Included in the MFN Model

In the October 2018 ANPRM, for purposes of a potential IPI Model, we stated that we were considering using pricing data from the following countries: Austria, Belgium, Canada, Czechia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom. We considered including these countries' data as they are either economies comparable to the U.S. or they are included in Germany's market basket for reference pricing for

their drug prices, and existing data sources contain pricing information for these countries.

We received wide-ranging and helpful feedback in response to the October 2018 ANPRM regarding which countries' data to include in a model. In addition to comments received to the October 2018 ANPRM, we also conducted significant outreach to stakeholders, such as stakeholder meetings and conference calls, to gather targeted feedback. There was also a substantial number of media and press reports surrounding which countries' data to include in the MFN Model.

Generally, we received a significant number of comments that expressed opposition to including data from countries that have health care systems that are substantially dissimilar to the U.S.'s health care system. Specifically, many commenters stated that data from countries utilizing government-run health care systems or imposing strict drug price controls should be excluded. Alternatively, other commenters noted that CMS should consider broadening the scope to include more countries, because the more countries that are included in the index, the harder it would be for pharmaceutical companies to manipulate or game the pricing changes. Commenters also recommended utilizing various criteria for selecting the countries that would be included, such as the launching speed of new drugs, the presence of rigorous health technology assessment, the proportions of public and private markets, the economies of those countries, and Human Development Index (HDI).⁴⁷

Based on the comments received, we believe the most appropriate criteria for considering a country for MFN pricing is membership in the OECD and GDP per capita relative to the U.S. The current list of OECD countries includes all countries included in the October 2018 ANPRM as well as Australia, Chile, Colombia, Estonia, Hungary, Iceland, Israel, Latvia, Lithuania, Luxembourg, New Zealand, Norway, Poland, Portugal, Republic of Korea, Slovakia, Slovenia,

⁴⁷ The Human Development Index is utilized by the United Nations and is "is a summary measure of average achievement in key dimensions of human development: a long and healthy life, being knowledgeable and have a decent standard of living. The HDI is the geometric mean of normalized indices for each of the three dimensions." Please see the United Nations Development Programme's Human Development Reports for more information: <http://hdr.undp.org/en/content/human-development-index-hdi>

Spain, Switzerland, and Turkey. OECD countries comprise a set of countries that share with the U.S. democratic principles and commitment to market-based economies, and these countries' GDP per capita (based on purchasing power parity) range from approximately 25 percent of the U.S. GDP per capita to over 175 percent of the U.S. GDP per capita. Based on this wide range of GDP per capita data, we believe it is most appropriate to include available international drug pricing information for countries with a GDP per capita of at least 60 percent of the U.S. GDP per capita, as codified in § 513.140(b). We believe that applying a minimum of 60 percent of the U.S. GDP per capita strikes a balance between-- (1) having too low a GDP per capita threshold and including data from countries with economies that are substantially different from the U.S., while; (2) also not having such a high GDP per capita threshold that the list of countries would be very short, which commenters suggested we should avoid. To avoid creating a potential incentive for countries to discontinue their membership in the OECD, we will include available international drug pricing information for countries that were OECD members as of October 1, 2020, regardless of whether they remain OECD members after October 1, 2020, unless the country's GDP per capita, as determined by CMS quarterly, falls below the threshold of 60 percent of the U.S. GDP per capita. Based on available data, this means that we will calculate the MFN Price for the first quarter of performance year 1 based on available international drug pricing information from Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.⁴⁸ These 22 OECD countries are among the countries with the highest GDP per capita worldwide.⁴⁹

We considered alternative approaches to including data from countries for the MFN Model. Specifically, we considered including all non-U.S. OECD countries or selecting

⁴⁸ The non-U.S. OECD countries that will not be an included country for purposes of calculating the MFN Price for MFN Model drugs for the first quarter of performance year 1 will be Chile, Colombia, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Mexico, Poland, Portugal, Slovakia, Slovenia, and Turkey.

⁴⁹ <https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html>.

countries based on factors such as World Health Organization (WHO) recognition as a Stringent Regulatory Authority (SRA) and intellectual property protections. We also considered including data from only countries that may represent large markets for drug manufacturers such as the European Union, Canada, Japan, and United Kingdom. Additionally, the Foundation for Research on Equal Opportunity (FREOPP) recommended an alternative approach called the Market-Based International Index (MBII) as a benchmark for evaluating other countries' prescription drug pricing systems;⁵⁰ this approach would include data from the following countries that FREOPP identified as having market-based health care systems: Austria, Belgium, Czechia, Denmark, France, Germany, Ireland, Japan, Netherlands, Portugal, Singapore, Slovakia, and Switzerland.

Based on analyses examining potential alternatives, we believe that none of these alternative approaches would be as objective and predictable for purposes of calculating MFN Prices as our approach. Our approach will result in a large set of countries that are economically similar, have reasonably comparable purchasing power to the U.S., and generally have existing international drug pricing information that is available. We considered an alternative that would phase-in countries over time based on a defined set of characteristics, such as GDP per capita or average drug prices. We believe that phasing in countries over time would create instability in the MFN Price. Thus we are adopting a set of included countries that meet the requirements in § 513.140(b), which allows for the inclusion of data from countries that were non-U.S. OECD member countries as of October 1, 2020, when CMS calculates the MFN Drug Payment Amounts for a calendar quarter. That means that at the end of each applicable ASP calendar quarter, CMS will assess the non-U.S. OECD member countries as of October 1, 2020, that have a GDP per capita that is at least 60 percent of the U.S. GDP per capita. Because available GDP data are updated infrequently, we believe this approach will result in a highly stable process for

⁵⁰ Roy, A. (2018) The Foundation for Research on Equal Opportunity, "What Medicare Can Learn From Other Countries on Drug Pricing," accessed via <https://freopp.org/what-medicare-can-learn-from-other-countries-on-drug-pricing-bf298d390bc5>

developing the MFN Prices.

We will include available international drug pricing information from the included countries when such data are contained in the data sources that we have described in § 513.140(c), as described in section III.E.1. of this IFC.

There are several existing sources for GDP data, including the Central Intelligence Agency (CIA) World Factbook,⁵¹ the World Bank,⁵² and the International Monetary Fund.⁵³ Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We will use the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency and includes estimates for all OECD member countries. We will use the following process to determine the countries that were non-U.S. OECD member countries as of October 1, 2020, with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. For each country, we will assess the GDP per capita based on purchasing power parity that is available in the CIA World Factbook at the end of the applicable ASP calendar quarter. The CIA World Factbook contains the most recent estimate of GDP per capita based on purchasing power parity for a country as well as historical data. We will identify whether a country has a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the most recent estimate of GDP per capita based on purchasing power parity for a country by the U.S. GDP per capita, using data for the same year, and assessing the results. We will use the GDP per capita from the same year as the international drug pricing information that is used to calculate the unadjusted country-level price, if available, or the most recent prior year.

3. Definition of the MFN Drug Payment Amount

As described later in this section, we will calculate the MFN Drug Payment Amount for a calendar quarter for the MFN Model drug based on a phased-in blend of the applicable ASP and

⁵¹ <https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html>

⁵² <https://data.worldbank.org/indicator/ny.gdp.mktp.cd>

⁵³ <https://www.imf.org/external/pubs/ft/weo/2019/01/weodata/weose1gr.aspx>

the MFN Price, which we will determine by selecting the lowest GDP-adjusted country-level price from the included countries for the applicable ASP calendar quarter.

4. Calculation of the MFN Drug Payment Amounts

We will calculate an MFN Drug Payment Amount for each MFN Model drug for which there is international drug pricing information from at least one data source that meets our criteria for at least one included country. Section III.E.6. of this IFC describes an alternative approach for calculating the MFN Drug Payment Amount for situations where no international drug pricing information is available for an MFN Model drug, for example, because the MFN Model drug is not approved for marketing by any included country.

When using international drug pricing information to calculate the MFN Drug Payment Amounts, we want to account for the relative economic resources of non-U.S. countries to be able to fairly compare country-level prices. We will address relative economic resources in two ways: (1) we will only use available international drug pricing information from non-U.S. OECD member countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita; and (2) we will adjust the extracted country-level prices using a GDP adjuster that adjusts for a country's GDP per capita if it is lower than that of the U.S.

Specifically, to calculate the MFN Drug Payment Amounts for a calendar quarter in a performance year, we will follow a multi-step process using the corresponding quarterly ASP pricing file, as well as the available international drug pricing information for included countries for the applicable ASP calendar quarter, where available. The key steps to calculate the MFN Drug Payment Amount for each MFN Model drug will be--

- Identify the available international drug pricing information for the MFN Model drug (by applying the hierarchy of data sources obtained by CMS and extracting the relevant data)⁵⁴;

⁵⁴ Applicable subsequent steps depend upon the level of the hierarchy for the selected data source. For example, when there are no international sales and volume data available for the drug for an applicable ASP calendar quarter or from any quarter beginning on or after October 1, 2019, in accordance with level 3 of the hierarchy, we will use the extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, including the data used by CMS to create the illustrative MFN Prices

- Remove incomplete and low sales and volume data, as applicable;
- Convert extracted volume data to the HCPCS code unit level and adjust for volume issues such as intentional overfill, as applicable;
- Calculate⁵⁵ the unadjusted country-level price (representing the average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit) for the MFN Model drug for each included country with available data in the selected data source for that drug;
- Calculate the GDP adjuster for each included country;
- Apply the GDP adjuster to the unadjusted country-level price;
- Select the lowest GDP-adjusted country-level price for each MFN Model drug, which, if available, will be the MFN Price;
- Identify the applicable ASP (which we define as the payment amount determined in accordance with 1847A of the Act, less the applicable add-on percentage, for the MFN Model drug's HCPCS code);⁵⁶
- Compare the MFN Price to the applicable ASP (to apply limit, if applicable);
- Identify the applicable phase-in formula and adjustments; and
- Apply the applicable phase-in formula and adjustments, if applicable, to calculate the MFN Drug Payment Amount.

The following paragraphs further describe how we will calculate the MFN Model Drug Payment Amounts for each MFN Model drug for each calendar quarter during the model:

a. Identify the Available International Drug Pricing Information for the MFN Model Drug

Using the data sources that we obtain and applying the hierarchy described previously in this IFC, we will extract the available international drug pricing information for an MFN Model

and MFN Drug Payment Amounts in Table 6 of this IFC. In such case, it will not be necessary to redo steps to extract data from the data source; however, CMS will follow the remaining steps in the MFN Drug Payment Amount calculation.

⁵⁵ The calculation used depends upon whether volume data is available.

⁵⁶ In general, the ASP Pricing File contains payment limits based on 106 percent of the volume weighted average of manufacturers' ASP for a given HCPCS code. To identify the applicable ASP, we will divide the payment limit by 1.06 after removing the blood clotting factor furnishing fee, if applicable. For a biosimilar, we will remove the amount that represents 6 percent of the reference biological product's ASP.

drug for the applicable time period (that is, the applicable ASP calendar quarter) by aligning the MFN Model drug's HCPCS code long description (in terms of name and dosage form) with the data sources' standard method for identifying scientific names or nonproprietary names (such as the International Nonproprietary Names). That is, for an MFN Model drug, we will identify the data sources' standardized scientific name or nonproprietary name for that drug, and then use that naming to identify data for all products within that data source with an applicable formulation. We will extract the applicable data (for example, data for all package sizes for injectable forms of the drug aligned with the identified scientific or nonproprietary name and formulations, for the included countries) from the data source for the applicable ASP calendar quarter, and in accordance with our hierarchy, select the data source for the MFN Model drug for that quarter.

As previously discussed in this IFC, we will only use extracted data from the selected data source that appears complete and represent dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor, as determined by CMS. For example, J0178, Aflibercept injection, represents injectable ophthalmic formulations whereas a data source may contain data for aflibercept for both ophthalmic and systemic formulations; only data for ophthalmic formulations will be used to calculate the MFN Price for such drug. The international drug pricing data used to calculate the MFN Price will not be limited to distinguish between products with different inactive ingredients (for example, different excipients) or whether or not the product is protein bound. However, we will limit the international drug pricing data for combination drugs that contain multiple active ingredients or biological products to the extent feasible, as determined by CMS. This approach is particularly relevant for four of the MFN Model drugs for performance year 1, aflibercept injection (J0178), which represents ophthalmic formulations compared to systemic formulations; paclitaxel protein bound (J9264), which represents protein bound formulations compared to formulations of paclitaxel that are not protein bound; ferric carboxymaltos (J1439), which represents injected formulations compared to

oral formulations; and rituximab, hyaluronidase (J9311), which represents formulations for subcutaneous administration compared to formulations of rituximab for intravenous administration.

In accordance with the hierarchy for selecting international drug pricing information data sources, we will prioritize use of international drug pricing information that includes sales and volume data for the applicable ASP calendar quarter if such information is available for a drug for one or more included countries. If more than one such data source is available, we will select the data source with international drug pricing information for the applicable ASP calendar quarter, even if another data source includes a higher number of included countries. For example, if the applicable ASP calendar quarter is the third quarter of 2021 and an available data source has sales and volume data for a drug for 20 of the included countries for the second quarter of 2021 and for 15 included countries for the third quarter of 2021, we would extract and then calculate unadjusted country-level prices for that drug based on sales and volume data from the third quarter of 2021 only for the 15 included countries for which data from that quarter are available.

If there are available data from a data source at the second level of our hierarchy (that is, no international sales and volume data for the applicable ASP calendar quarter, but sales and volume data from any quarter beginning on or after October 1, 2019), for a drug, we will use available international sales and volume data from that data source for the most recent prior quarter that begins on or after October 1, 2019 for that drug for included countries.

If there are no international sales and volume data available for the drug, we will use the extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, in accordance with the third level of the hierarchy.

If no MFN Drug Payment Amount has been publicly posted for the drug, we will use a data source at the fourth level of our hierarchy if available (the data source contains ex-

manufacturer price data but does not include volume data for the applicable ASP calendar quarter).

If ex-manufacturer price data for the applicable ASP calendar quarter are not available, we will use a data source at the fifth level of our hierarchy (the data source contains list price data for the applicable ASP calendar quarter).

b. Remove Incomplete Low Sales and Volume Data, as Applicable

If the data source we select has sales and volume data at the package level for an included country, we will apply the exclusions for data with incomplete data and low sales and volume. That is, we will exclude data without both sales and volume data, with less than \$1,000 in quarterly sales (expressed as U.S. currency), or with less than 1,000 units in quarterly volume.

c. Convert the Extracted Volume Data to the HCPCS Code Unit Level and Adjust for Volume Issues, such as Intentional Overfill, as Applicable

We will adjust the remaining volume data to the same level as the HCPCS billing unit, as applicable. For example, if the data for a package size shows the volume is 1,000 units and each unit represents a 1 MG vial package and for another package size the volume is 500 units and each unit represents a 10 MG vial package, and both of these data are for a drug assigned to the same HCPCS code with a HCPCS billing unit of 1 MG, the adjusted volume data for these packages would be 1,000 units and 5,000 units, respectively, for a total adjusted volume of 6,000 units. The volume for the 1 MG vial package is unchanged because the amount of drug in one package (that is, 1 MG) equals the amount of drug in one HCPCS billing unit. The volume for the 10 MG vial package is changed to be 10 times higher because the amount of drug in one vial (that is, 10 MG) equals 10 times the amount of drug in one HCPCS billing unit.

Before this step is performed, as applicable, we will adjust the extracted volume information before converting it to the HCPCS billing unit level when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product based on the available product information, such as package labeling, compared to the

data extracted from the data source. In addition, we will limit the number of billing units in a package when the available package labeling specifies use of a limited amount of drug is to be used from the package. For example, we will limit the number of billing units in a package for an aflibercept vial to one 2 mg dose in accordance with available package labeling, which specifies that each vial, regardless of the labeled volume, has one 2 mg dose. For injectable formulations for HCPCS codes with dosage specified as per dose, we will limit the number of billing units in a package to no more than one per vial. This approach was applied to illustrate the MFN Prices for J7324 (Orthovisc inj per dose) in Table 6.

d. Calculate the Unadjusted Country-Level Price for the MFN Model Drug's HCPCS Code for each Included Country with Available Data in the Selected Data Source for that Drug

Using the data available after completing the prior steps, we will calculate the unadjusted country-level price for each included country with available data. The unadjusted country-level price represents the average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

We will use a calculation that is applicable to the data available at this step. If volume data are available, we will use a calculation that includes volume-weighting across the different data (which often represent different package sizes) of the drug included in the data source for the country to calculate the unadjusted country-level price. If volume data are not available, we will use a calculation that treats all packages of the drug included in the data source for the country equally, after converting the pricing data to the HCPCS code unit level, in calculating the unadjusted country-level price.

If sales and volume data are available, we will first sum the adjusted volume data for all package sizes for the drug. We will then sum the total sales for all package sizes for the drug, and divide that sum by the sum the adjusted volume data for all package sizes for the drug, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit. If the data source we select has ex-manufacturer or list prices and does not

have volume data, we will calculate the number of HCPCS billing units in a package and divide the ex-manufacturer price or list price for a package by the number of HCPCS billing units in the package, resulting in a price per unit of drug for each package listed in the data source. We will then sum the price per unit of drug for each package listed in the data source for the drug and divide the sum by the number of packages listed in the data source for the drug, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

We will repeat this process for each country specified in § 513.140(b), to the extent international drug pricing information for the drug for the country is available from the selected data source. As explained previously and specified in § 513.140(c)(3)(i), we will use the highest tier data source, in accordance with the hierarchy, which includes data for the drug in at least one included country. If the selected data source for a drug for a calendar quarter does not include data from a particular included country, we will still calculate the MFN Price for that drug using the data from the selected data source based on the included countries from which there are data for the drug. We will not include any information from countries that did not have data in the selected data source for that drug. In cases where there is no data source that meets our criteria for using international drug pricing information (that is, there are no international sales, volume, or other pricing data available from any of the included countries in our international drug pricing information data sources, including data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, for an MFN Model drug for any quarter beginning on or after October 1, 2019 up to and including the model performance period, we will not calculate an unadjusted country-level price (or GDP-adjusted country-level price) and will instead use the applicable ASP (which we will define as the payment amount determined in accordance with section 1847A of the Act minus the applicable add-on percentage, for the MFN Model drug's HCPCS code) as the MFN Model Drug Payment Amount, as described in section III.E.6. of this IFC.

e. Calculate the GDP Adjuster for each Included Country

As discussed previously, we want the MFN Price to account for the relative economic resources and purchasing power for each included country to be able to fairly compare country-level prices. As such, we will calculate a GDP adjuster, using a country's GDP per capita based on purchasing power parity, that will be used to adjust the unadjusted country-level price for each drug (whether based on international sales and volume data or international ex-manufacturer or list prices) to reflect the country's economic resources relative to the U.S. We believe that GDP per capita based on purchasing power parity represents a broadly used and reliable measure of a country's economic resources to ensure a meaningful comparison of country-level prices.

As previously mentioned, there are several existing sources for GDP data, including the CIA World Factbook,⁵⁷ the World Bank,⁵⁸ and the International Monetary Fund.⁵⁹ Our analyses suggest that the GDP data across these sources are highly associated with one another. We will use the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency and includes estimates for all current OECD member countries. The GDP adjuster will be based on the GDP per capita available from the CIA World Factbook at the end of the applicable ASP calendar quarter. We will use the most recent GDP per capita data available for each included country and the U.S. GDP per capita from the same year as the GDP per capita data that is available from the included country. For example, if the most recent GDP per capita from the comparison OECD country is from 2016 and the most recent U.S. GDP per capita is 2017, then we will use the GDP per capita from 2016 for both countries when comparing. In cases where we use international drug pricing information from a quarter other than the applicable ASP calendar quarter (that is, an earlier time period) to determine the unadjusted country-level price, we will use the GDP per capita data for that time period, if available, or the

⁵⁷ <https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html>

⁵⁸ <https://data.worldbank.org/indicator/ny.gdp.mktp.cd>

⁵⁹ <https://www.imf.org/external/pubs/ft/weo/2019/01/weodata/weoselgr.aspx>

most recent earlier data available. That is, CMS will use the GDP per capita for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

To create a simple, easily understandable GDP adjuster, each country's GDP adjuster will be a straight ratio of its GDP per capita based on purchasing power parity divided by U.S. GDP per capita, subject to the limitation described later in this section. The U.S. GDP per capita for 2017, the most current data available, was \$59,800. Table 4 presents GDP per capita for 2017 and the GDP adjusters for each non-U.S. OECD member country, based on the U.S. GDP per capita of \$59,800 for 2017, that we will use to calculate the MFN Drug Payment Amounts for performance year 1, quarter 1. In cases when an included country's GDP per capita and the U.S. GDP per capita are not updated in the CIA World Factbook at the same time, we will use the most recent GDP per capita for the included country and the U.S. GDP per capita from the same year to ensure that the GDP adjuster for an included country is calculated using GDP data from both countries from the same time period. For example, if at the end of an applicable calendar quarter a 2018 estimate of a country's GDP per capita based on purchasing power parity becomes available in the CIA World Factbook but the most recent U.S. GDP per capita available in the CIA World Factbook continues to be for 2017, we will continue to use data from 2017 for both countries to calculate the GDP adjuster for that country.

The GDP adjuster will be capped at 1 such that the adjuster will only increase the unadjusted country-level price for a drug; it will not decrease it. We will cap the GDP adjuster at 1 because its purpose is to adjust for countries' economic resources when lower than those of the U.S. Capping the GDP adjuster at 1 will ensure that we do not make an adjustment that would result in an amount that would be lower than the unadjusted country-level price. For example, if Country X with a higher GDP per capita based on purchasing power parity than the U.S., such as a GDP per capita ratio of 2, has an unadjusted country-level price of \$100 for an MFN Model drug, we would use a GDP adjuster of 1.0 and calculate a GDP-adjusted country-level price of

\$100 rather than using a GDP adjuster of 2.0 and calculating a GDP-adjusted country-level price of \$50.

TABLE 4. NON-U.S. OECD MEMBER COUNTRY GDP PER CAPITA (BASED ON PURCHASING POWER PARITY) AND GDP ADJUSTERS FOR PERFORMANCE YEAR 1, QUARTER 1

OECD Countries	CIA GDP Per Capita, Based on Purchasing Power Parity (2017)	GDP Adjuster for Performance Year 1, Quarter 1
<i>The following countries have a GDP per capita of at least 60 percent of U.S. GDP per capita:†</i>		
Australia	\$50,400	0.843
Austria*	\$50,000	0.836
Belgium*	\$46,600	0.779
Canada*	\$48,400	0.809
Denmark*	\$50,100	0.838
Finland*	\$44,500	0.744
France*	\$44,100	0.737
Germany*	\$50,800	0.849
Iceland	\$52,200	0.873
Ireland*	\$73,200	1.000**
Israel	\$36,400	0.609
Italy*	\$38,200	0.639
Japan*	\$42,900	0.717
Republic of Korea	\$39,500	0.661
Luxembourg	\$105,100	1.000**
Netherlands*	\$53,900	0.901
New Zealand	\$39,000	0.652
Norway	\$72,100	1.000**
Spain	\$38,400	0.642
Sweden	\$51,200	0.856
Switzerland	\$62,100	1.000**
United Kingdom*	\$44,300	0.741
<i>The following countries have a GDP per capita below 60 percent of U.S. GDP per capita:</i>		
Chile	\$24,600	0.411
Colombia	\$14,400	0.241
Czechia*	\$35,500	0.594
Estonia	\$31,700	0.530
Greece*	\$27,800	0.465
Hungary	\$29,600	0.495
Latvia	\$27,700	0.463
Lithuania	\$32,400	0.542
Mexico	\$19,900	0.333
Poland	\$29,600	0.495
Portugal	\$30,500	0.510
Slovakia	\$33,100	0.554
Slovenia	\$34,500	0.577

OECD Countries	CIA GDP Per Capita, Based on Purchasing Power Parity (2017)	GDP Adjuster for Performance Year 1, Quarter 1
Turkey	\$27,000	0.452

*Indicates countries that were listed as potential included countries in the October 2018 ANPRM (83 FR 54557).

**Indicates that the GDP adjuster is capped at 1.000.

† The 2017 U.S. GDP per capita is \$59,800.

f. Apply the Applicable GDP Adjuster to Calculate the GDP-adjusted Country-level Price for the MFN Model Drug

Next, we will apply the country-specific GDP adjuster to the unadjusted country-level price for that country by dividing the unadjusted country-level price by the country's GDP adjuster. The result will be the GDP-adjusted country-level price for the MFN Model drug for that country. We will repeat this calculation to produce a GDP-adjusted price for every country for which we have calculated an unadjusted country-level price for the MFN Model drug.

g. Identify the Lowest GDP-adjusted Country-level Price for the MFN Model Drug

We will examine the GDP-adjusted country-level prices for the MFN Model drug, and identify the lowest GDP-adjusted country-level price for the MFN Model drug. The lowest GDP-adjusted country-level price will be the MFN Price for the MFN Model drug.

h. Compare the MFN Price to the Applicable ASP

As a safeguard for beneficiaries, we will compare the MFN Price to the applicable ASP in order to ensure that beneficiaries are always paying the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, we will establish the MFN Price as equal to the applicable ASP.

i. Identify the Applicable Phase-in Formula and Adjustments

As described in section III.E.5. of this IFC, we will phase-in the use of the MFN Price over the course of the MFN Model. As discussed in section III.E.9. of this IFC, we will also accelerate the applicable phase-in formula when the applicable ASP for an MFN Model drug rises faster than both a designated inflation factor and the change in MFN Price, and lower the

MFN Drug Payment Amount below the MFN Price by a certain percentage if the applicable ASP for an MFN Model drug continues to increase faster than the inflation factor and the MFN Price after the full phase-in of the MFN Price. In this step of the process to calculate the MFN Drug Payment Amount, we will determine the applicable phase-in formula and whether any of these adjustments will apply.

j. Calculate the MFN Drug Payment Amount

As the last step, we will calculate the MFN Drug Payment Amount for the MFN Model drug using the applicable phase-in formula, which blends the applicable ASP and the MFN Price as described in section III.E.5. of this IFC. This calculation, including any adjustments that apply, will result in the MFN Drug Payment Amount for the MFN Model drug (except as otherwise specified).

5. Phase-In of the MFN Price

We will use a phase-in approach that will blend the MFN Price with the applicable ASP to allow MFN participants time to adjust to the model payment amounts and processes. The phase-in formula will be stable for a given performance year, whereas the MFN Price and applicable ASP will vary quarterly based on fluctuations in drug prices in the U.S. and in included countries. We will phase-in the MFN Price by 25 percent per year for performance years 1 to 3 of the model, reaching 100 percent of the MFN Price for performance years 4 through 7 of the model. The phase-in formula uses a blend of the applicable ASP and MFN Price for an MFN Model drug as shown in Table 5. The MFN Drug Payment Amount will be based on 100 percent of the MFN Price starting in performance year 4, unless an adjustment that accelerates the phase-in applies as described in section III.E.9. of this IFC. Thus, the phase-in represents the outer bound in terms of the amount of time it will take for the MFN Drug Payment Amount to transition to 100 percent of the MFN Price.

We believe that a phase-in approach during the initial years of the model will enable MFN participants and the markets to adjust to the model's payment methodology, while enabling

CMS to test the full phase-in of the MFN Price over a 7-year model performance period. As noted in section III.E.11. of this IFC, when MFN Model drugs get added to the MFN Model Drug HCPCS Codes List during the model performance period, their MFN Drug Payment Amount gets determined as set forth for the corresponding performance year, meaning that if an MFN Model drug were to be added during performance year 4, the MFN Drug Payment Amount will equal 100 percent of the MFN Price.

TABLE 5. PHASE-IN OF MFN PRICES BY PERFORMANCE YEAR

Performance Year	Blend of the ASP and MFN Price for an MFN Model Drug at the HCPCS Code Level
Year 1	75 percent applicable ASP and 25 percent MFN Price
Year 2	50 percent applicable ASP and 50 percent MFN Price
Year 3	25 percent applicable ASP and 75 percent MFN Price
Year 4	100 percent MFN Price
Year 5	100 percent MFN Price
Year 6	100 percent MFN Price
Year 7	100 percent MFN Price

We are codifying the phase-in formula in § 513.210(b)(8).

6. Alternative Calculation for the MFN Drug Payment Amount

Over the course of the MFN Model, we may determine that the international drug pricing information data sources that we obtain do not contain any international drug pricing information (meaning no sales, volume, ex-manufacturer price, or list price data from any included country from any quarter beginning in the fourth calendar quarter of 2018 through the applicable quarter in the model performance period) for an MFN Model drug, for example, because the MFN Model drug is not approved for marketing in the included countries. For such cases, we will establish the MFN Drug Payment Amount at the applicable ASP for the applicable calendar quarter, subject to any adjustment in § 513.210(d) that applies, until international drug pricing information is available.

Because international drug pricing information may become available for a subsequent calendar quarter, we will use this method to establish the MFN Drug Payment Amount instead of

excluding or removing drugs without any international drug pricing information from the model until international drug pricing information becomes available. We believe having a stable list of MFN Model drugs will be more predictable for MFN participants, lessening MFN participants' need to monitor changes to the MFN Model Drug HCPCS Codes List, and will avoid creating an opportunity for manufacturers to get their products out of the model by stopping the reporting of international drug pricing information. Based on our experience with international drug pricing information data sources, we expect the potential of no international drug pricing information for an MFN Model drug across all included countries will be limited. We note that our approach may increase model payments compared to non-model payments for MFN Model drugs with no international drug pricing information because the alternative add-on payment, a single flat add-on amount per dose (see section III.F. of this IFC), could be greater than the add-on payment outside of the model.

7. Illustrative MFN Drug Payment Amounts

To illustrate how CMS will calculate the MFN Drug Payment Amounts under the MFN Model in accordance with §§ 513.130 and 513.140, we applied the methodology for determining the applicable ASPs, MFN Prices, and MFN Drug Payment Amounts using historical ASP-based payment limits,⁶⁰ available international drug pricing information from 2019 for the included countries, and the MFN Model performance year 1 phase-in formula. Table 6 shows illustrative data for applicable ASPs, MFN Prices, and MFN Drug Payment Amounts for one billing unit for the HCPCS codes that are included on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2. Actual MFN Drug Payment Amounts per billing unit for performance year 1, quarter 1, and thereafter will be calculated as specified in § 513.210. We will publish the quarterly MFN Drug Payment Amounts on a CMS website (such as the MFN Model website),

⁶⁰ We used the 2019 Quarter 3 and Quarter 4 and 2020 Quarter 1 and Quarter 2 ASP data that align with manufacturer-reported data based on sales during 2019 to identify the applicable ASPs. The ASP pricing files are posted at links available here: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

similar to how the ASP Drug Pricing Files are posted online prior to the start of the calendar quarter. The performance year 1, quarter 1 MFN Drug Payment Amounts will be published on a CMS website before the start of the MFN Model.

Illustrative MFN Drug Payment Amounts per billing unit are listed in Table 6 by HCPCS code. For this illustration, we partnered with ASPE, which purchases licenses to data products maintained by IQVIA™ (formerly known as Quintiles-IMS). IQVIA's proprietary MIDAS dataset⁶¹ is a widely used source of drug sales and volume data. MIDAS data contain estimates of drug sales (called "Monetary Value" within the MIDAS dataset) and volume (called "Quantity" within the MIDAS dataset) that are based on audits of drug transactions in different countries and distribution channels (for example, retail pharmacies and hospitals). The audits underlying the MIDAS data collect sales and volume information at the ex-manufacturer (that is, prices as drugs are sold by manufacturers), ex-wholesaler, and/or retail levels. IQVIA applies a set of country- and channel-specific assumptions on markups between manufacturer, wholesale, and retail prices to estimate ex-manufacturer and retail sales. Sales information within the database is stated in local and U.S. currency, as of the transaction date or current date, and are expressed as ex-manufacturer, trade, and public (retail) sales.⁶² MIDAS uses a variable called "Molecule List" (also called "Moleculelist") which identifies scientific and nonproprietary names for drug and biological products. Users extract data from the MIDAS database by selecting report filters, which are values for various data fields included in the database, such as "Molecule List" and "NFC123" (or "New Form Code," a 3-digit code which identifies the dosage form⁶³). The database has a standard method for identifying drugs within the U.S. and across countries, and a standard method for identifying drug forms. MIDAS data is updated monthly and retains up to 12 years of history.

⁶¹ <https://www.iqvia.com/solutions/commercialization/brand-strategy-and-management/market-measurement/midas>

⁶² Ex-manufacturer sales are: Manufacturer Selling Price or Wholesaler Purchasing Price or Price to Wholesaler (PTW). Trade sales are: Wholesaler Selling Price or Pharmacy Purchase Price or Price to Chemist (PTC). Public (retail) sales are: Pharmacy Selling Price or Consumer Purchase Price or Price to the Public (PTP).

⁶³ For more information on the New Form Codes see: <https://www.ephmra.org/classification/new-form-codes/>.

CMS obtained a MIDAS data extract of available 2019 international drug pricing information for the included countries for the MFN Model drugs for performance year 1 from ASPE. After identifying the MFN Price for each drug, we applied the phase-in formula for performance year 1 (75 percent of the applicable ASP and 25 percent of the MFN Price) and applied the exceptions in § 513.210(d) when no international drug pricing information was available in the MIDAS data. In Table 6, the illustrative MFN Prices, calculated using available international drug pricing sales and volume information at the ex-manufacturer level, represent the lowest of the GDP-adjusted country-level prices available in the single data source we used. For a complete discussion of how CMS used international drug pricing information available through IQVIA and CMS data to calculate the illustrative applicable ASPs, MFN Prices, and MFN Drug Payment Amounts displayed in Table 6, we refer readers to the supplemental documentation available on the MFN Model website.⁶⁴ We also refer readers to the Medicare Part B Drug Spending Dashboard⁶⁵ that can be used to search for brand name or generic name; search results present certain manufacturer information when available.

⁶⁴ See: <https://innovation.cms.gov/initiatives/most-favored-nation-model/>.

⁶⁵ See: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>.

TABLE 6. ILLUSTRATIVE MFN DRUG PAYMENT AMOUNTS PER BILLING UNIT

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
J0129	Abatacept injection	10 MG	Q1	\$ 50.891	\$ 12.977	\$ 41.412	Australia
			Q2	\$ 51.243	\$ 12.821	\$ 41.638	Australia
			Q3	\$ 51.744	\$ 12.862	\$ 42.024	Australia
			Q4	\$ 51.965	\$ 12.883	\$ 42.195	Australia
J0178****	Aflibercept injection	1 MG	Q1	\$ 903.173	\$ 399.359	\$ 777.219	Norway
			Q2	\$ 898.559	\$ 396.237	\$ 772.979	Norway
			Q3	\$ 891.537	\$ 386.957	\$ 765.392	Norway
			Q4	\$ 885.324	\$ 376.125	\$ 758.024	Norway
J0517	Inj., benralizumab, 1 mg	1 MG	Q1	\$ 159.283	\$ 102.884	\$ 145.183	Germany
			Q2	\$ 158.964	\$ 91.677	\$ 142.142	Germany
			Q3	\$ 160.841	\$ 88.523	\$ 142.761	Australia
			Q4	\$ 160.470	\$ 88.221	\$ 142.408	Australia
J0585	Injection,onabotulinumtoxina	1 UNIT	Q1	\$ 5.777	\$ 1.112	\$ 4.611	United Kingdom
			Q2	\$ 5.776	\$ 0.466	\$ 4.449	Ireland
			Q3	\$ 5.775	\$ 0.461	\$ 4.447	Ireland
			Q4	\$ 5.764	\$ 0.459	\$ 4.438	Ireland
J0717	Certolizumab pegol inj 1mg	1 MG	Q1	\$ 7.672	\$ 1.917	\$ 6.233	Australia
			Q2	\$ 7.569	\$ 1.884	\$ 6.148	Australia
			Q3	\$ 7.742	\$ 1.845	\$ 6.268	Australia
			Q4	\$ 7.535	\$ 1.839	\$ 6.111	Australia
J0881	Darbepoetin alfa, non-esrd	1 MCG	Q1	\$ 3.610	\$ 0.825	\$ 2.914	Republic of Korea
			Q2	\$ 3.634	\$ 0.635	\$ 2.884	Republic of Korea
			Q3	\$ 3.604	\$ 0.618	\$ 2.857	Republic of Korea
			Q4	\$ 3.462	\$ 0.627	\$ 2.753	Republic of Korea
J0885	Epoetin alfa, non-esrd	1000 UNITS	Q1	\$ 10.813	\$ 3.093	\$ 8.883	Republic of Korea
			Q2	\$ 10.407	\$ 2.931	\$ 8.538	Republic of Korea
			Q3	\$ 9.966	\$ 2.880	\$ 8.194	Republic of Korea
			Q4	\$ 9.451	\$ 2.936	\$ 7.822	Republic of Korea
J0897	Denosumab injection	1 MG	Q1	\$ 18.023	\$ 2.963	\$ 14.258	Norway
			Q2	\$ 18.185	\$ 2.940	\$ 14.374	Luxembourg
			Q3	\$ 18.187	\$ 2.873	\$ 14.358	Norway
			Q4	\$ 18.243	\$ 2.794	\$ 14.381	Norway
J1300	Eculizumab injection	10 MG	Q1	\$ 217.433	\$ 161.474	\$ 203.443	United Kingdom
			Q2	\$ 217.433	\$ 159.473	\$ 202.943	United Kingdom
			Q3	\$ 217.433	\$ 152.863	\$ 201.291	United Kingdom
			Q4	\$ 217.433	\$ 159.631	\$ 202.982	United Kingdom

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
J1439	Inj ferric carboxymaltos 1mg	1 MG	Q1	\$ 1.029	\$ 0.015	\$ 0.776	Japan
			Q2	\$ 1.035	\$ 0.015	\$ 0.780	Japan
			Q3	\$ 1.042	\$ 0.015	\$ 0.786	Japan
			Q4	\$ 1.033	\$ 0.015	\$ 0.779	Japan
J1602	Golimumab for iv use 1mg	1 MG	Q1	\$ 20.819	\$ 14.783	\$ 19.310	Republic of Korea
			Q2	\$ 20.358	\$ 14.446	\$ 18.880	Republic of Korea
			Q3	\$ 19.490	\$ 13.840	\$ 18.077	Republic of Korea
			Q4	\$ 19.030	\$ 14.138	\$ 17.807	Republic of Korea
J1745	Infliximab not biosimil 10mg	10 MG	Q1	\$ 61.201	\$ 27.427	\$ 52.757	Austria
			Q2	\$ 59.703	\$ 26.741	\$ 51.462	Australia
			Q3	\$ 54.100	\$ 25.685	\$ 46.996	Austria
			Q4	\$ 52.543	\$ 22.508	\$ 45.034	Australia
J1930	Lanreotide injection	1 MG	Q1	\$ 59.634	\$ 9.744	\$ 47.161	Norway
			Q2	\$ 58.796	\$ 9.667	\$ 46.514	Norway
			Q3	\$ 60.051	\$ 9.441	\$ 47.398	Norway
			Q4	\$ 62.125	\$ 9.177	\$ 48.888	Norway
J2182	Injection, mepolizumab, 1mg	1 MG	Q1	\$ 28.343	\$ 11.774	\$ 24.201	Sweden
			Q2	\$ 28.038	\$ 11.424	\$ 23.884	Sweden
			Q3	\$ 27.631	\$ 11.258	\$ 23.538	Sweden
			Q4	\$ 27.136	\$ 10.841	\$ 23.062	Norway
J2323	Natalizumab injection	1 MG	Q1	\$ 19.143	\$ 4.174	\$ 15.401	Australia
			Q2	\$ 19.096	\$ 3.744	\$ 15.258	Australia
			Q3	\$ 19.719	\$ 3.627	\$ 15.696	Australia
			Q4	\$ 19.701	\$ 3.603	\$ 15.676	Australia
J2350	Injection, ocrelizumab, 1 mg	1 MG	Q1	\$ 54.167	\$ 18.789	\$ 45.323	Switzerland
			Q2	\$ 54.167	\$ 17.698	\$ 45.050	Switzerland
			Q3	\$ 54.167	\$ 18.005	\$ 45.126	Switzerland
			Q4	\$ 54.167	\$ 17.932	\$ 45.108	Switzerland
J2353*****	Octreotide injection, depot	1 MG	Q1	\$ 193.102	\$ 27.519	\$ 151.706	Spain
			Q2	\$ 194.873	\$ 27.217	\$ 152.959	Spain
			Q3	\$ 194.420	\$ 26.939	\$ 152.550	Spain
			Q4	\$ 194.411	\$ 25.376	\$ 152.153	Spain
J2357	Omalizumab injection	5 MG	Q1	\$ 34.955	\$ 10.367	\$ 28.808	Norway
			Q2	\$ 34.696	\$ 10.281	\$ 28.592	Norway
			Q3	\$ 35.242	\$ 10.045	\$ 28.943	Norway
			Q4	\$ 35.044	\$ 9.764	\$ 28.724	Norway
J2505	Injection, pegfilgrastim 6mg	6 MG	Q1	\$ 4,270.573	\$ 780.548	\$ 3,398.067	Germany
			Q2	\$ 4,178.892	\$ 661.054	\$ 3,299.433	Austria
			Q3	\$ 4,010.890	\$ 566.107	\$ 3,149.694	Australia
			Q4	\$ 3,757.680	\$ 493.426	\$ 2,941.617	Australia
J2507	Pegloticase injection	1 MG	Q1	\$ 2,344.568	N/A	\$ 2,344.568	

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q2	\$ 2,370.328	N/A	\$ 2,370.328	
			Q3	\$ 2,473.369	N/A	\$ 2,473.369	
			Q4	\$ 2,444.249	N/A	\$ 2,444.249	
J2778	Ranibizumab injection	0.1 MG	Q1	\$ 337.116	\$ 31.070	\$ 260.604	Republic of Korea
			Q2	\$ 332.240	\$ 29.975	\$ 256.673	Republic of Korea
			Q3	\$ 327.618	\$ 31.920	\$ 253.694	Republic of Korea
			Q4	\$ 323.876	\$ 33.620	\$ 251.312	Republic of Korea
J2785	Regadenoson injection	0.1 MG	Q1	\$ 55.915	\$ 19.846	\$ 46.898	United Kingdom
			Q2	\$ 55.870	\$ 19.505	\$ 46.779	Sweden
			Q3	\$ 55.923	\$ 18.788	\$ 46.639	United Kingdom
			Q4	\$ 56.011	\$ 19.161	\$ 46.799	Sweden
J2796	Romiplostim injection	10 MCG	Q1	\$ 69.344	\$ 28.025	\$ 59.015	Japan
			Q2	\$ 70.071	\$ 18.245	\$ 57.114	Australia
			Q3	\$ 70.057	\$ 17.824	\$ 56.998	Australia
			Q4	\$ 70.433	\$ 17.840	\$ 57.285	Australia
J3262	Tocilizumab injection	1 MG	Q1	\$ 4.654	\$ 0.878	\$ 3.710	Australia
			Q2	\$ 4.677	\$ 0.863	\$ 3.724	Australia
			Q3	\$ 4.792	\$ 0.860	\$ 3.809	Australia
			Q4	\$ 4.797	\$ 0.866	\$ 3.814	Australia
J3357	Ustekinumab sub cu inj, 1 mg	1 MG	Q1	\$ 179.912	\$ 40.633	\$ 145.093	France
			Q2	\$ 180.554	\$ 39.529	\$ 145.297	France
			Q3	\$ 179.582	\$ 38.768	\$ 144.379	France
			Q4	\$ 175.250	\$ 37.857	\$ 140.902	France
J3380	Injection, vedolizumab	1 MG	Q1	\$ 18.992	\$ 6.871	\$ 15.961	France
			Q2	\$ 18.740	\$ 6.795	\$ 15.753	France
			Q3	\$ 19.096	\$ 5.275	\$ 15.641	Republic of Korea
			Q4	\$ 19.024	\$ 5.357	\$ 15.607	Republic of Korea
J7324	Orthovisc inj per dose	PER DOSE	Q1	\$ 138.594	\$ 11.495	\$ 106.819	Japan
			Q2	\$ 135.280	\$ 11.355	\$ 104.299	Japan
			Q3	\$ 132.474	\$ 11.674	\$ 102.274	Japan
			Q4	\$ 127.383	\$ 11.497	\$ 98.411	Japan
J9022	Inj, atezolizumab,10 mg	10 MG	Q1	\$ 72.809	\$ 42.141	\$ 65.142	Germany
			Q2	\$ 72.649	\$ 41.019	\$ 64.742	Germany
			Q3	\$ 73.450	\$ 20.395	\$ 60.186	Republic of Korea
			Q4	\$ 73.022	\$ 20.715	\$ 59.945	Republic of Korea
J9034	Inj., bendeka 1 mg	1 MG	Q1	\$ 22.454	\$ 0.473	\$ 16.959	Germany
			Q2	\$ 21.556	\$ 0.469	\$ 16.284	Germany
			Q3	\$ 20.495	\$ 0.466	\$ 15.488	Germany
			Q4	\$ 19.980	\$ 0.461	\$ 15.100	Germany
J9035	Bevacizumab injection	10 MG	Q1	\$ 76.681	\$ 29.541	\$ 64.896	Norway
			Q2	\$ 76.587	\$ 29.291	\$ 64.763	Norway

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q3	\$ 76.078	\$ 28.607	\$ 64.210	Norway
			Q4	\$ 75.052	\$ 27.444	\$ 63.150	Australia
J9041	Inj., velcade 0.1 mg	0.1 MG	Q1	\$ 42.008	\$ 14.837	\$ 35.215	Canada
			Q2	\$ 42.158	\$ 13.011	\$ 34.871	Canada
			Q3	\$ 42.316	\$ 10.029	\$ 34.244	Canada
			Q4	\$ 42.498	\$ 8.070	\$ 33.891	Canada
J9042	Brentuximab vedotin inj	1 MG	Q1	\$ 153.836	\$ 76.887	\$ 134.599	United Kingdom
			Q2	\$ 153.242	\$ 75.908	\$ 133.909	United Kingdom
			Q3	\$ 159.787	\$ 72.729	\$ 138.022	United Kingdom
			Q4	\$ 159.336	\$ 76.009	\$ 138.504	United Kingdom
J9047	Injection, carfilzomib, 1 mg	1 MG	Q1	\$ 35.140	\$ 17.144	\$ 30.641	Switzerland
			Q2	\$ 35.471	\$ 17.036	\$ 30.862	Switzerland
			Q3	\$ 35.415	\$ 17.332	\$ 30.894	Switzerland
			Q4	\$ 35.452	\$ 17.261	\$ 30.904	Switzerland
J9055	Cetuximab injection	10 MG	Q1	\$ 58.596	\$ 21.422	\$ 49.303	Belgium
			Q2	\$ 58.536	\$ 21.183	\$ 49.198	Belgium
			Q3	\$ 59.628	\$ 20.964	\$ 49.962	Belgium
			Q4	\$ 59.388	\$ 20.874	\$ 49.759	Belgium
J9145	Injection, daratumumab 10 mg	10 MG	Q1	\$ 50.708	\$ 47.053	\$ 49.795	Japan
			Q2	\$ 50.894	\$ 42.527	\$ 48.803	Republic of Korea
			Q3	\$ 50.972	\$ 41.538	\$ 48.613	Republic of Korea
			Q4	\$ 51.080	\$ 42.189	\$ 48.858	Republic of Korea
J9173	Inj., durvalumab, 10 mg	10 MG	Q1	\$ 70.619	\$ 61.519	\$ 68.344	Germany
			Q2	\$ 70.411	\$ 60.844	\$ 68.020	Germany
			Q3	\$ 71.302	\$ 60.221	\$ 68.532	Germany
			Q4	\$ 71.221	\$ 56.940	\$ 67.651	Germany
J9176	Injection, elotuzumab, 1mg	1 MG	Q1	\$ 6.124	\$ 3.888	\$ 5.565	Germany
			Q2	\$ 6.128	\$ 3.895	\$ 5.570	Germany
			Q3	\$ 6.209	\$ 3.859	\$ 5.622	Germany
			Q4	\$ 6.211	\$ 3.789	\$ 5.606	Germany
J9217	Leuprolide acetate suspnsion	7.5 MG	Q1	\$ 216.526	\$ 81.556	\$ 182.784	Belgium
			Q2	\$ 211.979	\$ 78.666	\$ 178.651	Belgium
			Q3	\$ 217.051	\$ 77.860	\$ 182.253	Belgium
			Q4	\$ 222.045	\$ 103.103	\$ 192.310	Spain
J9228	Ipilimumab injection	1 MG	Q1	\$ 144.395	\$ 80.859	\$ 128.511	Germany
			Q2	\$ 144.460	\$ 80.302	\$ 128.421	Germany
			Q3	\$ 146.398	\$ 78.540	\$ 129.433	Germany
			Q4	\$ 146.442	\$ 75.848	\$ 128.793	Germany
J9264	Paclitaxel protein bound	1 MG	Q1	\$ 11.608	\$ 0.127	\$ 8.738	Australia
			Q2	\$ 11.805	\$ 0.123	\$ 8.884	Australia
			Q3	\$ 11.843	\$ 0.127	\$ 8.914	Australia

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q4	\$ 11,998	\$ 0.129	\$ 9.031	Australia
J9271	Inj pembrolizumab	1 MG	Q1	\$ 46,777	\$ 23.308	\$ 40.910	Switzerland
			Q2	\$ 46,593	\$ 23.162	\$ 40.735	Switzerland
			Q3	\$ 47,419	\$ 23.563	\$ 41.455	Switzerland
			Q4	\$ 47,192	\$ 23.468	\$ 41.261	Switzerland
J9299	Injection, nivolumab	1 MG	Q1	\$ 26,230	\$ 8.321	\$ 21.753	Japan
			Q2	\$ 26,231	\$ 7.438	\$ 21.533	Japan
			Q3	\$ 26,568	\$ 7.415	\$ 21.780	Japan
			Q4	\$ 26,568	\$ 7.393	\$ 21.774	Japan
J9305	Pemetrexed injection	10 MG	Q1	\$ 65,607	\$ 1.920	\$ 49.685	Canada
			Q2	\$ 65,540	\$ 1.882	\$ 49.625	Canada
			Q3	\$ 66,786	\$ 0.623	\$ 50.245	Australia
			Q4	\$ 66,542	\$ 0.611	\$ 50.059	Australia
J9306	Injection, pertuzumab, 1 mg	1 MG	Q1	\$ 11,557	\$ 6.192	\$ 10.216	Australia
			Q2	\$ 11,594	\$ 6.087	\$ 10.217	Australia
			Q3	\$ 11,903	\$ 5.967	\$ 10.419	Australia
			Q4	\$ 11,921	\$ 5.712	\$ 10.368	Norway
J9311	Inj rituximab, hyaluronidase	10 MG	Q1	\$ 41,810	\$ 11.659	\$ 34.273	Norway
			Q2	\$ 41,064	\$ 11.483	\$ 33.669	Republic of Korea
			Q3	\$ 40,442	\$ 11.216	\$ 33.136	Republic of Korea
			Q4	\$ 40,032	\$ 11.392	\$ 32.872	Republic of Korea
J9312	Inj., rituximab, 10 mg	10 MG	Q1	\$ 89,597	\$ 22.642	\$ 72.858	Norway
			Q2	\$ 89,308	\$ 22.446	\$ 72.593	Republic of Korea
			Q3	\$ 89,067	\$ 21.935	\$ 72.284	Norway
			Q4	\$ 88,847	\$ 15.631	\$ 70.543	Australia
J9354	Inj, ado-trastuzumab emt 1mg	1 MG	Q1	\$ 29,515	\$ 18.764	\$ 26.827	Canada
			Q2	\$ 29,589	\$ 18.790	\$ 26.889	Canada
			Q3	\$ 30,290	\$ 19.050	\$ 27.480	Canada
			Q4	\$ 30,243	\$ 19.034	\$ 27.441	Canada
J9355	Inj trastuzumab excl biosimi	10 MG	Q1	\$ 100,920	\$ 21.917	\$ 81.169	Republic of Korea
			Q2	\$ 100,587	\$ 21.008	\$ 80.692	Republic of Korea
			Q3	\$ 99,863	\$ 20.521	\$ 80.028	Republic of Korea
			Q4	\$ 98,301	\$ 20.837	\$ 78.935	Republic of Korea
Q2043	Sipuleucel-t auto cd54+	Per infusion (minimum 50 million cells)	Q1	\$ 41,532.639	N/A	\$ 41,532.639	
			Q2	\$ 43,749.244	N/A	\$ 43,749.244	
			Q3	\$ 43,342.102	N/A	\$ 43,342.102	
			Q4	\$ 45,270.100	N/A	\$ 45,270.100	
Q5111	Injection, udenyca 0.5 mg	0.5 MG	Q1	\$ 337.854	\$ 65.046	\$ 269.652	Germany
			Q2	\$ 326.162	\$ 55.088	\$ 258.393	Austria
			Q3	\$ 316.466	\$ 47.176	\$ 249.143	Australia

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q4	\$ 303.061	\$ 41.119	\$ 237.575	Australia

N/A means not available; international drug pricing information was not available in the data source CMS used.

† HCPCS codes on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, with short descriptions effective January 1, 2021.

††MFN Country means the country with the lowest GDP-adjusted country-level price.

*Based on the calendar quarter in which manufacturer sales occurred; note, the calendar quarter shown is two calendar quarters prior to when the applicable ASP was used to calculate the payment amounts under the methodology in section 1847A of the Act. For example, the applicable ASPs for Q1 2019 shown in this table align with the payment amounts shown in the July 2019 ASP Pricing File available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles>.

**Based on available international drug pricing sales and volume information for the calendar quarter for non-U.S. OECD countries with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the U.S. GDP per capita in 2017.

*** The MFN Drug Payment Amount reflects the exception in § 513.210(d)(1) and equals the applicable ASP when the MFN Price is not available.

**** The MFN Price for J0178 (Aflibercept injection) is based on data for the ophthalmic formulation only.

***** The MFN Price for J2353 (Octreotide injection, depot) is based on data for long acting formulations only.

We note that, as codified in § 513.210(d)(5), and described in section III.E.10. of this IFC, the MFN Drug Payment Amount will not exceed the non-model drug payment amount for line items submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

8. Timing of Data and MFN Drug Payment Amount Calculations

As discussed in section III.E.4. of this IFC, we will calculate the MFN Drug Payment Amounts on a calendar quarter basis using the most recent ASP and correlated international drug pricing information (that is, data from the highest level of hierarchy available). Under the reporting requirements outlined in section 1927(b)(3)(A)(iii), manufacturers that report ASPs are required to submit them to CMS no later than 30 days after the last day of the previous quarter. CMS uses these data to calculate the ASP-based Medicare payment amounts for the next calendar quarter. As a result, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts.

We will use international drug pricing information from the same time period (that is, the same calendar quarter), if available in accordance with the hierarchy specified in § 513.140(c)(3), in order to align information across the ASP Drug Pricing files and the data sources for international drug pricing information that we will use. This approach will consistently correspond to the two-quarter lag used for the ASP pricing files when an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available. Table 7 illustrates how the information we will use to calculate the MFN Drug Payment Amounts for each calendar quarter during performance year 1 using data from the applicable ASP calendar quarter will align when an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available. We will use the same approach for each performance year.

TABLE 7. ALIGNMENT OF PERFORMANCE YEAR CALENDAR QUARTERS FOR ASP AND MFN PRICE DATA BASED ON JANUARY 2021 MODEL START

Performance Year	Performance Year Calendar Quarter	ASP Pricing File for Calendar Quarter	Applicable ASP Calendar Quarter	MFN Price for Calendar Quarter*
1	2021, Quarter 1	2021, Quarter 1	2020, Quarter 3	2020, Quarter 3
1	2021, Quarter 2	2021, Quarter 2	2020, Quarter 4	2020, Quarter 4
1	2021, Quarter 3	2021, Quarter 3	2021, Quarter 1	2021, Quarter 1
1	2021, Quarter 4	2021, Quarter 4	2021, Quarter 2	2021, Quarter 2

*When an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available.

For example, for the initial calculations to calculate payment amounts for the start of the MFN Model on January 1, 2021, the beginning of the first calendar quarter in 2021, we will use the January 2021 ASP Pricing File (which will be based on manufacturers’ ASP for the third quarter of 2020, from July 1, 2020, to September 30, 2020) and international drug pricing information for the third quarter of 2020, from July 1, 2020, to September 30, 2020. For each subsequent calendar quarter for a performance year, the MFN Drug Payment Amount will be established by calculating the MFN Price based on more recent international drug pricing information, using data for the applicable ASP calendar quarter, if available, as illustrated in Table 7, and calculating the MFN Drug Payment Amount.

9. Adjustments to Phase-In Formula and Incentives for Manufacturers to Address Rising U.S. Drug Prices

In response to the October 2018 ANPRM, we received several comments asking that we consider including model design features to address potential spillover effects and cost-shifting to the commercial market and Medicare payment outside of the model geographic area. The commenters requested that CMS carefully consider the potential impacts of a potential model on other markets—including the potential for cost-shifting to other segments of the Medicare program, the Medicaid program, and the commercial market. The commenters recommended that in order to avoid unintended consequences and cost-shifting, CMS should closely monitor prices for included drugs and consider additional policies or actions if drug prices in other markets rise above certain pricing thresholds (for example, above the Consumer Price Index (CPI) or inflation).

We appreciate these concerns, as it is possible that, in response to the MFN Model, manufacturers may take steps to increase U.S. prices outside of the MFN Model, such as in the commercial and Medicare Advantage markets, which may be seen in increases in manufacturers' ASPs. In response to the concerns expressed in the October 2018 ANPRM comments and to minimize the possibility of a spillover impact on beneficiaries outside of the MFN Model, we will make adjustments to the phase-in formula in order to mitigate cost-shifting in the market and incentivize manufacturers of MFN Model drugs to maintain stable ASPs of MFN Model drugs to minimize the potential for spillover impacts. In addition to creating spillover impacts, rapid increases in ASP that outstrip not only U.S. inflation but also changes in international prices over time would reduce our ability to test the phase-in of the MFN Price over time, as the MFN Price's contribution to the MFN Drug Payment Amount could be obscured by a significant increase in the MFN Model drug's ASP.

As discussed in section III.E.5. of this IFC, we will phase-in the MFN Prices to allow MFN participants time to adjust to the MFN Model payment amounts and processes. Calculating the MFN Prices and MFN Drug Payment Amounts each calendar quarter will allow manufacturers to address the large difference between prices in the U.S. and in other countries for MFN Model drugs during the course of the MFN Model and serves as an incentive for manufacturers to refrain from raising U.S. prices faster than a reasonable inflation allowance. Furthermore, as discussed in section III.M. of this IFC, we are waiving requirements of section 1847A in order to exclude units of MFN Model drugs from the calculation of the manufacturer's ASP. However, if these incentives prove to be insufficient to deter manufacturers from raising U.S. prices for MFN Model drugs faster than a reasonable inflation allowance, we will adjust the calculation of the MFN Drug Payment Amount by adjusting the phase-in formula for MFN Model drugs where such concerns are observed.

Specifically, to preserve the integrity of the model test as described previously, we will make an adjustment to the phase-in formula for an MFN Model drug if the applicable ASP or

monthly U.S. list price (defined as Wholesale Acquisition Cost (WAC) available in a U.S. drug pricing compendium or if WAC is not available, other available list prices, such as Average Wholesale Price (AWP) available in a U.S. drug pricing compendium) increases faster than both inflation and the MFN Price. CMS will accelerate the phase-in of the MFN Price by 5 percentage points at the next quarterly update for each MFN Model drug with: (1) a greater cumulative percentage increase in either the applicable ASP⁶⁶ or any monthly U.S. list price for any of the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U)⁶⁷ based on all items in U.S. city average and not seasonally adjusted; and (2) a greater cumulative percentage increase in either the applicable ASP or any monthly U.S. list price for any of the NDCs assigned to the MFN Drug's HCPCS code compared to the cumulative percentage increase in the MFN Price. To apply these conditions for an MFN Model drug, we will identify the cumulative percentage increase from a baseline to the applicable ASP calendar quarter. For all MFN Model drugs with an applicable ASP for the first quarter of performance year 1, we will set the baseline as the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1 (that is, the third calendar quarter of 2020 (July 2020 through September 2020)). For all MFN Model drugs that do not have an applicable ASP for the first quarter of performance year 1 (for example, a drug that is first marketed in the U.S. after the start of the model), the baseline will be the ASP calendar quarter for the first applicable ASP based on the manufacturer's average sales price for that MFN Model drug that occurs after the third quarter of 2020. For example, the baseline for an MFN Model drug with its first applicable ASP based on the manufacturer's average sales price occurring in the second quarter of performance year 1 (that is, April 2021 through June 2021) will have a baseline of the fourth calendar quarter of 2020 (October 2020 through December 2020).

⁶⁶ We note that the manufacturers' ASPs will be based on non-model sales only as codified in § 513.600(b) and as discussed in section III.M. of this IFC.

⁶⁷ All references to CPI-U are based on all items in U.S. city average and not seasonally adjusted.

The cumulative percentage change will be calculated from the end of the baseline to the end of the applicable ASP calendar quarter. We will apply the adjustment to the phase-in formula similarly for all MFN Model drugs regardless of when the MFN Model drug is added to the MFN Model Drug HCPCS Codes List.

Further, if both conditions are not met, such as the cumulative percentage increase in any monthly U.S. list prices for the NDCs assigned to the MFN Drug's HCPCS code outpaces the cumulative percentage increase in CPI-U but is less than the cumulative percentage increase in the MFN Price, then the trigger conditions will not be met and the phase-in formula will not be accelerated. If the cumulative percentage change in the CPI-U or MFN Price is negative, we will use zero as the cumulative percentage increase in the CPI-U or MFN Price, as applicable, for the relevant quarter.

We will accelerate the phase-in formula by 5 percentage points as we believe this amount strikes a balance between moving the MFN Drug Payment Amount more quickly toward the MFN Price while still retaining the stepwise nature of the phase-in. As an example, in the case that both trigger conditions are met for an MFN Model drug during the applicable ASP calendar quarter for the second quarter of performance year 1, the phase-in formula would be 70 percent applicable ASP and 30 percent MFN Price for that quarter and remaining quarters in performance year 1, assuming both trigger conditions are not met in the ASP calendar quarters for the third and fourth quarter of performance year 1.

We will apply the acceleration of the phase-in formula for each calendar quarter of the MFN Model where both trigger conditions are met. That is, for an MFN Model drug that is subject to the accelerated phase-in of the MFN Price, we will further accelerate the phase-in of the MFN Price by an additional 5 percentage points at the next quarterly update if the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code continues to be greater than the cumulative percentage increase in the CPI-U and MFN Price. In the previous example, if both of the trigger

conditions were met for the same MFN Model drug during the applicable ASP calendar quarter for quarters 3 and 4 of performance year 1, the phase-in formula would be 65 percent applicable ASP and 35 percent MFN Price for quarter 3 of performance year 1, and 60 percent applicable ASP and 40 percent MFN Price for quarter 4 of performance year 1. The accelerated phase-in of the MFN Price will not be reversed, but will remain in place for the duration of the model performance period for that drug, even if the manufacturer lowers its ASP and U.S. list prices after the accelerated phase-in is in effect.

Further, after the full phase-in of the MFN Price is reached, if both of the trigger conditions are met, there will be a decrease in MFN Model Drug Payment Amount equal to the largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U and in the MFN Price. This additional adjustment will lead to the affected drug's MFN Drug Payment Amount falling below the MFN Price for that drug. For example, for an MFN Model drug, if 100 percent of the MFN Price was already applied in the calculation of the MFN Model Drug Payment Amount for a quarter and its applicable ASP cumulatively increased by 14 percent, the largest cumulative percentage increase of any of the monthly U.S. list prices for the NDCs assigned to the HCPCS code was 13 percent, the CPI-U cumulatively increased by 12 percent, and the MFN Price cumulatively increased by 11 percent, we would reduce the MFN Drug Payment Amount for the quarter (in this case, previously established as to equal the MFN Price) by 3 percent (that is, the difference between 14 and 11) of the MFN Price.

Any such additional adjustment will apply for the duration of the model performance period, unless a larger additional adjustment is triggered. As with the adjustment before the full phase-in is reached, we will update the calculation for the additional adjustment for each additional calendar quarter of the model. That is, for an MFN Model drug that is subject to the additional adjustment of the MFN Price, each calendar quarter thereafter, we will calculate the

largest difference between the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code and the cumulative percentage increase in CPI-U and in MFN Price and increase the additional adjustment if the result of the updated calculation results in a larger additional adjustment. CMS will not reduce the additional adjustment based on the results of the updated calculation. We believe this policy will serve as a strong incentive for manufacturers to avoid taking steps that could cause spillover impacts and will help to address commenters' concerns.

10. Limitation on MFN Drug Payment Amount to Protect Beneficiaries

To avoid potentially increasing beneficiary cost-sharing or coinsurance, we are codifying in § 513.210(b)(6) to compare the MFN Price to the applicable ASP in order to ensure that beneficiaries are always paying the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, we will establish the MFN Price as equal to the applicable ASP. In addition, in § 513.210(a), we are codifying that the allowed MFN Drug Payment Amount will not exceed the billed amount on the claim for the MFN Model drug. In addition, to maintain beneficiary protections for all claims paid under the OPSS, we are codifying in § 513.210(d)(4) that the MFN Drug Payment Amount cannot exceed the non-model drug payment amount for line items submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable. We will apply this limitation to line items submitted with the JG modifier. We refer readers to the Calendar Year (CY) 2021 OPSS/ASC Notice of Proposed Rulemaking (CMS-1736-P)⁶⁸ (85 FR 48880) for a discussion of CMS's proposal for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. If CMS

⁶⁸ <https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf>

finalizes the proposed OPPTS payment policy to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 34.7 percent. In such cases, the MFN participant will also receive the per-dose add-on payment amount described in section III.F. of this IFC.

In the CY 2021 OPPTS/ASC Notice of Proposed Rulemaking, CMS proposed in the alternative to continue its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs. If CMS finalizes this alternative proposal, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 22.5 percent (85 FR 48890). In such cases, the MFN participant will also receive the per-dose add-on payment amount described in section III.F. of this IFC.

11. Method for Establishing MFN Drug Payment Amounts for Drugs Added to the MFN Model

We will add annually any top 50 drugs that are not already included on the MFN Model Drug HCPCS Codes List, after taking the exclusions in § 513.130(b) into account. In accordance with § 513.210, we will calculate the MFN Price that will apply to drugs that are added to the list of MFN Model drugs and the applicable phase-in formula for a given performance year and adjustments will apply. We will apply the applicable phase-in formula for drugs that are added to the MFN Model Drug HCPCS Codes List, in order to simplify and maintain consistent payment policies for all MFN participants and MFN Model drugs. For example, for a drug added as an MFN Model drug for performance year 2, the phase-in formula will be a blend of 50 percent of the ASP and 50 percent of the MFN Price for the drug. Thus, Medicare Part B drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 2 and beyond will have an MFN Drug Payment Amount that will start more heavily based on the MFN Price than drugs that were included in earlier performance years. We believe this approach is appropriate because the MFN Model seeks to test a new payment methodology that takes into account the discounts that other countries enjoy and delaying the phase-in of the MFN Price for

drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 2 and beyond will not allow CMS to fully evaluate the model payment test for such drugs during the model performance period.

For drugs added to the MFN Model Drug HCPCS Codes List in a later performance year, this approach could result in a more significant change in payment for the drug upon entry to the model compared to drugs that are included from the beginning of the model. Although there is the potential for a larger change in payment for drugs that are added later in the model, we believe that it is necessary to maintain the same phase-in for all included drugs to enable us to test the full phase-in of the MFN Price by performance year 4. We also believe that MFN participants are aware of which separately payable Medicare Part B drugs have high annual spending and therefore will have a basis for assessing which drugs that are not on the MFN Model Drug HCPCS Codes List in performance year 1 are more likely to be added to the MFN Model Drug HCPCS Codes List in a later performance year. For future years, we seek comment on whether additional information that CMS could provide would be helpful to MFN participants for their planning purposes, for example drug utilization reports developed through the model monitoring activities that CMS could make available on the model website.

12. Payment Exceptions for MFN Model Drugs in Short Supply

Rather than broadly excluding drugs that are in short supply from the model, we will keep MFN Model drugs in the model while they are in short supply, but revert the MFN Drug Payment Amount to the applicable ASP, which could be the amount determined under section 1847A(e) of the Act if the conditions set forth in that provision are met, beginning with the first day of the next calendar quarter after the date on which the MFN Model drug is reported as “Currently in Shortage” by FDA, as available on these websites:

<https://www.accessdata.fda.gov/scripts/drugshortages/> and <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages>, and continuing for subsequent calendar quarters as warranted. Once the MFN Model drug is no longer reported

as “Currently in Shortage” by FDA, the MFN Model payment will resume the first day of the next quarter after the date on which it is no longer reported in shortage. For example, as noted in section III.D.2. of this IFC, one of the HCPCS codes with high aggregate 2019 Medicare Part B total allowed charges (J1569, Gammagard liquid infusion) represents a drug that is currently on the FDA shortages list. If this HCPCS code were to be included on the MFN Model Drug HCPCS Codes List and remain on the FDA shortages list, the MFN Drug Payment Amount will be the applicable ASP until the first day of the next quarter of the model performance period after it is no longer reported as “Currently in Shortage” by FDA. However, we note that we are excluding HCPCS codes that describe intravenous immune globulin from the MFN Model Drug HCPCS Codes List as discussed in section III.D.2 of this IFC.

13. Payment of Blood Clotting Factor Furnishing Fee under the MFN Model

Currently, payment for the blood clotting factor furnishing fee under 42 CFR 410.63(c) is made along with payment for the blood clotting factor. Under the MFN Model, a HCPCS code that is used to bill for a blood clotting factor may be an MFN Model drug if such HCPCS code is included on the MFN Model Drug HCPCS Codes List. To maintain the current payment approach for the blood clotting factor furnishing fee during the MFN Model, we are codifying in § 513.210(e), that when applicable, the blood clotting furnishing fee under § 410.63(c) will be payable along with the MFN Drug Payment Amount. We believe this approach will eliminate the need to establish different billing instructions for MFN Model drugs that are blood clotting factors.

F. MFN Model Alternative Add-on Payment

1. Overview of the Alternative Add-on Payment

In the October 2018 ANPRM, we sought public comment on testing an alternative add-on payment to the current system, required by section 1847A of the Act, under which Medicare Part B pays a fee based on 6 percent of the ASP of the drug so that the dollar amount of the add-on increases with the price of the drug rather than reflecting the service being performed. In

general, the amount of add-on realized by providers and suppliers has been described by commenters as 4.3 percent as a result of sequestration.⁶⁹ In the October 2018 ANPRM, we described our belief regarding how a potential model could pay a drug add-on amount that would be different from the current drug add-on amount. We sought public comment on potential ways to structure the alternative add-on, including but not limited to: an amount based on drug class, the physician's specialty, or the practice's historical billing patterns, with a possible bonus pool tied to clinically appropriate utilization. We requested feedback on several design topics, such as how we could best define and determine the alternative add-on payment amount, whether CMS should develop an encounter-based or monthly add-on payment approach, and potential inclusion of a quality bonus pool to incentivize evidence-based care. We stated that our goal was to maintain relative stability in provider and supplier revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments.

In response to the October 2018 ANPRM, we received feedback from a number of stakeholder groups on the structuring of an alternative add-on payment. Overall, there was no consensus on the best approach to designing an alternative add-on payment, though several commenters supported calculating the alternative add-on payment in such a way that model participants would be held harmless. Some commenters supported the idea of testing an alternative add-on payment that is not tied to increases in drug prices over time, with one commenter noting that this could promote revenue stability. One commenter noted an approach that varies the alternative add-on payment between different drugs would risk creating perverse incentives in prescribing decisions between alternative treatment options. Several commenters

⁶⁹ Stakeholders have reported that the add-on percentage is slightly further reduced when the OPSS beneficiary cost-sharing limitation applies. Further, we note that current payments under the OPSS for certain drugs when the drug is acquired under the 340B program are made based on ASP-22.5 percent and are not considered to include a drug add-on payment amount. We refer readers to the Calendar Year (CY) 2021 OPSS/ASC Notice of Proposed Rulemaking (CMS-1736-P) (85 FR 48880) for a discussion of CMS's proposal for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. We also refer readers to the alternative proposal in the CY 2021 OPSS/ASC Notice of Proposed Rulemaking (85 FR 48890) to continue the current policy of paying ASP-22.5 percent for 340B drugs and biologicals under the OPSS.

supported a flat fee with more than one tier. Several commenters expressed concern about linking a bonus pool to prescribing lower cost drugs. One commenter opposed reducing the add-on amount to allow for a bonus pool.

After considering the comments we received, we were persuaded that potential model requirements to qualify for a modest quality bonus would be challenging and may be burdensome for MFN participants to implement and adhere to consistently for all MFN beneficiaries, and would add potential financial risk for MFN participants, which is not necessary for purposes of testing an alternative add-on payment approach under the MFN Model. Thus, we are not including a quality bonus in the MFN Model. We were also persuaded that the alternative add-on should be designed in as straightforward a manner as possible to minimize administrative burden for MFN participants and potential confusion for beneficiaries.

We will pay MFN participants a single add-on payment amount per dose of an MFN Model drug; this payment will not vary based on the amount of drug furnished in a dose, billing units billed on the claim line, or by MFN participant or specialty. 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.

With the MFN alternative add-on payment, we will test a single add-on payment amount that will be paid per dose, where "dose" for the purposes of the MFN alternative add-on payment is defined as the number of HCPCS billing units reported on a claim line⁷⁰ (also called service line or line item). We are codifying this alternative add-on payment at § 513.220. We will waive beneficiary cost-sharing for the add-on payment. As such, the add-on approach will test a

⁷⁰ An exception is when a claim line is billed with the modifier JW, indicating discarded drug.

separate standardized add-on payment amount per dose that is not tied to the Medicare Part B payment amount for a drug. We will start with an amount that is calculated based on 6.1224 percent of historical applicable ASPs for 2019 final action claim lines for the selected MFN Model drugs for the beginning of performance year 1 as further described in § 513.220, trended forward using an inflationary adjustment for the start of performance year 1. With this approach, the per-dose add-on payment amount will be calculated once at the beginning of the model and will not be recalculated as the MFN Model Drug HCPCS Codes List changes. For each calendar quarter thereafter, beginning with performance year 1, quarter 2, we will update the per-dose add-on payment amount using an inflation factor.

For the MFN Model drugs for the beginning of performance year 1 that are biosimilar biological products, we will use 6.1224 percent of the historical applicable ASPs for the reference biological product in the calculation of the per-dose add-on amount rather than 6.1224 percent of the historical applicable ASPs for the biosimilar biological product to align with the determination of the add-on amount to such products under section 1847A. Based on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, this applies to Q5111 (Injection, udenyca 0.5 mg).

We selected 6.1224 percent because that amount results in an add-on pool that will allow MFN participants to realize, on average, a 6 percent add-on per dose after sequestration, which generally applies.⁷¹ In the absence of actual drug acquisition costs for eligible providers and suppliers, we believe it is appropriate to use an amount for the add-on pool that represents, on average, a 40 percent increase compared to 4.3 percent of ASP in use in the baseline period to achieve a goal of the model to provide increased add-on revenue for MFN participants on average.

2. Per-Dose Add-On Payment Amount Methodology

⁷¹ Note that Section 3709 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act temporarily suspends Medicare sequestration from May 1, 2020 to December 31, 2020. Available at: <https://www.govinfo.gov/content/pkg/BILLS-116hr748enr/pdf/BILLS-116hr748enr.pdf>

a. Calculation of the Single Per-Dose Add-On Payment Amount

In § 513.220(b), we specify how we calculated a single per-dose add-on payment amount for the start of the MFN Model. Using 2019 historical claims data, we calculated a per-dose add-on payment amount by applying the applicable ASP (that is, the payment amount determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage) to the identified 2019 claims lines, based on the calendar quarter in which the claim's date of service falls, which corresponds to the manufacturer-reported ASPs from two calendar quarters prior, with an exception for biosimilar biological products as described previously. We used all 2019 Medicare Part B FFS claims lines for separately paid drugs (by HCPCS code) included on the MFN Model HCPCS Codes List for the beginning of performance year 1 that were furnished by eligible Medicare-participating providers and suppliers (that is, entities that are eligible to be an MFN participant). We excluded claims submitted by excluded providers and suppliers described in § 513.100(c) (such as CAHs, and cancer hospitals) as well as certain claims described in § 513.100(d) (such as claims processed by the DME MAC), as applicable in 2019, as well as claims where Medicare was not the primary payer. We included all relevant claim lines for an MFN Model drug with an allowed charge greater than zero dollars in the calculation. As we used nearly all 2019 claims for drugs included on the MFN Model HCPCS Codes List for the beginning of performance year 1 furnished from any eligible Medicare-participating provider or supplier, we believe that one calendar year provided sufficient data for purposes of calculating a single per-dose add-on payment amount. Calendar year 2019 represents the same baseline year that we used to select the MFN Model drugs for the beginning of performance year 1, as identified in Table 2.

Once all relevant 2019 claim lines were identified for each drug (by HCPCS code) on the MFN Model HCPCS Codes List for the beginning of performance year 1, we multiplied the number of HCPCS units billed on each claim line by 6.1224 percent of the 2019 applicable ASP (which we define as the payment amount determined in accordance with 1847A of the Act less

the applicable add-on percentage for the MFN Model drug's HCPCS code) for the calendar quarter that matches the claim line's date of service and then summed across all claim lines for that drug to yield a total add-on spending amount for that drug. For biosimilar biological products, we used the applicable ASP for the reference biological product.

Then we pooled together the total add-on spending amounts for all drugs on the MFN Model HCPCS Codes List for performance year 1 and the total number of claim lines for those drugs (excluding claim lines billed with the JW modifier). Lastly, we calculated the per-dose add-on payment amount as the total pooled add-on spending amount divided by the total pooled number of claim lines.

Using the drugs (by HCPCS code) included on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, available 2019 claims data subject to the exclusions and exception previously noted, and applicable ASPs from 2019, we calculated a single per-dose add-on payment amount in the amount of \$146.55. This amount represents the single per-dose add-on payment amount for a dose of any MFN Model drug prior to application of the inflationary factor as described in section III.F.2.b. of this IFC.

b. Trending the Single Per-Dose Add-On Payment Amount Forward Each Calendar Quarter During the MFN Model

We will trend forward the single per-dose add-on payment amount each calendar quarter during the MFN Model to account for inflation over time by using a cumulative inflationary factor as described in this section of this IFC. We will not use changes in ASP or MFN Drug Payment Amount to trend forward the single per-dose add-on payment amount to align with our intention to test the removal of the link between a drug's add-on payment and its price.

As specified in § 513.220(b)(7), after calculating the single per-dose add-on payment amount, we multiplied the single per-dose add-on payment amount (\$146.55) by an inflationary factor, which equals the percentage increase in the CPI-U from the midpoint of the baseline year (2019) through the first month of the calendar quarter prior to the start of the model (that is, the

percentage increase in CPI-U from July 2019 through October 2020). The resulting per-dose alternative add-on payment amount for the first calendar quarter of performance year 1 (January 1, 2021 through March 31, 2021) is \$148.73.

To calculate the per-dose alternative add-on payment amount for each subsequent calendar quarter during the model performance period, as specified in § 513.220(c), we will multiply the performance year 1, quarter 1 alternative add-on payment amount by a cumulative inflation factor that will ensure the amount will remain equal to or greater than the alternative add-on payment amount calculated for performance year 1, quarter 1. We will calculate a cumulative inflation factor as equal to the percentage increase in the CPI-U from October 2020 through the first month after the end of the applicable ASP calendar quarter. If the cumulative percentage change in the CPI-U is negative, we will use an inflation factor of 1. For example, the cumulative inflation factor for performance year 1, quarter 2 (that is, April 1, 2021 through June 30, 2021) will be the percentage increase in the CPI-U from October 2020 through January 2021. Similarly, the cumulative inflation factor for performance year 1, quarter 3 will be the percentage increase in the CPI-U from October 2020 through April 2021.

As discussed in section III.G. of this IFC, MFN participants will use a new HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim.

3. Discussion of the Per-Dose Add-On Payment Approach

The per-dose add-on payment amount approach will test an alternative way to calculate the add-on payment that is not tied to the sales price of the drug that is furnished. This approach also aims to boost add-on revenue, on average, for MFN participants by setting the per-dose add-on payment amount based on 6.1224 percent of historical ASP payment allowances trended forward for inflation. However, the impact on MFN participants will vary based on the MFN participant's prescribing patterns, including the amount and types of MFN Model drugs they

furnish to Medicare FFS beneficiaries.

Compared with the current add-on payment policy, on an average per dose basis based on 2019 historical claims, the single per-dose add-on approach will initially decrease add-on payments for MFN Model drugs with relatively higher historical applicable ASP-based payment amounts per dose and increase add-on payments for MFN Model drugs with relatively lower historical applicable ASP-based payment amounts per dose. Average 2019 historical add-on payment amounts per dose for the MFN Model drugs for performance year 1 ranged from \$10.44 to \$2,575.47 per average dose for a drug. Based on 2019 claims, on average, a single per-dose add-on payment amount, calculated as described in this IFC and after sequestration is applied, will represent an increase in the add-on payment amount for 70 percent of doses on average compared to the effective historical add-on amount of 4.3 percent of the applicable ASP after sequestration.

To examine the potential impact of the single per-dose add-on approach on MFN participants using 2019 claims data, we considered the overall potential change in the add-on payment amount at the eligible entity level, specialty level, and type of provider and supplier. That is, for this entity level analysis, we grouped 2019 claim lines for the drugs (by HCPCS code) identified in Table 2 based on the provider's or supplier's CMS Certification Number ("CCN") or Taxpayer Identification Number ("TIN"). To examine the potential impact of the single per-dose add-on payment amount at the specialty level, we assigned claims to a specialty category based on the primary specialty of the National Provider Identifier (NPI) associated with the furnishing of the drug as listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Eligible providers were assigned to the specialty that was most frequently associated with their 2019 claims for the drugs (by HCPCS code) identified in Table 2. We also used the type of bill to examine the potential impacts on various types of providers and suppliers.

These analyses highlight that different subsets of providers and suppliers will potentially gain (or lose) under the single per-dose add-on approach. For 340B covered entities that were

paid under the OPPS during calendar year 2019, the entirety of the alternative add-on payment amount represent an increase in payment when drugs are acquired under the 340B program. Thus, we removed these entities from the following analyses.

To explore the potential entity level change in the add-on amount for the single per-dose add-on payment approach, we assigned each CCN or TIN to only one specialty based on the specialty code with the highest total allowed spending for the entity's claim lines, regardless of setting (for example, hospitals, ASCs, and physician office). We also assigned each specialty a value of "low," "medium," or "high," based on the percentage of its Medicare revenue that is related to Part B drugs, such that "high" means the specialty's drug revenue is more than 50 percent of its total Medicare revenue, "medium" means the specialty's drug revenue is 25 to 50 percent of its total Medicare revenue, and "low" means the specialty's drug revenue is less than 25 percent of its total Medicare revenue.

Based on the single per-dose add-on payment amount of \$146.55 (prior to the application of the inflationary factor that applies during the model) and using 2019 drug utilization, MFN participants will fare, on average, 40 percent better overall across all specialties with the per-dose add-on payment amount than they did historically based on 4.3 percent of ASP after sequestration. Some MFN participants will see more than a 40 percent increase in revenue related to the MFN add-on payment amount compared to their 2019 historical Part B drug claims, and others will see less than a 40 percent increase, including some who will see a reduction in add-on revenue. Based on our analysis, in general, physician practices will be better off under the per-dose add-on payment approach than hospital outpatient departments, and single specialty practices will be better off than multi-specialty practices. Table 8 shows the estimated variation in impacts for the top specialties by comparing 2019 baseline add-on payments based on 4.3 percent of the applicable ASP with a post-sequestration single per-dose add-on payment amount (that is, for this comparison, we used the per-dose add-on payment amount prior to the application of the inflationary factor (\$146.55) and applied the effects of sequestration for this

comparison). The Entity-Level Percentage Change By Percentile portion of Table 8 shows the distribution of entities based on size of the difference between their 2019 baseline add-on payments (based on 4.3 percent of the applicable ASP) and the single per-dose add-on amount (post-sequestration). Each row shows the size of the impact for the given specialty. The 5th percentile will experience the largest negative impact whereas the 95th percentile will experience the largest positive impact.

TABLE 8: ESTIMATED IMPACT BY SPECIALTY FOR THE PER-DOSE ADD-ON AMOUNT (BASED ON 2019 CLAIMS DATA)

Specialty*	Number of Entities**	Percentage of MFN Model Drug Spend†	Proportion of Specialty Revenue that is for Medicare Part B Drugs	Overall Specialty-Level Percentage Change (on average)	Entity-Level Percentage Change By Percentile***				
					5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile
Hematology/Oncology	2083	29.2%	High	-8%	-48%	-24%	-7%	25%	493%
Ophthalmology	3175	18.0%	Medium	140%	69%	104%	349%	884%	4253%
Internal Medicine	5249	14.1%	Low	4%	-36%	7%	210%	652%	23511%
Rheumatology	2020	10.9%	High	9%	-47%	-9%	11%	62%	356%
Medical Oncology	624	8.3%	High	-13%	-49%	-25%	-9%	22%	333%
Neurology	2681	3.7%	Low	-21%	-88%	-62%	153%	201%	470%
Nurse Practitioner	2763	1.9%	Low	32%	-34%	103%	211%	393%	3706%
Hematology	509	1.5%	High	-6%	-52%	-28%	-7%	31%	356%
Urology	2385	1.5%	Low	143%	54%	169%	280%	414%	994%
Gastroenterology	1778	1.5%	Low	-20%	-46%	-29%	-7%	83%	493%
Family Practice	3595	1.0%	Low	115%	-21%	203%	214%	372%	35294%
Allergy/Immunology	1325	1.0%	Medium	46%	-29%	21%	54%	89%	31863278%
Physician Assistant	2079	0.6%	Low	222%	-25%	189%	233%	780%	2361%
Cardiology	2567	0.5%	Low	1284%	21%	1408%	1414%	1427%	2111%
Pulmonary Disease	905	0.5%	Low	37%	-29%	7%	31%	96%	36000%
Orthopedic Surgery	1678	0.4%	Low	794%	103%	527%	827%	1215%	2316%
Obstetrics/Gynecology	1285	0.4%	Low	55%	-44%	206%	214%	290%	1313%
Radiation Oncology	724	0.3%	Low	1%	-61%	-28%	20%	216%	584%
Endocrinology	1032	0.3%	Low	194%	67%	211%	212%	218%	19227%
Gynecological/Oncology	119	0.3%	High	-33%	-59%	-45%	-30%	-16%	356%
Infectious Disease	152	0.3%	Medium	-10%	-54%	-24%	42%	221%	3911%
Physical Medicine and Rehabilitation	1215	0.3%	Low	159%	28%	96%	189%	478%	1541%
Nephrology	1068	0.2%	Low	634%	-30%	424%	987%	1535%	3934%
Hematopoietic Cell Transplantation & Cellular Therapy	48	0.1%	Low	-15%	-45%	-27%	-15%	31%	287%
Hospitalist	398	0.1%	Low	8%	-62%	-5%	209%	348%	2977%
Dermatology	529	0.1%	Low	-31%	-72%	-46%	67%	556%	786658%
Interventional Cardiology	546	0.1%	Low	1383%	121%	1397%	1414%	1428%	1792%
General Practice	525	0.1%	Low	62%	-42%	96%	216%	334%	18269%
Interventional Pain Management	374	0.1%	Low	149%	-4%	189%	230%	592%	2316%
Pediatric Medicine	172	0.1%	Low	1%	-64%	-6%	74%	215%	2977%
Sleep Medicine	304	0.1%	Low	20%	-80%	-29%	22%	101%	379%
General Surgery	589	0.1%	Low	23%	-47%	4%	211%	488%	2225%
Emergency Medicine	695	0.1%	Low	106%	-61%	-16%	88%	369%	2908%
Ambulatory Surgical Center	460	0.1%	Low	300%	157%	290%	436%	509%	57743%
Sports Medicine	243	0.1%	Low	965%	189%	534%	781%	1290%	2361%

*Some MFN participants may be multispecialty.

** Estimated number of entities in the specialty.

*** Large percentage changes are due to a small number of drugs furnished by entities in the category.

† Table 2 provides the MFN Model Drugs (by HCPCS code) used for this analysis; this column provides the percentage of total 2019 Medicare spending by specialty for these drugs.

Based on these data, as shown in Table 8, all but 9 of the top 35 specialties (in terms of overall 2019 allowed dollars) impacted by the MFN Model will on average see increases in add-on revenue compared to 4.3 percent of the applicable ASP with a single payment amount (the exceptions are hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecological/oncology, infectious disease, hematopoietic cell transplantation & cellular therapy, and dermatology). At the 25th percentile, 57 percent of the entities will see increased add-on revenue for the top 35 specialties with the single per-dose add-on payment amount; whereas at the 50th percentile, 83 percent of the entities will see increased add-on revenue for the top 35 specialties with the single per-dose add-on payment amount. Please note that some of the large percentage increases seen shown in the 95th percentile column are likely driven by the small volume of drugs furnished by entities in this percentile.

We observed that volume is not consistently associated with whether an entity will be better or worse off under the per-dose add-on payment approach when we look at the single per-dose add-on amount approach for the top five specialties in terms of total aggregate Medicare spending on MFN Model drugs in 2019: internal medicine, hematology/oncology, ophthalmology, rheumatology, and medical oncology. When we specifically looked at the top, middle, and bottom of a distribution of all entities based on how much better or worse off each entity will be under the per-dose add-on payment amount compared to their add-on revenue (based on their 2019 claims), we found that entities in the top 5 percent (that is, those that will do the best) had very low volume (that is, few claims for these drugs in 2019 claims). Entities in the bottom 5 percent (that is, those that will do the worst) tended to have lower volume than the middle 10 percent, though volume was highest in the bottom 5 percent of entities in the internal medicine and ophthalmology specialties. Overall, entities that will be worse off compared to their add-on revenue (based on their 2019 claims) under the per-dose add-on payment approach tended to furnish more drugs with higher drug add-on payment amounts per dose more frequently than the entities that will be better off. We estimate that similar impacts will be

experienced across the performance years unless ASPs for MFN Model drugs rise faster than inflation, in which case the overall increase in add-on revenue compared to non-model add-on revenue will diminish over time.

4. Beneficiary Cost-Sharing Responsibilities

In response to the October 2018 ANPRM, which suggested continuing beneficiary cost-sharing for the alternative add-on payment, some commenters suggested that CMS should ensure any alternative add-on payment does not increase out-of-pocket costs for beneficiaries. Other commenters noted that an alternative add-on payment could be confusing to beneficiaries since currently they pay cost-sharing based on a single amount, versus separate amounts, such as the MFN Model Drug Payment Amount and alternative add-on that we are including in the MFN Model. We appreciate these commenters' feedback.

To support reducing out-of-pocket drug costs and minimizing potential confusion for MFN beneficiaries related to the alternative add-on payment amount, and decreasing administrative burden for MFN participants, we will waive beneficiary cost-sharing (coinsurance and deductible amounts) on the portion of the allowed MFN Model Payment amount that is based on the alternative add-on payment. Under the MFN Model, the MFN Drug Payment Amount will be subject to beneficiary coinsurance and the annual deductible amount. MFN participants will continue to collect beneficiary cost-sharing applicable to the portion of the allowed payment amount that is based on the MFN Drug Payment Amount. For the alternative add-on, Medicare will pay the entire allowed payment amount that is based on the alternative add-on payment to ensure that beneficiaries do not experience an increase in cost-sharing under the MFN Model as a result of testing an alternative add-on amount. That is, beneficiaries will not owe any coinsurance or amount for the annual deductible for the per-dose add-on payment amount.

G. Billing and Claims Processing Approach

We intend to issue model-specific claims submission instructions that MFN participants

will be required to follow. Currently, for separately payable Part B drugs, providers and suppliers submit separate claim lines for each drug. Among the information included in each claim line for the applicable bill type, providers and suppliers specify the appropriate HCPCS code to indicate the drug that was furnished, the number of billing units to indicate the total amount of the drug that was furnished, billing code modifiers as necessary, and a billing amount (or charge). In general, providers and suppliers routinely use one claim line to bill for a furnished drug dose, and using billing modifiers when doing so may be necessary to comply with billing instructions. In certain situations, a second claim line may be necessary to report the amount of drug that was furnished, for example, when the number of billing units necessary to indicate the dosage given exceeds the character size of the units field or when appropriately discarded drug is billed. When applicable, a separate line item is billed with the modifier JW to identify the amount of unused drugs (or biologicals) from single use vials or single use packages that was appropriately discarded. The Medicare claims processing system calculates payment for the amount of discarded drug when the modifier JW is present. MFN participants will be required to submit a separate claim line using a new model-specific HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim. The MFN participant will indicate in the units field of the claim line with HCPCS code M1145 the number of doses of a separately payable MFN Model drug that are billed on the claim. To do so, the MFN participant will count the number of claim lines with a HCPCS code that is included on the applicable MFN Model Drug HCPCS Codes List (based on the date of service), including all claim lines when the number of billing units necessary to indicate the dosage given exceeds the character size of the units field and the claim has more than one claim line for such MFN Model drug (we note that this is expected to be a rare situation), and excluding the number of claim lines billed with the JW modifier. This approach will allow the Medicare claims processing system to apply the alternative add-on payment amount for each dose, and not apply beneficiary cost-sharing to the

alternative add-on payment amount. MFN participants will still bill for wastage as they otherwise would, using a separate claim line and the JW modifier, and the payment for such claim lines will be based on the MFN Drug Payment Amount (the alternative add-on payment amount is not applicable to such claim lines).

This billing and claims processing approach will initiate from the MFN participant's billing system and will establish a clear mechanism for MFN participants to track when the alternative add-on amount was billed and paid. This approach will simplify Medicare claims processing changes for the MFN Model. However, this approach may increase administrative burden for MFN participants and requires MFN participants to count the number of claim lines for MFN Model drugs included on a claim, indicate this number in the units field of the claim line for the alternative add-on (using HCPCS code M1145), and submit a billing amount (or charge) on the claim line for the alternative add-on. In addition, the alternative add-on payment amount will be updated quarterly. Because Medicare allows the lesser of the applicable payment amount or the billed amount, MFN participants will have to ensure that they submit an appropriate billing amount (or charge) for the alternative add-on for the applicable quarter. Because the same HCPCS code will be used to bill for the alternative add-on for all MFN Model drugs, we believe this approach minimizes, but does not eliminate, the additional administrative burden for MFN participants.

We are waiving program requirements in section 1833(a)(1)(S), section 1833(a)(1)(G) and section 1833(t) of the Act, respectively to allow flexibility in the way in which claims subject to the MFN Model payment will be processed. Section 1833(a)(1)(S) of the Act specifies that the Medicare payment for drugs and biologicals not paid on a cost or prospective payment basis is 80 percent of the lesser of actual charge or the amount established in section 1842(o) of the Act. Similarly, section 1833(a)(1)(G) of the Act specifies that the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC shall be 80 percent of the lesser of the actual

charge for the services or the amount determined by the Secretary under such revised payment system. Section 1833(t) of the Act specifies how payment under the OPSS is calculated including beneficiary copayment. Specifically, we are waiving these program requirements to the extent necessary to allow the total allowable model payment for the service as specified in § 513.210 and § 513.220 (that is, the sum of the allowed MFN Drug Payment Amount and the allowed alternative add-on payment amount) and to not apply beneficiary cost-sharing to the alternative add-on payment amount.

H. Quality Measures

The October 2018 ANPRM stated our intention to include quality measures as part of the potential IPI Model, and our interest in several categories of potential measures, specifically: patient experience measures, medication management measures, medication adherence measures, and measures related to patient access and utilization. We sought public input on ways to assess quality of care for purposes of real-time monitoring of utilization, hospitalization, mortality, shifts in site-of-service and other important indicators of patient access and outcomes, without requiring providers or suppliers to report additional data. We received numerous comments in response to the October 2018 ANPRM on this topic. Several commenters expressed concern that testing alternative payments for Part B drugs in general may impact beneficiaries' access to care and may impact the overall patient experience of care. Some commenters requested that any quality measurement not add burden to model participants. Some commenters also discussed the importance of adherence to nationally recognized clinical guidelines in treatment decisions, stating that adherence to nationally recognized clinical guidelines would reduce drug spending while also maintaining and possibly increasing quality of care.

We appreciate the public feedback on ways we could structure a model to enhance and monitor quality of care. In the MFN Model, we will implement robust monitoring activities, such as analyzing claims data, using patient survey data, and site visits, to identify any

unintended consequences and ensure that MFN beneficiaries' access to medications is not impeded and that quality of care is preserved or enhanced. Further, we believe the following principles are appropriate for a quality measurement approach for the MFN Model: (1) use quality measures for the purpose of monitoring quality of care and beneficiary access to treatment and experience with care; (2) avoid unnecessary participant reporting burden as many providers and suppliers are currently reporting quality measures to other programs and payers, for example, the MFN Model should use claims-based measures where appropriate; and (3) establish standards for adding quality measures, if necessary, during the model. We believe that this approach will allow CMS to test the MFN Model's alternative drug payment methodology, while creating a safeguard for beneficiary access and quality of care, as well as a means to monitor patient access and quality of care. We are also sensitive to concerns regarding adding administrative burden to MFN participants and beneficiaries and, thus, seek to minimize burden on them. As such, in § 513.400(b)(1) we will collect only one quality measure, focused on patient experience, to help better understand the impact of the MFN Model on beneficiary access and quality of care. This survey will be fielded by CMS to avoid any quality measure reporting burden for MFN participants, although there will be reporting burden on beneficiaries. CMS will also monitor for quality as outlined in section III.I.4. of this IFC, including monitoring access to medications through rapid analysis of claims data, using monthly claims extracts that will provide frequent assessments of beneficiary access to MFN Model drugs and that complement existing methods to receive, assess, and respond to beneficiary and health care provider feedback on the MFN Model.

For the patient experience focused quality measure, we will use a patient experience survey, which we will field periodically to a sample of Medicare beneficiaries, beginning in performance year 1. The patient experience survey will be administered to these beneficiaries by a third party contractor throughout the model performance period. A sample of beneficiaries will be surveyed regarding their experience of care, access, or other issues they experienced under the

MFN Model, and we may also sample beneficiaries who are not in the MFN Model.

Beneficiaries will not be required to complete the survey.

Survey results will be used to monitor the impact of the MFN Model on MFN beneficiaries' care experience and potentially to inform educational materials for MFN participants. As is outlined in section III.I.4. of this IFC, claims data will also be monitored to assess patient access and outcomes.

If during the model the patient experience of care quality measure and claims-based monitoring strategies are found to be insufficient to adequately measure the quality of care that MFN beneficiaries are receiving or MFN participants are providing, CMS may specify additional measures to monitor quality. If additional quality measures are added, they will meet the following criteria: 1) Additional measures would be among one or more of the following categories: patient experience of care, patient activation, shared decision making, adherence, utilization, and process measures; 2) Additional measures would not add significant burden to MFN participants or beneficiaries; and 3) Additional measures would utilize an instrument that CMS has used previously in a model to adjust payment or for monitoring or evaluation. We are codifying the inclusion of the patient experience quality measure and its use as well as the criteria for adding measures during the MFN Model in § 513.400.

I. Beneficiary Protections and Monitoring Actions

We are interested in enhancing protections for beneficiaries included in the MFN Model. In addition to existing beneficiary protections, we will actively monitor the MFN Model to ensure it is operating effectively and meeting the needs of beneficiaries, providers and suppliers, and the Medicare program. We will coordinate with the Medicare Beneficiary Ombudsman and other customer facing components to ensure that any MFN Model-related beneficiary complaints, grievances, or requests for information submitted are responded to in an appropriate and timely manner, per CMS protocol.

We believe it will also be necessary to have additional protections in place in the MFN

Model to ensure that beneficiaries retain their existing rights and are not harmed by the model test. Further, we believe it is important for beneficiaries to know and understand their rights as beneficiaries who are receiving care from MFN participants. We therefore believe it is necessary to include certain policies regarding beneficiary choice, appeals, and the availability of services.

1. Beneficiary Freedom of Choice

A beneficiary's ability to choose his or her provider or supplier is an important principle of Medicare fee-for-service and is reflected in section 1802 of the Act. We are codifying in § 513.410(a) that any MFN participant must not commit any act or omission, nor adopt any policy that inhibits a beneficiary from exercising his or her freedom to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare. We believe these provisions are necessary to ensure the MFN Model does not prevent beneficiaries from the general rights and guarantees provided under Medicare.

2. Appeals Processes and Financial Hardship Exemption

a. Appeals Processes

In § 513.410(b), we are codifying that MFN beneficiaries and their assignees will have access to the existing formal claims appeals process under 42 CFR part 405, subpart I. In other words, once an MFN Model drug is furnished by an MFN participant to a beneficiary and a claim is submitted and processed for payment, that claim will be eligible for the current Medicare claims appeals processes. If a beneficiary receives an MFN Model drug from an MFN participant it does not mean that he or she should lose this right, but instead this right should necessarily be applicable to included beneficiaries as it would be if they were not a part of the MFN Model.

b. Financial Hardship Exemption

To include financial protection for physicians and other MFN participants, specifically those who furnish substantial amounts of MFN Model drugs as part of the services they furnish to Medicare FFS beneficiaries, especially MFN Model drugs with the greatest difference

between the MFN Price and the applicable ASP, we are including a financial hardship exemption codified in § 513.230. The financial hardship exemption process for MFN participants will be available in the event unintended consequences arise to ensure access to MFN Model drugs for MFN beneficiaries and financial protections for MFN participants who are unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs and are significantly affected by their participation in the MFN Model.

The financial hardship exemption process will occur independently of existing Medicare claims processing and appeals processes. In § 513.230(a), we codify that a financial hardship exemption for a performance year may be granted to an MFN participant by CMS, in its sole discretion and will not be subject to appeal, when the provisions in § 513.230 are met. This means that a financial hardship exemption, if granted, will be applied at the MFN participant level (as defined in § 513.2). As further described in this section of this IFC, a financial hardship exemption will be limited to cases where the MFN participant experienced a financial loss.

Specifically, to be eligible for a financial hardship exemption, the MFN participant must submit its request for a financial hardship exemption to CMS in accordance with the submission process that CMS will post on the MFN Model website prior to October 1, 2021, and in the form and manner and with the content that will be specified by CMS, including without limitation the requirements specified in § 513.230(b). Such requests must be submitted to CMS within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption. The MFN participant must include the following in its request for a financial hardship exemption:

- Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient;
- Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price

concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries;

- Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries;

- Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug;

- Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address; and

- The MFN participant's attestation that--

- ++ It experienced a reduction in Medicare Part B FFS payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;

- ++ It has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers, and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and

- ++ Its submission is true, accurate, and complete.

In addition, MFN participants must use a template that CMS will post on the MFN Model website for submission of their net acquisition costs for MFN Model drugs and administrative information. This template will be similar to the template CMS provided for the 2020 Hospital

Survey for Specified Covered Outpatient Drugs (SCODs) Average Acquisition Cost.⁷² The MFN participant will submit the other required materials to CMS along with the template.

In § 513.230(c), we codify the standards that CMS will use to determine if an MFN participant is granted a financial hardship exemption. Specifically, to be eligible for the financial hardship exemption, we codify in § 513.230(c)(2)(i) that the MFN participant must submit a timely, complete request for a financial hardship exemption in accordance with the requirements specified in § 513.230(b) that in the sole discretion of CMS demonstrates all of the following:

- The MFN Participant exhausted all reasonable methods to obtain the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year.
- The MFN participant's average net acquisition cost for each MFN Model drug (including on- and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries was not less than the MFN participant's average net acquisition costs for such MFN Model drug (including on- and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to MFN beneficiaries.
- Any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug.

In addition, in § 513.230(c)(2)(ii), we are codifying that the agency in its sole discretion must also determine that the MFN participant's excess reduction amount per beneficiary (as determined by CMS in accordance with § 513.230(d)(6)) is greater than zero. That is, the MFN participant must have experienced a reduction in Medicare FFS allowed charges for separately payable Medicare Part B drugs on a per beneficiary basis during the performance year as

⁷² The template for the 2020 Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709; OMB 0938-1374) available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index> .

compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) that is greater than 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis during the prior year. We are establishing a threshold of 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis as a criterion to qualify for the financial hardship exemption because the exemption is designed to be limited to MFN participants that experience a significant year-to-year reduction in total allowed charges as a result of the MFN Model. We believe this threshold will protect MFN participants from significant financial hardship under the MFN Model while also preserving the model test of aligning payment for Medicare Part B drugs with the lowest international prices using a phase-in approach.

Incomplete financial hardship exemption requests will not be considered by CMS.

In § 513.230(d), we are codifying how CMS will calculate the MFN participant's excess reduction amount per beneficiary. CMS will calculate the MFN participant's excess reduction amount per beneficiary using available final action claims data that are estimated to be more than 90 percent complete (claims are generally complete within 2 months after the service month) where Medicare was the primary payer, as determined by CMS. This approach will not include non-claims based payments or other transactions, for example, performance-based payment or repayments. CMS will calculate, for dates of service within the performance year, the MFN participant's total allowed charges for separately payable Medicare Part B drugs, and the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0. Then, CMS will divide the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance

year. CMS will repeat this calculation using the available claims data for the prior year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year. Then, CMS will subtract the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year from the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year. This difference will then be compared to 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year, using subtraction as described in § 513.230(d)(6). The latter quantity will be calculated by identifying 25 percent of the MFN participant's total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year, then dividing this amount by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a date of service within the prior year. If the resulting amount, called the excess reduction amount per beneficiary, is greater than zero, then the MFN participant will meet this eligibility criterion for the financial hardship exemption.

In § 513.230(e)(1), we are codifying that if CMS in its sole discretion grants a financial hardship exemption to an MFN participant for a performance year, CMS shall provide to such MFN participant, a reconciliation payment for the performance year. To calculate the reconciliation amount for the MFN participant, CMS will multiply the excess reduction amount per beneficiary by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance year.

The reconciliation payment amount will be paid by a CMS contractor using Medicare Part B funds as soon as practical after CMS notifies the MFN participant of CMS's decision regarding the MFN participant's financial hardship exemption request and the amount of the

reconciliation payment, if any, to be made to the MFN participant. In § 513.230(e)(2), we are codifying that there will be no appeal of the amount of the reconciliation payment, if any, to be made to the MFN participant. In addition, the reconciliation payment amount will not be subject to beneficiary cost sharing (including any deductible or coinsurance) because the reconciliation payment will not be tied to specific beneficiary claims, beneficiaries will have been responsible for 20 percent cost-sharing on the allowed payment amounts for the Medicare Part B drugs they received during the performance year, and steps to seek additional cost-sharing from beneficiaries would likely cause significant confusion and burden for beneficiaries and MFN participants.

We do not foresee that many MFN participants will qualify for a reconciliation payment for performance year 1, because the estimated overall reduction in Medicare Part B drug payment during performance year 1 is 7 percent on average. This reflects the MFN Price phase-in formula in section III.E.5. of this IFC which will begin with the MFN Price making up 25 percent of the MFN Drug Payment Amount and the alternative add-on payments in section III.F. of this IFC will represent a 40 percent increase on average for MFN participants relative to historical Medicare add-on payments. Given the financial hardship exception threshold of 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis in the prior year will be determined at the entity level, MFN participants with a high proportion of their overall Medicare payments related to MFN Model drugs will be more likely to qualify for the hardship exemption if their Medicare Part B drug allowed charges on a per beneficiary basis during a performance year were to decrease significantly compared to the prior year. MFN participants that are hospitals will likely have significant Medicare Part A revenues and purchasing abilities that will lessen the likelihood that they will qualify for a financial hardship exemption based on their experience in the MFN Model during performance year 1. Non-hospital MFN participants will be more likely to potentially qualify in later performance years.

For future years, we seek comment on whether an alternative threshold might better protect beneficiary access to MFN Model drugs or mitigate impacts on physicians and other MFN participants under the MFN Model. For example, we are interested in whether a uniform threshold should be applied for all MFN participants, and whether certain physician specialties or types of MFN participants would find the threshold insufficient in protecting beneficiary access to MFN Model drugs. For future rulemaking, we also seek comment on how CMS could refine the design of the financial hardship exception to advance the model goals to reduce program expenditures and maintain or improve quality of care.

CMS pledges to maintain confidentiality of individual financial hardship exemption requests to the extent provided by law. However, CMS may make public descriptive information about MFN participants that are granted a financial hardship exemption and the extent to which they were unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs. We do not intend to make such information available in an individually identifiable manner.

3. Availability of Services

The MFN Model is designed to test potential improvements to the delivery of and payment for healthcare to reduce Medicare expenditures while preserving or enhancing the quality of care for beneficiaries. As such, an important aspect of testing models is that beneficiaries must continue to have access to and receive needed care.

In § 513.410(c), we are codifying that MFN participants must not take any action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels, or other factors that would render them “at-risk beneficiaries” as that term is defined at 42 CFR 425.20 (“lemon dropping”). We will use monitoring to ensure that MFN participants are complying with this requirement. We believe that this is a necessary precaution to protect beneficiaries against potential beneficiary selection bias from MFN participants and ensure that MFN beneficiaries retain access to medically necessary treatment.

4. Monitoring and Compliance Activities

Consistent with other CMS Innovation Center models, CMS will implement a monitoring program for the MFN Model to ensure that the MFN Model is implemented safely and appropriately. Given that MFN participants will receive model-specific payments and access to payment rule waivers while participating in the MFN Model, we believe that enhanced compliance review and monitoring of MFN participants is necessary and appropriate to ensure the integrity of the MFN Model. In addition, as part of the CMS Innovation Center's assessment of the impact of new models such as the MFN Model, we have a special interest in ensuring that model tests do not interfere with ensuring the integrity of the Medicare program. Our interests include ensuring the integrity and sustainability of the MFN Model and the underlying Medicare program from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, as a part of the models currently being tested by the CMS Innovation Center, CMS or its designee(s) monitors model participants to assess compliance with model terms and with other applicable program laws and policies. We believe our monitoring efforts help ensure that model participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries.

In § 513.420, we are codifying a framework for conducting compliance monitoring activities for the MFN Model that is consistent with the standard practices in other CMS Innovation Center models. Under the monitoring policy at § 513.420(b), MFN participants will be monitored to assess compliance with the MFN Model requirements, to determine the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. Further, under § 513.420(a)(2), an MFN participant will be required to notify CMS within 15 calendar days after becoming aware that the MFN participant is under investigation or has been sanctioned by the

federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing rights).

In § 513.420(b)(2), we are codifying that when we are conducting compliance monitoring and oversight activities, CMS or our designees will be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to MFN beneficiaries. In § 513.420(b)(3), we are codifying that MFN participants will be required to cooperate with the model monitoring and evaluation activities, comply with the government's right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the MFN Model, and to retain and provide the government with access to records.

In § 513.420(b)(1), we are codifying that monitoring activities will include, but will not be limited to: (1) documentation requests sent to the MFN participant, including surveys and questionnaires; (2) audits of claims data, medical records, and other data from the MFN participant; (3) interviews with any individual or entity participating in the MFN Model, including members of the MFN participant's leadership, management, and staff; (4) interviews with beneficiaries and their caregivers; (5) site visits to the MFN participant; and (6) tracking complaints and appeals. We believe these specific monitoring activities, which align with those currently used in other models being tested by the CMS Innovation Center, are necessary in order to ensure compliance with the terms and conditions of the MFN Model and to protect beneficiaries from potential harms that may result from activities of an MFN participant, such as attempts to reduce access to medically necessary covered services or appropriate drugs.

We anticipate that monitoring of the MFN Model activities will include gathering and analyzing data captured through the Ombudsman's service, the evaluation of the MFN Model, the patient experience survey, and audits of charts, claims data, medical records, among other data as available. As previously noted in this IFC, one purpose of monitoring and analyzing

these data sources will be to provide timely information about the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program, and to facilitate real time identification and response to potential issues. We anticipate that these findings will inform model oversight and the potential need for action to address identified issues.

In § 513.420(c), we outline parameters for site visits. We will require that MFN participants cooperate in periodic site visits conducted by CMS or its designee. Such site visits will be conducted to facilitate the model implementation.

In order to operationalize this model, CMS or its designee will provide the MFN participant with no less than 15 calendar days advance notice of a site visit, to the extent practicable. Furthermore, to the extent practicable, CMS will attempt to accommodate a request that a site visit be conducted on a particular date, but that the MFN participant will be prohibited from requesting a date that was more than 60 calendar days after the date of the initial site visit notice from CMS. We believe the 60-calendar day period will reasonably accommodate MFN Model participants' schedules while not interfering with the operation of the MFN Model. Further, we will require MFN participants to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Finally, CMS or its designee can perform unannounced site visits to all physical locations of MFN participants at any time to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues, notwithstanding these provisions. Further, nothing in part 513 will limit CMS from performing other site visits as allowed or required by applicable law. We believe that, regardless of the model being tested, CMS must always have the ability to timely investigate concerns related to the health or safety of beneficiaries or other patients, or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it will be necessary for us to monitor, and for

MFN participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to beneficiaries in an attempt to change the MFN Model results or their MFN Model payments, including discrimination in the provision of services to at-risk beneficiaries (for example, due to eligibility for Medicaid based on disability).

We intend to monitor MFN participants through any of the previously described monitoring activities (such as documentation requests, audits of claims data, audits of medical records, etc.) to ensure that MFN Model drugs are not being inappropriately billed (for example, excessive doses or units). We anticipate that this monitoring activity will discourage MFN participants from furnishing smaller and more frequent doses of MFN Model drugs to beneficiaries in order to maximize the alternative add-on payments. If it is found that an MFN participant has been engaged in inappropriate billing, then we will use applicable remedial actions set forth in § 513.440(a)(2).

We may employ longer-term analytic strategies to confirm our ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study.

a. Reduced Access

We will monitor claims data from MFN participants – for example, to compare MFN participants' case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. To the extent that the use of a patient experience survey includes items focused on access, we will analyze these data as well to determine whether MFN beneficiaries continue to be able to access the right drug at the right time. We will use these data to promote transparency and develop an understanding of the MFN Model's effects. We intend to review and audit MFN participants if we have reason to believe that they are compromising beneficiary access to care.

We intend to conduct analyses of claims data, such as monthly updates and historic comparisons of trends including drug utilization, program spending, and prescribing patterns (including observing for any shift to compounded or other categories of drugs that are not included in the MFN Model) as well as changes in site of service delivery, mortality, hospital admissions, and other indicators present in claims data. We will monitor physician visits, days in a hospital, and other services as part of the thorough look at how MFN beneficiaries are receiving care to determine whether any treatment patterns are changing systematically. We will use the monitoring results to detect potential issues with beneficiary access to care or potential provider and supplier payment issues.

b. Quality of Care Monitoring

We anticipate that quality monitoring activities may include claims and survey data analytics, site visits, medical record review, and tracking patient complaints and appeals. We will also use the most recent claims data available to track utilization and beneficiary outcomes under the MFN Model. We believe this type of monitoring is important as we want to ensure to the greatest extent possible that patients continue to receive high-quality care.

We believe that this set of monitoring activities will allow us to promptly identify any unintended consequences of the MFN Model. We anticipate that by identifying unintended potential consequences of the MFN Model, that we will then be able to determine methods to address or alleviate those potential consequences.

c. Remedying Improper Payment

We anticipate that our monitoring activities may identify instances of incorrect MFN Model payments. As such, we are codifying that CMS is authorized to correct model-specific payments under § 513.420(d). Specifically, under this section if CMS discovers that it has made or received an incorrect model-specific payment under the terms of the MFN Model, then CMS may make payment to, or demand payment from, the MFN participant. Should these monitoring activities identify a need for additional protections, we will consider appropriate action.

d. Compliance with Laws

MFN participants will remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the MFN Model. In § 513.420(a)(1), we therefore require that MFN participants must comply with all applicable laws and regulations. We note that a law or regulation is not “applicable” to the extent that its requirements have been waived under section 1115A(d)(1) of the Act solely for purposes of testing the MFN Model.

5. Enforcement Authority and Remedial Action

We are codifying at § 513.440(b) that nothing contained in the terms of the MFN Model or part 513 will limit or restrict the authority of the HHS Office of Inspector General (OIG) or any other Federal Government authority, including its authority to audit, evaluate, investigate, or inspect the MFN participant.

It is necessary for CMS to have the ability to impose remedial actions to address non-compliance with the requirements of the MFN Model and to ensure that the MFN Model does not interfere with the program integrity interests of the Medicare Program. Thus, in § 513.440(a)(1), CMS may take remedial action against an MFN participant if CMS determines, in CMS’ sole discretion, that the MFN participant--

- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has failed to comply with any of the terms of the MFN Model, including applicable requirements of part 513;
- Systematically engaged in the under delivery or over delivery of an MFN Model drug;
- Has taken any action that threatens the health or safety of an MFN beneficiary or other patient;
- Has undergone a change of control that presents a program integrity risk;

- Has submitted false data or made false representations, warranties, certifications or attestations in connection with any aspect of the MFN Model;
- Has avoided at-risk beneficiaries, as this term is defined in § 425.20;
- Has avoided patients on the basis of payer status;
- Is subject to any sanctions or final actions of an accrediting organization or a Federal, State, or local government agency;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the MFN Model, or the Medicare program, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the MFN Model or Medicare program;
- Is subject to investigation or action by HHS (including the HHS Office of the Inspector General (OIG)) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act *qui tam* matter in which the Federal Government has intervened, or similar action;
- Is the subject of administrative enforcement action imposed by CMS; or
- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 513.440(a)(2), we are codifying that if CMS determines that one or more grounds for remedial action exists, CMS may take one or more of the following remedial actions:

- Notify the MFN participant of the violation.
- Require the MFN participant to provide additional information to CMS or its designees.
- Require the MFN participant to develop and implement a corrective action plan in a form and manner and by a deadline specified by CMS.
- Subject the MFN participant to additional monitoring, auditing, or both.

- Remove the MFN participant from the MFN Model;
- Recoup model-specific payments.
- Such other action as may be permitted under the terms of § 513.420.

6. Audits and Record Retention

By virtue of participation in the MFN Model, MFN participants will receive model-specific payments and access to payment rule waivers. We therefore believe that CMS' ability to audit, inspect, investigate, and evaluate records and other materials related to participation in the MFN Model is necessary and appropriate. In order to expand a phase 1 model tested by the CMS Innovation Center, among other things, the Secretary must first determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. Thus, there is a particular need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in CMS Innovation Center models to allow us to ensure that the model is not denying or limiting the coverage or provision of benefits for beneficiaries.

We note that there are audit and record retention requirements under the Medicare Shared Savings Program (42 CFR 425.314) and in current models being tested under section 1115A (such as under 42 CFR 510.110 for the CMS Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, in § 513.430(a), the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the MFN Model. Additionally, in order to align with the policy of current models being tested by the CMS Innovation Center, we are codifying in §§ 513.430(b) and (c) that MFN participants must--

- Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection,

or investigation of the MFN Model, including without limitation, documents and other evidence regarding all of the following:

- ++ The MFN participant's compliance with the terms of the MFN Model, including new subpart E of part 513.

- ++ Quality measure information and the quality of services performed under the terms of the MFN Model, including new subpart E of part 513.

- ++ Patient safety.

- ++ The accuracy of model-specific payments under the MFN Model.

- ++ Utilization of items and services furnished under the MFN Model.

- ++ Any other program integrity issues.

- Maintain the documents and other evidence for a period of 6 years from the last payment received by the MFN participant under the MFN Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless –

- ++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MFN participant at least 30 calendar days before the normal disposition date; or

- ++ There has been a termination, dispute, or allegation of fraud or similar fault against the MFN participant in which case the records must be maintained for an addition 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the MFN participant of the special need to retain records or group of records at least 30 calendar days before the normal disposition date, the records must be maintained for such period of time determined by CMS.

J. Interaction with Other Models and Programs

1. Approach for Overlap with Other Models

In designing each CMS Innovation Center model, CMS considers potential overlap

between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as health care provider or beneficiary, operating rules may be established for whether or not health care providers and beneficiaries can be part of both models as well as how to handle overlap when it occurs. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that double counting of beneficiaries and dollars across different models does not occur.

In response to the October 2018 ANPRM, several commenters expressed concern regarding model overlap, specifically with the Oncology Care Model (OCM) and initiatives involving accountable care organizations (ACOs). Some commenters noted that OCM participants should be excluded from the potential IPI Model or excluded from mandatory participation. Some commenters also requested that ACO initiatives take precedence in terms of calculating shared savings as well as for clarity on how overlap between ACO initiatives and the potential IPI Model would work.

We appreciate commenters' request for detailed information about model overlap policies. In developing the MFN Model, CMS conducted an internal review of which models will have potential overlap with the MFN Model. As a result of our review, we expect there will be situations where a Medicare beneficiary who receives an MFN Model drug will also be assigned, aligned, or attributed to another CMS Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, for example, a health care practitioner or a physician group practice could participate in multiple CMS Innovation Center models and CMS programs concurrently. Of note, some existing models and programs will not have overlap at the health care practitioner or participant level due to the way in which the model or program operates and makes payments.

We believe that the MFN Model is operationally compatible with existing models and programs that provide opportunities to improve care and reduce spending, especially total cost of care-focused CMS programs and Innovation Center models. The MFN Model will test an

innovative way to pay for Medicare Part B drugs that seeks to address any existing incentives for prescribing higher cost drugs and ways to lower costs for beneficiaries and the Medicare program; total cost of care-focused CMS programs and Innovation Center models incentivize more appropriate provision of care across multiple clinical areas, including use of Medicare Part B drugs; the MFN Model addresses only use of certain Medicare Part B drugs. To some degree, incentives for inappropriate use of higher cost drugs are reduced, and intended effects of the MFN Model are already built into total cost of care-focused models, so the addition of the MFN Model should not have further effects in those programs. We do not plan to make adjustments to the MFN Drug Payment Amount or MFN alternative add-on payment due to overlap between the MFN Model and another model or program, unless such model tests an alternative approach to the add-on portion of payment for Medicare Part B drugs as specified in § 513.220(d)(2). However, for certain models and programs, adjustments to those models and programs may be necessary to account for payment changes under the MFN Model.

Because the MFN Model will focus on approximately 50 separately payable Medicare Part B drugs, when claims are considered from all beneficiaries aligned with or assigned to some other Innovation Center models or CMS programs that focus on total cost of care, such as the Medicare Shared Savings Program, we do not expect that the MFN Model will have a significant impact on shared savings, total cost of care, or other benchmarks and measures. Therefore, changes to benchmarks, targets, and reconciliation methodologies may not be necessary, and will be determined by each other model, program, or initiative as appropriate.

However, we recognize that the design of some other models, programs, and initiatives could create unique challenges at the organization, clinician, or beneficiary level. As a result, we will work with such models, programs, or initiatives to resolve any potential overlaps that could result in overpayment of savings due to double counting of the impact of a result that could be attributed to the interventions from two different models. For example, OCM focuses on improved care management and coordination for Medicare beneficiaries with cancer who receive

chemotherapy during 6-month episodes of care. An OCM practice has the opportunity to receive a performance-based payment if it reduces the total cost of care in its OCM episodes compared to a target. Based on the performance year 1 MFN Model Drug HCPCS Codes List, we anticipate substantial overlap between MFN participants and MFN beneficiaries with OCM practices and OCM beneficiaries. To avoid paying performance-based payments in OCM that are due simply to the drug payment change that will occur under the MFN Model and not to changes in care delivery, for OCM, we will adjust reconciliation calculations such that the drug payments included in OCM episode expenditures will be calculated as if the MFN Model were not occurring. OCM participants will be notified and provided with further information through OCM's typical channels of communication.

As discussed in the section III.C.1. of this IFC, CMMI has already waived section 1833(t) of the Act for certain acute care hospitals due to their participation in models under section 1115A of the Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis. For the first and second quarters of performance year 1, we will exclude these entities from the MFN Model with limitation. That is, the acute care hospitals that participate in another CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act, such as the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model, will be excluded from the MFN Model. For the third quarter of performance year 1 and beyond, acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model if the parameters of the other CMS Innovation Center model adjust for the difference in payment for MFN Model drugs

between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model. These exclusions will apply only during the period of the hospital's participation in such model under which it is paid on a fully capitated or global budget basis. Upon termination of such participation for any reason or if the model is revised such that the waiver of section 1833(t) of the Act no longer applies under such model, the hospital—if it otherwise meets the definition of MFN participant—will be required to participate in the MFN Model.

We anticipate model overlap may occur between the MFN Model and future CMS models or programs not yet implemented. As discussed in section III.F.5. of this IFC, if there are MFN participants that concurrently participate in a future CMS model that also tests an alternative approach to the add-on portion of payment for Part B drugs, we will not make the MFN alternative add-on payment to those MFN participants for those MFN Model drugs that overlap with the other model. Instead, we will follow the other model's approach to making an alternative add-on payment. We expect this overlap policy will maintain the intended financial effects of the MFN Model, while allowing operational compatibility with other models that test alternative approaches to Medicare Part B drug payment.

2. Quality Payment Program

The MFN Model will not qualify as an Advanced APM under the Quality Payment Program. Specifically, the MFN Model does not require participant health care providers to use CEHRT, does not base payment to participant health care providers on quality measures, and does not satisfy the financial risk criteria because it does not involve requiring participating APM Entities to bear risk for monetary losses of more than nominal amounts under the APM and is not a Medical Home Model expanded under section 1115A(c) of the Act. The MFN Model also will not qualify as a MIPS APM, because it does not hold participant health care providers financially accountable for both the cost and quality of care provided to Medicare beneficiaries.

K. Interaction with Other Federal Programs

The MFN Model may have impacts on other federal programs, such as Medicaid, the 340B Program, the Veterans Health Administration, the Department of Defense, the Public Health Service, the Coast Guard, and Medicare.

1. Impact on Medicaid

a. Impact on Medicaid “Best Price”

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologicals), the term “Medicaid Best Price” is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. That is, a manufacturer’s best price determination represents the lowest price available from the manufacturer during a rebate period (a quarter) to best price eligible entities or purchasers in the U.S. only.

Since the MFN Drug Payment Amount will be paid to MFN participants for each MFN Model drug as a Medicare payment, and it will not be a “price available from the manufacturer,” the MFN Drug Payment Amounts themselves will not be included in the manufacturer’s determination of best price. However, in order for MFN participants to purchase MFN Model drugs at prices that does not lead to financial loss, the manufacturer will need to make available prices that are competitive with the MFN Drug Payment Amounts. We expect that the MFN Drug Payment Amounts will likely drive manufacturer drug prices available to MFN participants down over the course of the model, and the model may indirectly impact a manufacturer’s best price to the extent that a manufacturers’ U.S. best price will be lower than what it would be otherwise. In other words, if during the course of the MFN Model, market forces result in manufacturers reducing prices available to MFN participants, such available prices to MFN participants will be considered in a manufacturer’s determination of best price and could potentially lower best price and possibly increase Medicaid rebates.

Specifically, if the manufacturer lowers prices available to an MFN participant at or below the MFN Drug Payment Amount, such prices will be considered in the manufacturer's determination of best price and may reset the manufacturer's best price if the reduced price is lower than the manufacturer's best price that would otherwise apply. This is particularly possible because the MFN Drug Payment Amount, which is expected to be lower than the payment amounts for the same drugs outside of the model, will include the impact of pricing outside of the U.S., which is typically lower than prices in the U.S., and will likely impact the prices made available by the manufacturer in the U.S.

b. Impact on Average Manufacturer Price (AMP)

AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a covered outpatient drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer with certain exclusions. Because the MFN Model will focus on certain Part B drugs that are furnished in the outpatient setting and these drugs are most likely injected or infused, the AMP for an MFN Model drug is likely determined using the AMP computation for 5i drugs,⁷³ which includes sales that are not generally dispensed through retail community pharmacies (see section 1927(k)(1)(B)(i)(IV) of the Act, 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals. Thus, a manufacturer's sales of MFN Model drugs to MFN participants (or price paid by MFN participants) will be included in the AMP or 5i AMP. If, as described in section III.K.1.a. of this IFC, the manufacturer lowers prices available to an MFN participant at or below the MFN Drug Payment Amount, the manufacturer's AMP for an MFN Model drug may be lower. If a drug's AMP decreases, it may result in potentially lowering the applicable Medicaid drug rebate paid (the rebate, in part, is based on a percentage of AMP). However, the MFN Model may also lower a manufacturer's best price for an MFN Model drug as previously

⁷³ Inhalation, infusion, instilled, implanted or injectable drugs.

discussed. The resulting effect on the Medicaid drug rebate will depend upon the relationship of any AMP change and any best price change.

We also note that if the AMP for an MFN Model drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for an MFN Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS's determination of the non-model payment allowance for such drug would occur. We refer readers to section III.L. of this IFC for a discussion of excluding units of MFN Model drugs from manufacturers' ASP, which may also increase the likelihood that the ASP for an MFN Model drug will be greater than the AMP for such drug.

2. Interaction with 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers ("covered entities") to obtain discounted prices on "covered outpatient drugs" (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Such entities will be included in the MFN Model and will be subject to the MFN Model payment test. That is, these 340B covered entities will be MFN participants and receive the MFN Drug Payment Amount and alternative add-on payment. To the extent these entities receive payment under the model that is lower than their current Medicare payment, there may be fewer resources available for their 340B program activities.

Under the MFN Model, MFN participants will be paid for MFN Model drugs according to the payment approach discussed in section III.E. of this IFC. If the MFN participant is a 340B covered entity, the drug portion of the model payment will be the lower of the MFN Drug

Payment Amount or the non-model payment amount paid to 340B covered entities for 340B drugs under the OPSS for the MFN Model drug for that corresponding calendar quarter. The MFN alternative add-on payment will be paid to MFN participants that are 340B covered entities in the same way as MFN participants that are non-340B covered entities.

We are including certain 340B covered entities in the MFN Model in order to test the innovative payment approach, including the alternative (per-dose) add-on payment amount, broadly. MFN participants that are 340B covered entities may need to enhance their direct contracting with manufacturers in order to obtain MFN Model drugs within the MFN Drug Payment Amount. Our analyses estimate that 340B covered entities will realize a total add-on percentage amount of 4.5 percent in the first year of the model due to the mix of MFN Model drugs they historically furnish. The amount of the alternative add-on that 340B entities realize will be an increase in revenue compared to their historical baseline. However, these entities will face the same or increased burden from model participation. Thus, we believe the modest increase in add-on revenue that will be paid to these entities through the alternative add-on payment approach will potentially be offset through higher facility costs for acquiring included drugs (for example, higher costs for direct contracting). Programs that support vulnerable Americans are a vital safety net. We refer readers to section III.C. of this IFC where we discuss providers and suppliers that will be MFN participants. We discuss potential impacts on 340B covered entities in more detail in section VI. of this IFC.

a. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase covered outpatient drugs at no more than a “ceiling price,” which is calculated as AMP minus Medicaid unit rebate amount. We note that a ceiling price is just a ceiling; some 340B hospitals can obtain covered outpatient drugs at less than the ceiling price. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the MFN Model affects a drug’s AMP and best price, the 340B prices will be affected. We discuss the potential impacts on a drug’s AMP and

best price in section III.K.1. of this IFC.

3. Interaction with Medicare

a. Medicare Part B

As discussed in section VI. of this IFC, we believe the MFN Model will result in lower Medicare spending for MFN Model drugs, including lower program spending and lower beneficiary cost-sharing, and in overall reduced Medicare Part B Trust Fund expenditures, which in turn will lower Medicare FFS expenditures and beneficiaries' Part B premiums.

As discussed in section III.K. of this IFC, manufacturers' ASPs for MFN Model drugs may be higher or lower than they otherwise would be absent the MFN Model. In turn, non-model Medicare Part B FFS payment for MFN Model drugs could be higher or lower. We are excluding from the calculation of the manufacturer's ASP any units of an MFN Model drugs furnished to MFN beneficiaries and billed by MFN participants. Thus, during the MFN Model, manufacturers' ASPs for MFN Model drugs could be higher or lower than they might be absent the model, resulting in Medicare payments to providers and suppliers that are not MFN participants that would be higher or lower than what the payments would have been absent the model.

We note that if the AMP for an MFN Model drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for an MFN Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS's determination of the non-model payment allowance for such drug would occur.

b. Medicare Advantage

Medicare Advantage (MA) plans will not be MFN participants. We note that when MA plans pay non-contracted, out of network providers who have administered an MFN model drug to an enrollee, the amount paid will be based on the non-model Medicare FFS payment amount (that is, the amount that MA plans pay to these providers will not be the MFN Model payment

amounts).

As discussed in section VI. of this IFC, we expect the MFN Model will lower overall Medicare FFS expenditures; that is, Medicare Part B MFN Drug Payment Amounts will be lower than such payment would be absent the model, the Medicare Part B alternative add-on payments will be greater than such payment would be absent the model, there could be increases in Medicare Part A spending, and taken together the model will result in an overall reduction in Medicare expenditures. The overall decrease in Medicare FFS expenditures will be considered in determining the historical FFS claims experience for calculating the rates for plan service areas. Payments to Medicare Advantage Organization plans are anticipated to be lower than they would be absent the model. At a high level, the FFS component of the non-ESRD MA rates is based on the product of the projected national per-capita spending and a county-level relative cost index. Thus, the MA ratebook calculations will reflect changes in actual FFS spending due to the impact of the MFN Model. We note that this approach is consistent with treatment of payments made under other CMS Innovation Center models and the Medicare Shared Savings Program.

As discussed in more detail in section VI. of this IFC, we estimate that total payments to MA plans over the 7-year course of the model will be substantially lower as a result of reduced FFS spending under the MFN Model, that is, total payments to MA plans may be approximately \$49.6 billion lower in the OACT estimate and \$28.5 billion lower in the ASPE estimate. We note that there is much uncertainty around the assumptions for these estimates.

L. Exclusion of Certain MFN Model Sales from Manufacturers' Calculation of ASP for MFN

Model Drugs

In accordance with sections 1847A and 1927(b)(3)(A)(iii) of the Act, manufacturers^{74 75} submit ASP data for their products to CMS on a quarterly basis. The manufacturer's ASP is based on sales to all purchasers in the U.S. with limited exceptions (that is, exclusions are limited to sales exempt from best price (as defined in section 1927(c)(1)(C)(i) of the Act), sales at a nominal charge, and units sold to a CAP vendor), and is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than certain rebates specified in section 1927 of the Act). Specific ASP reporting requirements are set forth in section 1927(b)(3) of the Act. In accordance with sections 1847A and 1927(b)(3) of the Act, manufacturers report most ASP data by National Drug Code (NDC), which identifies products in terms of the labeler, product, and package size and type. The reported ASP data are used to establish the Medicare payment amounts. In general, Medicare's payment limit for most separately payable Part B drugs is based on the methodology in section 1847A of the Act, that is, 106 percent of the volume-weighted average of manufacturers' ASP for a drug (at the billing and payment code level), and is updated quarterly. The payment requirements in section 1847A of the Act will be waived for purposes of testing the MFN Model as discussed in section III.M.1. of this IFC, but will continue to apply outside of the model as discussed in this section.

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. The MFN Model will test an alternative

⁷⁴ For the purposes of reporting under section 1847A of the Act, the term "manufacturer" is defined in section 1927(k)(5) of the Act and means any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products; either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in certain wholesaler activities are required to report ASP data for those drugs that they manufacture. Note that the definition of manufacturers for the purposes of ASP data reporting includes repackagers.

⁷⁵ Manufacturer is also defined in 42 CFR 447.502.

approach for determining Medicare's payment limit for MFN Model drugs, which will phase down the Medicare payment amount for selected Part B drugs to more closely align with available international prices, and test an alternative add-on payment. Under the MFN Model, the model's payment test will apply when Medicare makes separate payment for an MFN Model drug that was furnished on an outpatient basis by an MFN participant to an MFN beneficiary within the model's nationwide geographic area.

In designing the MFN Model, we considered ways to mitigate potential impacts on manufacturers' ASPs stemming from price concessions given to MFN participants for purchases related to the MFN Model and on Medicare payment for units of MFN Model drugs that are not subject to the MFN Model payment test. For example, sales to MFN participants may include larger price concessions than are typical today, resulting in lower net sales prices as compared to what net sales prices would be absent the MFN Model. As such, the manufacturer's ASP for an MFN Model drug, which will reflect the average price for all non-excluded sales – including sales to MFN participants to the extent applicable – may be lower than the manufacturer's ASP would be absent the MFN Model. Because CMS will base the non-model Medicare payment limit for an MFN Model drug on 106 percent of the manufacturer's ASP, payment to providers and suppliers for such drug outside of the model may be lower than it otherwise would be absent the MFN Model. To conduct the MFN Model test it is necessary to minimize this potential spillover effect for providers and supplier that are not MFN participants to best observe the impacts of the payment change. Thus, we will exclude from the calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants where the MFN Drug Payment Amount is based on available international drug pricing information and Medicare Part B is the primary payer. policy will only apply when the MFN Price is based on available international drug pricing information. That is, the policy will not apply when there is no available international drug pricing information and the MFN Price is equal to the applicable ASP because there will be no concern for spillover impacts in such cases. We are waiving

requirements of section 1847A of the Act as necessary to exclude such units of MFN Model drugs from the calculation of the manufacturer's ASP. We will also indicate the MFN Drug Payment Amounts that are (and are not, when applicable) based on available international drug pricing information within the quarterly MFN Model drug pricing files posted on a CMS website.

This approach is responsive to comments we received in response to the October 2018 ANPRM. Several commenters requested clarification about how sales for purposes of the model would be taken into account in computing the ASP under section 1847A of the Act. Some commenters who expressed concern about potential spillover effects of the potential model payment test recommended that purchases made for use under the potential model be excluded from the ASP calculation. Based on our interactions with stakeholders, particularly those with experience operating chargebacks related to the 340B program, we believe our exclusion of units of MFN Model drugs that are billed by MFN participants and have the MFN Drug Payment Amount paid by Medicare from manufacturers' ASPs will be feasible. Manufacturers have existing processes and tools to exclude various prices from the calculation of their ASPs, and excluding certain MFN Model related units of MFN Model drugs could be similar.

Distribution management systems are employed throughout the drug distribution system to order drugs, track sales and shipments, trace custody, manage price and customer lists, record financial transactions, and support other industry processes. Separate purchasing accounts are often used to align with purchasing arrangement terms, and through a process called the "chargeback process," manufacturers reduce the final drug prices to wholesalers and other distributors to reflect the purchasing terms and contract prices that apply to the end purchaser. End purchasers of drugs who purchase under more than one contract use virtual inventory or replenishment purchasing tools or business processes to manage their purchases under their various contract arrangements. For example, a provider or supplier that belongs to more than one group purchasing organization could use such tools or business processes to track drug

purchasing, maintain records toward volume targets and, should the need to return a product occur, conduct returns. However, based on stakeholder feedback, we understand that all MFN participants are unlikely to have such tools in place. Hospitals, particularly those that participate in the 340B program, are more likely to currently have these tools compared to other hospitals, physician offices and ASCs. Thus, manufacturers may establish mechanisms to obtain information from MFN participants about the number of units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed, which would increase MFN participants' activities related to the model.

CMS also seeks to minimize the potential for excessive increases in non-model Medicare drug payment amounts during the MFN Model. For example, during the model, manufacturers' ASPs may increase causing a concomitant increase in non-model Medicare drug payment amounts outside of the model if: (1) the policy that manufacturers not include units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount is paid by Medicare and Medicare Part B is the primary payer in the manufacturer's ASP for the MFN Model drug results in higher ASPs; or (2) manufacturers raise drug prices or lower existing discounts for U.S. sales that are not subject to the model's payment test. Because manufacturers will continue to have the ability to set their own drug prices, as a behavioral response to the MFN Model, manufacturers could raise prices for MFN Model drugs in the United States in part to make up for price concessions that may be given to model participants.

We believe the policy for manufacturers not to include in the manufacturer's ASP units of an MFN Model drug administered to an MFN beneficiary and billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer will minimize the potential for manufacturers to choose to increase purchase prices for non-model participants and for MFN participants' purchases of MFN Model drugs for use outside of the MFN Model. Additionally, we believe that the adjustments to the MFN Price phase-in, as described in section III.E. of this

IFC, will also minimize the potential for manufacturers to increase prices for non-model participants and non-model purchases. We also believe this policy is necessary for a rigorous test of the model payment for MFN drugs because price concessions tied to the model will not lower Medicare payment when MFN Model drugs are purchased for use outside the model, which would limit our ability to observe the impacts of the payment change.

We will not collect the number of units that manufacturers exclude from ASP as part of their ASP submission to CMS to avoid establishing a new data collection effort and to minimize administrative burden for manufacturers.

As an alternative approach, we considered whether manufacturers should exclude from the manufacturer's ASP for the MFN Model drug price concessions on units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer. We believe that excluding from the manufacturer's ASP price concessions on units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer, and not excluding the manufacturer's ASP the units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount is applied by Medicare is based on available international drug pricing information and Medicare is the primary payer would inappropriately raise the ASP. We believe this is the case because those units would likely be factored into the manufacturer's ASP calculation as undiscounted sales. Thus, this approach, while it may be less complex, would likely lead to inappropriately higher Medicare payment outside of the model.

We are waiving requirements in section 1847A(c) to the extent necessary to exclude from the calculation of the manufacturer's ASP any units of an MFN Model drug administered to an MFN beneficiary and billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is

the primary payer. Consistent with section 1847A(c)(5) of the Act, we will issue program instructions to further describe how the waiver will impact manufacturers' calculation of the manufacturer's ASP. For example, we envision that manufacturers will take reasonable steps and make reasonable assumptions to exclude applicable units. We note that all other existing statutory requirements and regulations will continue to apply. For example, manufacturers who misrepresent or fail to report manufacturer ASP data will remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act and codified in regulations at § 414.806.

M. Program Waivers and Model Termination

1. Waivers of Medicare Program Requirements for Purposes of Testing the Model

We will test the MFN Model under the authority of section 1115A of the Act and waive certain Medicare program requirements as necessary solely for purposes of testing the model. Under section 1115A(d)(1) of the Act, the Secretary may waive the requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. The purpose of these waivers will be to allow Medicare to test the MFN Model described in this IFC, with the goal of reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care.

In § 513.500, we waive program requirements that are necessary solely for purposes of testing the MFN Model--

- Sections 1833(t)(6) and 1833(t)(14) of the Act and 42 CFR 419.62 and 419.64 related to Medicare payment amounts for drugs and biologicals under the OPSS as necessary to permit testing of an adjusted payment amount for MFN Model drugs using the pricing approaches described in this IFC;

- Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and

biologicals as necessary to permit testing of an adjusted payment amount for MFN Model drugs using the pricing approaches described in this IFC;

- Sections 1847A(b) and 1847A(c) of the Act and 42 CFR 414.904 and 414.802 related to use of the ASP-based, WAC-based, or other applicable payment methodology and calculation of manufacturers' ASP as necessary to permit testing of an adjusted payment for MFN Model drugs and to exclude certain units of MFN Model drugs from manufacturers' ASPs;

- Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug that is determined under § 513.220 as necessary to permit testing of an innovative payment approach for the alternative add-on payment amount;

- Section 1833(a)(1)(S) related to Medicare payment for drugs and biologicals at 80 percent of the lesser of actual charge or the amount established in section 1842(o) of the Act as necessary to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount;

- Section 1833(a)(1)(G) of the Act related to the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system as necessary to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount;

- Section 1833(t) of the Act related to how Medicare payment under the OPSS is calculated including beneficiary copayment to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount; and

- Section 1833(t)(9)(B) of the Act related to the requirement that Medicare account for adjustments to ensure that the amount of expenditures under the OPSS for the year does not increase or decrease from the estimated amount of expenditures under the OPSS that would have

been made if the adjustments had not been made (that is, OPSS budget neutrality). CMS intends to continue to maintain budget neutrality under the OPSS as it currently does, including as described in 42 CFR 419.32(d)(1). This includes continuing to use the applicable payment amount for each separately payable drug under that payment system, rather than the MFN Drug Payment Amount and alternative add-on payment amount. CMS may consider using volume for drugs included in the MFN Model for purposes of the budget neutrality calculations under the OPSS beginning in 2022, but would utilize the applicable OPSS payment amount for the drug or biological, rather than the MFN Drug Payment Amount. We believe a waiver of the OPSS budget neutrality requirements for Part B drugs furnished under the MFN Model is necessary solely for purposes of testing the MFN Model because if reductions in Medicare Part B drug expenditures were redistributed through the OPSS budget neutrality process to non-drug Part B services under the OPSS, the model would change pricing for numerous other services that are not related to Part B drugs. This would make it difficult to determine the independent impact of a change in Part B drug payment levels to MFN Model pricing if there is also a corresponding change in the payment amount for all non-drug hospital outpatient items and services as a result of the OPSS budget neutrality requirements.

Our intent is to include a waiver for all program requirements in title XVIII of the Act as may be necessary solely to test separate payment for MFN Model drugs furnished to MFN beneficiaries by MFN participants. To the extent that MFN participants receive separate payment for MFN Model drugs under program requirements that we have not listed in § 513.500, we waive such requirements as necessary to effectuate part 513.

2. Model Termination

CMS may terminate the MFN Model for reasons including, but not limited to, the following: CMS determines that it no longer has the funds to support the model; or CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act. As provided by

section 1115A(d)(2) of the Act, termination of the model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review. We are codifying these policies in § 513.1000.

N. Evaluation

We will conduct an evaluation of the MFN Model, as required under section 1115A(b)(4) of the Act. The evaluation of the MFN Model will include an analysis of the quality of care furnished under the model and the changes in spending under Medicare by reason of the model.

There will be several populations of interest for the MFN Model evaluation. A population of interest for the evaluation will be Medicare beneficiaries who are likely to receive one of the MFN Model drugs based on recent diagnoses and/or prior treatment. One possible prescriber behavior change due to the MFN Model could be shifts from prescribing MFN Model drugs to other alternative Part B or Part D drugs or vice versa. A population defined by recent diagnoses and/or prior treatment will capture the model's impact on beneficiaries affected by these prescribing behavioral changes due to the model. Other populations such as, but not limited to, MFN Model drug users and subgroups of particular patient populations (for example, cancer, rheumatoid arthritis, ophthalmologic conditions) will be considered in the evaluation.

For each of the populations of interest, we will create separate impact estimates for two types of outcomes: Medicare spending and drug/other health care utilization. Medicare spending will be examined in terms of total Part B drug spending for MFN Model drugs, total Part B drug spending for any Part B drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). The evaluation of the model's impact on quality of care will examine drug access, measured by utilization (for example, rates of any use and duration of use) of both Part B (both MFN Model drug and non-MFN Model drugs) and Part D drugs. We will also examine non-drug health care utilization that may change as a result of the MFN Model to estimate any impacts on access to care. Examples of other non-drug health care utilization include hospitalizations, emergency

department visits, and condition-specific utilization related to a given subgroup of beneficiaries. The impact estimates will reflect the collective effect of the MFN Model’s changes to Medicare payments and beneficiary cost-sharing for MFN Model drugs.

Because the MFN Model will be a nationwide, mandatory model, we must employ an evaluation design that does not require an independent comparison group to establish the counterfactual (what would have happened in the absence of the model). The term “interrupted time series” (ITS) refers to the situation in which multiple observations for the treatment group are available both before and after the intervention is implemented.⁷⁶ ITS models can be employed both with and without comparison groups, and be used to imply causality without comparison groups.⁷⁷ The design is used when data are available both for the pre-intervention period and the post-intervention period, and the intervention takes place at a specific, identifiable point in time.⁷⁸ The time-relationship between the data points can then be used to estimate treatment effects. The trends from the pre-intervention period establish a baseline that is used to project what would be expected in the absence of the intervention. The typical ITS approach assumes linear trends before and after the intervention, but ITS models can be made more general to address potential non-linear trends.^{79,80} Intervention effects are demonstrated when observations gathered after the intervention start period deviate from the baseline projections.

Using this design for evaluating the effects of an intervention— that is, implying a causal relationship between the intervention and its target outcomes – relies on a strict set of conditions.

⁷⁶ Wagner, A. K., Soumerai, S. B., Zhang, F. and Ross-Degnan, D. (2002), Segmented regression analysis of interrupted time series studies in medication use research. *Journal of Clinical Pharmacy and Therapeutics*, 27: 299–309. doi: 10.1046/j.1365-2710.2002.00430.x

⁷⁷ Sheingold, S., Bir, A, (2019), *Evaluation for Health Policy and Health Care: A Contemporary Data Driven Approach*, Sage Publications.

⁷⁸ Bernal, J.L., Cummins, S., Gasparrin, A., (2017) Interrupted time series regression for the evaluation of public health interventions: a tutorial, *International Journal of Epidemiology*, 2017, Vol. 46, No. 1: 348-355, doi: 10.1093/ije/dyw098

⁷⁹ Kontopantelis, E., Doran, T., Springate, D.A., Buchan, I Reeves, D, (2015), Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis, *BMJ* 2015;350:h2750, doi: 10.1136/bmj.h2750

⁸⁰ Valsamis, E. M., Ricketts, D., Husband, H., and Rogers, B. A. (2019), Segmented linear regression models for assessing change in retrospective studies in healthcare. *Computational and Mathematical Methods in Medicine*. doi: 10.1155/2019/9810675.

As previously described, when there is no comparison group, the counterfactual is established as the continuation of the pre-intervention trend for the treated group. The intervention impact is estimated as the difference between the actual post- intervention trend and the pre-intervention trend extended.

The most common statistical method for analyzing ITS data is called segmented regression.^{81,82} Segmented regression focuses on two parameters, the level (intercept) and the trend (slope). For observations before the model, we will have a level (intercept) and trend (slope). After the model begins, the data may exhibit changes in any one of these features. The fundamental idea behind segmented regression is to estimate a regression specification with a linear trend for the data points before the model and estimate a regression specification with a linear trend for the data points after the model start. The level and trend before and after the model start will then be compared. We will use quarterly observations for the pre- and post-model start time periods ending with the most recent data that will be currently available. Given the MFN Model design, we provide our specification in this section of this IFC for the longitudinal regression using a more general specification of the trends to capture the non-linear nature of the data.

In the longitudinal regression equation provided in this section of this IFC, the vector \mathbf{X}_{it} consists of factors that will change from the pre-model time period to the model performance period and may include, but is not necessarily limited to, the medical care component of the Consumer Price Index (CPI-U), national unrelated policy changes, economic factors (for example, unemployment rate). The unit of analysis (for example, a hospital referral region (HRR) as defined by the Dartmouth Atlas⁸³ or beneficiary) on which the quarterly observations

⁸¹ Wagner, A. K., Soumerai, S. B., Zhang, F. and Ross-Degnan, D. (2002), Segmented regression analysis of interrupted time series studies in medication use research. *Journal of Clinical Pharmacy and Therapeutics*, 27: 299–309. doi: 10.1046/j.1365-2710.2002.00430.x

⁸² Valsamis, E. M., Ricketts, D., Husband, H., and Rogers, B. A. (2019), Segmented linear regression models for assessing change in retrospective studies in healthcare. *Computational and Mathematical Methods in Medicine*. doi: 10.1155/2019/9810675.

⁸³ <https://www.dartmouthatlas.org/faq/#research-methods-faq>.

are measured will be allowed to vary in order to estimate the model's impact at these different levels of aggregation. The anticipated statistical model specification includes a polynomial time trend variable $f(t)$ to account for trends in spending and utilization over time. In addition, the statistical model includes separate indicator variables ($I_{t=k}$) for each of the model performance period quarters, which will allow for estimates of the model's impact in each performance period quarter relative to the entire pre-period after adjusting for the time trend and other factors.

$$Y_{it} = b_0 + b_1 \cdot X_{it} + b_2 \cdot f(t) + a_1 \cdot I_{t=1} + a_2 \cdot I_{t=2} + a_3 \cdot I_{t=3} + a_4 \cdot I_{t=4} + \dots + u_{it}$$

where

Y_{it} = outcome (see the previous section for cost and utilization measures), for a particular unit of analysis in a specific quarter

X_{it} = vector of adjustment factors

$f(t)$ = polynomial function to account for time trend

$I_{t=k}$ = denotes an indicator for time period k (all after model implementation)

u_{it} = unaccounted variation

i = unit of analysis (for example, beneficiary, HRR)

t = time quarter (-12, -11...0, 1, 2, 3...) using a 3 year pre-model time period, with 0 indicating the start of the model

$b_0, b_1, b_2, a_1, \dots, a_n$ are the statistical model coefficients

b_0 = the statistical model intercept

b_1 = vector of estimates for the adjustment factors

b_2 = estimate of the time trend $f(t)$ across the pre-period and model performance period

a_1 thru a_n = estimate of change per model performance period quarter (t) relative to entire pre-period

With the statistical model specification as previously described, in an initial, exploratory data assessment, the null hypothesis ($H_0: a_1 = a_2 = a_3 = a_4 = \dots = a_n = 0$) will be that there is no change in each of the model performance period quarters when compared to the pre-period after

adjusting for the time trend and the other factors. The corresponding alternate hypothesis (H_a : a_1 or a_2 or a_3 or a_4 or ... $a_n \neq 0$) will be that any of the model performance period quarters is statistically significantly different than the pre-model time period, suggesting that the model either positively or negatively impacted Medicare spending and quality of care in at least one model performance period quarter. These null and alternate hypotheses will apply to each outcome and population of interest.

The assessment just described will not directly indicate success or failure of the model. CMS will need to observe a consistent statistically significant directional pattern over multiple consecutive time periods for the outcome and population of interest in order to draw sound conclusions about the model's impact. Based on a combination of results from exploratory data assessment and policy goals, CMS will set a hypothesis that encompasses the chosen outcome and population of interest. This hypothesis will be tested using data that is different from what was used in the exploratory assessment—for instance, due to being gathered later in time or consisting of a different randomly assigned subset of contemporaneous data.

Statistical inference will be conducted using cluster-robust standard errors.⁸⁴ Cluster-robust standard errors account for serial correlation as well as spatial correlation within geographies (such as an HRR). We will conduct hypothesis testing using an alpha-level of 5 percent and CMS will report the p-value and standard error to allow for inferences at other alpha-levels.

As an illustration of a potential subgroup analysis and the expected changes that could be detected in the MFN Model evaluation, CMS identified two groups of Medicare cancer patients using 2018 data. CMS defined the first narrower group as Medicare cancer patients who received an MFN Model drug. CMS defined the second broader group as Medicare cancer patients who either received an MFN Model drug or would have been considered eligible to receive an MFN

⁸⁴ Cameron, A. C., & Miller, D. L. (2015). A practitioner's guide to cluster-robust inference. *Journal of Human Resources*, 50(2), 317-372.

Model drug. Specifically, CMS estimated that in 2018 approximately 400,000 Medicare beneficiaries were being treated for the most prevalent cancer types (that is, colorectal, endometrial, breast, lung, prostate, and certain forms of leukemia and lymphoma) and received an MFN Model drug. These 400,000 Medicare beneficiaries were identified using the inclusion and exclusion criteria for the model, including the use of an MFN Model drug. Cancer treatment was determined by the utilization of Part B and/or Part D cancer drugs and the presence of cancer diagnosis codes on Parts A and B claims. A subgroup analysis that requires MFN Model drug use, as in the narrower definition that identified 400,000 Medicare beneficiaries being treated for cancer and who received an MFN Model drug, would exclude cancer patients using an alternative non-MFN Model drug cancer therapy. A broader cancer population definition based on any Part B and/or Part D cancer drug use or just an incident cancer diagnosis based on new evidence of diagnosis codes on Parts A and B claims in the current year would capture the model's impact on beneficiaries affected by prescribing behavioral changes due to the model. This second broader cancer subgroup population definition applied to approximately 1.1 million Medicare beneficiaries in 2018.

CMS believes that looking for unintended consequences will be critical for the monitoring and evaluation of the MFN Model. In the narrower definition of the cancer subgroup, CMS expects that approximately 100,000 Medicare cancer patients who receive a MFN Model drug will be eligible for inclusion in the quarterly evaluation analysis. In the broader cancer subgroup population, CMS expects that approximately 280,000 Medicare cancer patients will be included in the quarterly evaluation analysis. With a nationwide MFN Model (and the assumptions of an alpha-level of 5 percent and power of 80 percent), CMS will have the sample sizes needed in these two populations to detect small changes in Medicare total cost of care (approximately a 1 percent change), drug access, and other important measures of quality of care. With multiple quarterly assessments of the impact of the model on subgroup populations, CMS will be able to intervene early in the model's performance period should any potential

unintended consequences be detected in the potential subgroups of interest. Although CMS uses the cancer subgroup patient population in the previously discussed example, we recognize that other patient populations (for example, patients diagnosed with rheumatoid arthritis and wet macular degeneration) and certain types of providers could be differentially impacted by the MFN Model. These other patient and provider subgroups will be of interest in the evaluation. The model's impact on the Medicaid program and commercial insurance (including Medicare Advantage) population is also of interest.

The evaluation will explore the experiences of MFN participants (beneficiaries and providers) and other stakeholders affected by the changes in payment and conditions included in the model. In particular, CMS will interview MFN participants and beneficiaries, either by focus groups, surveys, or one-on-one stakeholder interviews, to assess the model's influence on access to and quality of care, and administrative burden from their perspectives. Further, CMS intends to ask beneficiaries about their total out of pocket costs under the MFN Model to determine if those costs were reduced. MFN participants will be asked for their opinions about the MFN Model's payment changes to the drug and add-on payment amounts separately. The evaluation will also include qualitative analyses of primary data collected from MFN participants and beneficiaries. The results of the qualitative analyses will be used to provide additional context for the results of the quantitative analyses on health care spending and to help further explain the observed changes.

Evaluation reports detailing the results and findings will be developed and publicly posted on the CMS website. The evaluation reports will include the results of the quantitative and qualitative analyses of the MFN Model's impact on spending and quality of care and the model's implementation as described in this section. The evaluation reports covering the earlier performance years of the MFN Model will be used in the decision making process on whether or not to continue the MFN Model into performance years 5 to 7.

The evaluation may require that MFN participants collect and submit additional data

specifically for the evaluation (please see § 513.100(e) and § 513.100(f)). Such requirements for additional data to carry out model evaluation will be in compliance with 42 CFR 403.1110(b), which requires entities participating in the testing of a model under section 1115A to collect and report such information, including protected health information (as defined at 45 CFR 160.103), as the Secretary determines is necessary to monitor and evaluate the model.

O. Limitations on Review

In § 513.450, we are codifying the preclusion of administrative and judicial review under section 1115A(d)(2) of the Act. Section 1115A(d)(2) of the Act states that there is no administrative or judicial review under section 1869 or 1878 of the Act or otherwise for the all of the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites, or participants to test models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such section.

We interpret the preclusion from administrative and judicial review regarding the CMS Innovation Center's selection of organizations, sites, or participants to test models selected to preclude from administrative and judicial review CMS' selection of an MFN participant, as well as CMS' decision to terminate an MFN participant, as these determinations are part of CMS' selection of participants for CMS Innovation Center model tests.

We interpret the preclusion from administration and judicial review regarding the

elements, parameters, scope, and duration of models for testing or dissemination to preclude from administrative and judicial review the following CMS determinations made in connection with the MFN Model:

- The selection of the model geographic area for the MFN Model by CMS;
- The selection of MFN Model drugs by CMS; and
- The selection of included international data, including selection of countries,

international drug pricing databases, and international drug pricing information.

In addition, we interpret the preclusion from administrative and judicial review regarding the elements of the MFN Model to preclude from administrative and judicial review the methodology for determining MFN Prices, MFN Drug Payment Amounts, Alternative Add-on Amounts, and reconciliation payments related to financial hardship exemptions.

V. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of CMS Innovation Center Models. As a result, the information collection requirements contained in this IFC need not be reviewed by the Office of Management and Budget. However, costs incurred through information collections are included in section VI.C.5. of this IFC.

V. Response to Comments

Because of the large number of public comments we normally receive on documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This IFC is necessary to address the current Medicare Part B payment system for

separately payable Medicare Part B drugs, which has several features that may be incentivizing avoidable costs and causing greater utilization of higher priced drugs. By testing ways to address these payment issues, the MFN Model seeks to improve quality of care, address features of the current payment system that may be incentivizing unnecessary Medicare Part B drug spending and utilization of high cost drugs, and ensure that the Medicare program and its beneficiaries pay generally comparable prices for Medicare Part B drugs relative to certain other countries.

As detailed in section III of this IFC, this IFC will establish a 7-year nationwide MFN Model alternative payment test for approximately 50 separately payable Medicare Part B drugs furnished by certain providers and suppliers. As discussed in section III.C. of this IFC, MFN participants will include Medicare-participating providers and suppliers that furnish MFN Model drugs, with certain exclusions. Most of the MFN participants will be: physicians; non-physician practitioners; supplier groups; HOPDs (including on- and off-campus outpatient provider-based departments, but excluding cancer hospitals, children's hospitals, CAHs, and other hospitals exempt from the OPSS); and ASCs. When other providers and suppliers that are not excluded bill for separately payable MFN Model drugs (for example, pharmacies and independent diagnostic testing facilities), they will be included in the MFN Model as MFN participants; based on 2018 Medicare Part B claims data, their aggregate annual volume of separately payable Part B drugs was less than \$3.6 million. MFN participants will be subject to the participation requirements described in section III. of this IFC.

B. Overall Impact

We have examined the impacts of this IFC, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C.

804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. This IFC triggers these criteria.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, reflects the economic impact of the policies contained in this IFC.

C. Detailed Economic Analysis

The MFN Model will test different payment rates for certain separately payable Medicare Part B drugs and their associated drug add-on payment. The payment rates for these Medicare Part B drugs will be phased in over 4 years, ultimately arriving at the lowest price for a particular drug from a selected group of countries. Eligible providers and suppliers participating in the 340B program will be paid the lesser of this amount or the payment outside the model for MFN

Model drugs they purchase under the 340B program. This IFC includes a single alternative add-on payment, with MFN participants receiving an amount that represents 6 percent (after sequestration) of the average sales price (ASP) baseline for the initial set of included drugs trended forward. The phased-in MFN Price discount relative to applicable ASP is shown in Table 9, assuming the relationship remains constant.

TABLE 9—MOST FAVORED NATION DISCOUNT FROM ASP BY CALENDAR YEAR

Calendar Year:	2021	2022	2023	2024	2025	2026	2027
MFN Price impact:	-16%	-33%	-49%	-65%	-65%	-65%	-65%

The model will require participation by eligible providers and suppliers for the selected separately payable Medicare Part B drugs included in the model. Certain provider types, defined previously in this IFC, will be excluded from the model. We assume that acute care hospitals that are paid for outpatient hospital services on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model.

Because current payment rates for 340B covered entities that are paid under the OPPS (hereafter called 340B providers) are different from those for other providers and suppliers (hereafter called non-340B providers), the impact of the MFN Model varies between the two provider types, and therefore OACT and ASPE estimated the financial impacts separately. Similarly, both analyses calculated the impact of the drug add-on payment separately from the MFN Price impact. Since the drug add-on payment inside the model will not be subject to beneficiary cost sharing, and will be an additional payment to 340B covered entities, the associated Medicare expenditures are higher.

The baseline for these analyses is shown in Table 10, separately for OPPS 340B providers, OPPS non-340B providers, and physician settings. These values include all drugs, exclude providers and suppliers that are exempt from the model, and assume that 53% of the hospital outpatient claims will be from 340B providers. These payments were then adjusted for beneficiary responsibility, add-on payments, and federal payments relative to ASP. These values

are on a pre-COVID-19 basis, and the baseline is not are adjusted for the effects of the pandemic. Similarly, the impact analysis does not include the effects of the COVID-19 pandemic. Many assumptions such as utilization, mortality, and morbidity are more uncertain than usual due to the pandemic. The direction and magnitude of the financial impact of the pandemic on Part B drug spending is uncertain. For example, higher mortality due to COVID-19 could lead to lower drug utilization. A COVID-19-related drug discovery could lead to higher drug utilization. Beneficiaries seeking treatment for quality of life improvement may defer care during the pandemic.

TABLE 10- BASELINE EXPENDITURES FOR CLAIMS INCLUDED IN THE MFN MODEL

	(in billions)								
	2020	2021	2022	2023	2024	2025	2026	2027	2020–27
OPPS Non-340B Providers	\$6.1	\$6.7	\$7.5	\$8.3	\$9.2	\$10.1	\$11.2	\$12.3	\$71.4
OPPS 340B Providers	\$6.9	\$7.6	\$8.4	\$9.4	\$10.4	\$11.4	\$12.6	\$13.9	\$80.5
Other Providers and Suppliers	\$19.4	\$21.2	\$23.3	\$25.7	\$28.1	\$30.8	\$33.8	\$37.0	\$219.3
Total	\$32.4	\$35.5	\$39.2	\$43.4	\$47.6	\$52.4	\$57.5	\$63.2	\$371.3

As the model does not dictate the price that a drug manufacturer must charge an MFN participant, there are many possible behavioral responses by manufacturers, providers, suppliers, and beneficiaries. Because the estimates are highly sensitive to these behavioral assumptions, OACT provided three scenarios: (i) an OACT estimate; (ii) an illustrative estimate based on pricing-effects only; and (iii) an additional illustration under the assumption that manufacturers will refuse to change prices and MFN participants will be unwilling to administer drugs for which model payment will be below their acquisition cost. ASPE also developed a bottom-up estimate built from analysis of the IFC’s likely potential effects on different types of separately payable Part B drugs.

To better understand the values shown in the three OACT scenarios, the ASPE estimate, and the policy of the model, consider the following example. Suppose the current ASP for a given drug is \$100. The total payment to the provider for this drug under the current system is \$104.30, inclusive of the federal payment for the drug and the add-on, beneficiary cost-sharing,

and net of sequestration. Now suppose the MFN Price of this drug is also \$100. The total payment to the provider under the model would be \$104.40. Under the model, the drug payment after sequestration is unchanged (\$98.40) but the add-on increases from \$5.90 to \$6.00.

1. OACT Estimate

Manufacturers could adopt several strategies in response to the model, such as (i) charging a lower price to providers and suppliers inside the model; (ii) refusing to adjust their price from the non-model amounts; or (iii) altering the availability and terms of their international prices. Given that the international price data represent a challenge to their U.S. market revenues, manufacturers are expected to devote considerable resources to the third option. This assumption is included in the OACT estimate as a different discount relative to ASP compared with the values in Table 9. For drugs with significant use outside of Medicare, manufacturers may be willing to sacrifice utilization and revenue within the model. For drugs that are used primarily in the Medicare program, manufacturers may believe that offering some pricing relief is necessary to preserve a significant portion of their revenue.

Eligible providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs. For 340B providers, the payment rates in the first year will match their payments outside the model. Accordingly, no change to utilization or costs is expected under the model in the first year for 340B providers. In later years, the impact varies depending on the assumed change to international price data. For non-340B providers, some may be willing to provide the drugs under a lower payment rate to retain utilization on other associated services.

Should an eligible provider or supplier be unable to offer access to the included drugs, beneficiaries will be left with several options. They could seek access to the drugs by traveling to an excluded provider or supplier, access the drugs through a 340B provider in the model, or forgo access.

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.

The OACT assumptions consider that the separately payable Medicare Part B drugs make up approximately 5 percent of the overall U.S. prescription drug market. Drug manufacturers could see this model as an obstacle to their pricing throughout the market, which could cause strong resistance to the model. The OACT assumptions reflect that some manufacturers will adhere to their current pricing instead of lowering sales prices in response to the model. This behavior may persist in spite of pricing in other sectors of the market or other countries that demonstrates an ability to offer the drug at the model payment rates, and would result in unmet demand for these Medicare Part B drugs. After considering the relative size of the Medicare Part B market, the current price control of drug manufacturers, the size of the model price reductions, the nature of the Medicare Part B drug providers and suppliers, the flexibility that manufacturers may have in adjusting pricing and arrangements in other countries, and many other factors, actuarial judgment was applied to determine the assumptions that are reflected in the OACT estimate, as shown in Table 11.

Beneficiaries lacking continued availability of their drugs through their current provider or supplier are assumed to seek access outside the model, to obtain their drugs through 340B providers, or to forgo access. The schedule of the phase-in to the MFN price gives manufacturers

<i>340B providers</i>							
Behavior							
Continued Availability	100%	100%	100%	100%	100%	100%	100%
MFN Price impact	0%	-3%	-3%	-3%	-3%	-3%	-3%

Table 12 shows the estimated financial impacts under the model based on the assumptions in Table 11. Medicare savings are estimated to be \$85.5 billion, net of the premium offset. 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. This estimate does not capture any impacts to other program costs as a result of lower utilization. This estimate is on a pre-COVID-19 basis, and is not adjusted for the effects of the pandemic.

To the extent that manufacturers discount their products for Medicare sales, there may be a reduction in Medicaid Best Price or AMP. Reductions in Best Price could result in increased Medicaid rebates and thus lower Medicaid costs. However, reductions in AMP generally result in lower statutory and inflationary rebates under the Medicaid program. Therefore, if the manufacturer discounts a drug so that it is closer to the Medicaid best price, there is a possibility of increased Medicaid costs as a result of the model. Furthermore, the effects on AMP may be reduced or eliminated, if manufacturers respond by increasing prices in the private health insurance market. These estimates do not include secondary impacts to other sectors of the market as a result of the changes in Medicare payments under the model in part due to the significant uncertainty around manufacturer pricing behavior in response to this model.

TABLE 12—ESTIMATED FINANCIAL IMPACT OF MFN MODEL

	(in billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
<i>Drug price reduction</i>								
FFS impact*	-4.7	-7.5	-9.3	-10.2	-11.2	-12.3	-13.5	-68.7
Gross impact (FFS+MA)**	-4.7	-7.5	-17.6	-19.5	-21.6	-24.0	-26.5	-121.4
Net of premium offset***	-3.5	-5.6	-13.2	-14.6	-16.2	-18.0	-19.9	-91.1
<i>Medicaid impact</i>								
Federal	-0.4	-0.6	-1.3	-1.5	-1.6	-1.8	-2.0	-9.1
State	-0.2	-0.3	-0.8	-0.8	-0.9	-1.0	-1.1	-5.2
	-0.2	-0.2	-0.6	-0.6	-0.7	-0.8	-0.9	-3.9
<i>Drug add-on payment</i>								
FFS impact	0.6	0.6	0.5	0.6	0.6	0.7	0.8	4.4
Gross impact (FFS+MA)	0.6	0.6	1.0	1.1	1.2	1.4	1.5	7.4
Net of premium offset	0.4	0.4	0.7	0.8	0.9	1.0	1.2	5.6
<i>Medicaid impact</i>								
Federal	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.2	-0.8
State	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.5
	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.1	-0.4
<i>Total impact</i>								
FFS impact	-4.1	-7.0	-8.8	-9.6	-10.6	-11.6	-12.7	-64.4
Gross impact (FFS+MA)	-4.1	-7.0	-16.6	-18.4	-20.4	-22.6	-25.0	-114.0
Net of premium offset	-3.1	-5.2	-12.4	-13.8	-15.3	-16.9	-18.7	-85.5
<i>Medicaid impact</i>								
Federal	-0.4	-0.7	-1.4	-1.6	-1.8	-1.9	-2.1	-9.9
State	-0.3	-0.4	-0.8	-0.9	-1.0	-1.1	-1.2	-5.7
	-0.2	-0.3	-0.6	-0.7	-0.8	-0.8	-0.9	-4.3

*Projected spending impact in the traditional Medicare FFS program under the model.

** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).

***Premium offset represents the change in the Part B premium income that would result from the change in Part B drug expenditures.

These impacts are based on the President’s Fiscal Year 2021 Budget baseline for Medicare Part B drugs, including those dispensed by 340B providers. Due to rounding, the sum of values in the table may differ slightly from the total results in the table. In addition to the behavioral assumptions in Table 11, these estimates reflect a number of other technical assumptions, including the following:

- Amounts illustrate the potential impact on Medicare Part B drug spending, assuming the reductions are achievable and realized.
- Amounts are presented by calendar year and are based on the date the service is incurred and have therefore not been adjusted to reflect when payment is made.
- The model runs from January 1, 2021 through December 31, 2027. If any of the provisions of this rule are not effective on January 1, 2021, the impacts will differ.
- The model will include the top 50 Medicare Part B drugs with the highest spending each year and will account for roughly 73 percent of Medicare Part B drug spending in each affected year.
- All included providers and suppliers receive an add-on payment of 6 percent (after sequestration) of the average sales price (ASP) and this add-on payment is not subject to

State	0.0	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.3
<i>Total impact</i>								
FFS impact	-2.3	-6.4	-12.0	-19.0	-21.7	-23.9	-26.2	-111.4
Gross impact (FFS+MA)	-2.3	-6.4	-22.7	-36.3	-41.9	-46.5	-51.4	-207.4
Net of premium offset	-1.7	-4.8	-17.0	-27.2	-31.5	-34.9	-38.6	-155.6
Medicaid impact	-0.3	-0.6	-2.0	-3.0	-3.5	-3.8	-4.2	-17.4
Federal	-0.2	-0.4	-1.1	-1.7	-2.0	-2.2	-2.4	-9.9
State	-0.1	-0.3	-0.8	-1.3	-1.5	-1.6	-1.8	-7.5

*Projected spending impact in the traditional Medicare FFS program under the model.

** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).

***Premium offset represents the change in the Medicare Part B premium income that would result from the change in Medicare Part B expenditures.

b. Extreme Disruption Illustration

To cover the spectrum of possible outcomes, the impact of a greater behavioral response from manufacturers and MFN participants was also considered. Under this scenario, it is assumed that non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model. All non-340B utilization will then be divided among the three beneficiary choices of traveling to an excluded provider or supplier, using a 340B provider, or forgoing access. Because there are a small number of excluded providers and suppliers, OACT assumed they only have capacity for a 25 percent increase in utilization. Additionally, manufacturers are assumed to not change the international prices; as a result, 340B providers will have reduced reimbursement beginning in 2022, when the MFN Price dips below the baseline payment of ASP less 22.5 percent—leading to reduced beneficiary access through 340B providers as well. The financial hardship exemption could possibly apply under this scenario, but as this payment is retrospective and the losses prior to the payment would be severe, it is unclear whether providers will be in a position to request the exemption.

The illustrative results under these assumptions are shown in Table 14. They were developed with the same technical assumptions listed under the OACT estimate. The overall impact of the model would be a substantial savings to Medicare of \$286.3 billion, but nearly half of that impact would be due to lost utilization.

TABLE 14— ESTIMATED IMPACT OF EXTREME DISRUPTION ILLUSTRATION

	(in billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
<i>Drug price reduction</i>								
FFS impact*	-17.6	-21.2	-26.9	-30.5	-33.7	-37.0	-40.6	-207.5
Gross impact (FFS+MA)**	-17.6	-21.2	-50.9	-58.4	-65.0	-72.0	-79.7	-364.8
Net of premium offset***	-13.2	-15.9	-38.2	-43.8	-48.7	-54.0	-59.8	-273.6
Medicaid impact	-1.3	-1.6	-3.8	-4.4	-4.9	-5.4	-6.0	-27.4

Federal	-0.8	-0.9	-2.2	-2.5	-2.8	-3.1	-3.4	-15.6
State	-0.6	-0.7	-1.6	-1.9	-2.1	-2.3	-2.6	-11.8
<i>Drug add-on payment</i>								
FFS impact	-0.6	-0.8	-1.2	-1.5	-1.6	-1.8	-1.9	-9.4
Gross impact (FFS+MA)	-0.6	-0.8	-2.3	-2.8	-3.1	-3.4	-3.8	-16.9
Net of premium offset	-0.5	-0.6	-1.8	-2.1	-2.3	-2.6	-2.9	-12.7
Medicaid impact	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.2	-0.8
Federal	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.5
State	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.1	-0.4
<i>Total impact</i>								
FFS impact	-18.2	-22.0	-28.2	-32.0	-35.3	-38.7	-42.5	-217.0
Gross impact (FFS+MA)	-18.2	-22.0	-53.2	-61.2	-68.1	-75.5	-83.5	-381.7
Net of premium offset	-13.7	-16.5	-39.9	-45.9	-51.1	-56.6	-62.6	-286.3
Medicaid impact	-1.4	-1.7	-3.9	-4.5	-5.0	-5.5	-6.1	-28.2
Federal	-0.8	-1.0	-2.2	-2.6	-2.9	-3.2	-3.5	-16.1
State	-0.6	-0.7	-1.7	-1.9	-2.2	-2.4	-2.6	-12.1

*Projected spending impact in the traditional Medicare FFS program under the model.

** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).

***Premium offset represents the change in the Medicare Part B premium income that would result from the change in Medicare Part B expenditures.

c. Additional Considerations

Because the model will make substantial changes to payment for Medicare Part B drugs, there are many other potential responses not considered in this analysis. It is possible that manufacturers could increase prices for non-Part B drugs, which would affect both private market and Part D expenditures, although that potential impact has not been quantified for this estimate. It is also possible that moving to a flat add-on payment from a percentage of drug cost will have additional effects, which are not considered in the OACT analysis. The analysis is on a pre-COVID-19 basis, and neither the baseline nor the impact analysis are adjusted for the effects of the pandemic.

2. ASPE Estimate

The behavioral responses of manufacturers, providers, suppliers, and beneficiaries to the MFN Model are critical to estimating its impact on key outcomes. Lack of direct experience with policies such as the MFN Model, however, results in great uncertainty for making these behavioral assumptions. For a robust approach, ASPE made a number of assumptions based on published literature and expert consensus, and applied such assumptions on a drug-by-drug basis. Please note that ASPE has not adjusted the assumptions and estimates based on the effects of the COVID-19 pandemic.

The behavioral assumptions in this approach first address manufacturers' responses in the

international market that might increase MFN Prices; and then the potential responses to the MFN Drug Payment Amounts by the manufacturers and providers and suppliers that purchase MFN Model drugs and submit a claim to Medicare after administering such drugs to beneficiaries. In general, these assumptions represent the proposition 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 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.

To assess the likelihood of each of the alternative manufacturer responses to the MFN Model, ASPE reviewed published literature on the impacts and interviewed a small cohort of experts regarding the potential impacts. Published literature suggests that when a large country establishes an international reference price, smaller reference countries experience price increases and longer launch delays for new products.⁸⁵ ASPE's conversations with experts suggested that as a result of the MFN Model, prices in other countries could increase at the ex-manufacturer level, potentially up to current ASP levels, and manufacturers could change formulations of MFN Model drugs to lessen the impact of the model. The experts generally believe that manufacturers will be able to price discriminate between the Medicare Part B market and other markets within the U.S. Potential utilization impacts will thus be limited to Medicare Part B beneficiaries, as payments to providers and suppliers for drugs provided to other patients will not be affected by the model.

Considering this information, ASPE made a series of assumptions for a base analysis. First, ASPE considered a static group of 50 drugs for this analysis. Based on the literature and interviews with experts, ASPE assumed manufacturers of newly launched brand products that

⁸⁵ Patricia M. Danzon, "The Economics of the Biopharmaceutical Industry", in Sherry Glied and Peter C. Smith (eds.), The Oxford Handbook of Health Economics, Oxford University Press 2011, pp. 520-554.

become MFN Model drugs would adjust their international pricing strategies so that the MFN Payment Amount will be equal to ASP absent of the MFN Model. This assumption does not necessarily mean that net international prices (ex-manufacturer sales prices minus the value of rebates or other financial concessions) will be equal to the ASP. In addition, ASPE assumed that manufacturers of currently marketed drugs outside but near the top 50 Medicare Part B drugs based on annual allowed charges (with certain exclusions and exemptions) will lower their U.S. prices in an attempt to prevent them from becoming MFN Model drugs. To compensate for this response, ASPE assumed that manufacturers will increase prices for non-MFN Model drugs. Since companies often sell many different drugs, ASPE assumed they will have some flexibility to allocate discounts between different drugs to ensure no currently marketed non-MFN Model drugs enter the top 50 while maintaining near constant revenues. In some cases, there are relatively new drug products that may not have launched or may be recently launched in the included countries that may enter the top 50. In those cases, ASPE assumed the manufacturers will re-evaluate their international pricing strategies to ensure the MFN Price is comparable to ASP absent of the MFN Model. ASPE assumed that these changes to U.S. prices of non-MFN Model drugs will ultimately fully offset one another in terms of Medicare Part B drug spending as well.

For the 50 MFN Model drugs, the MFN Price ultimately depends on the prices for the drugs in the included countries. The exact mechanisms in which prices are determined in included countries differ by country and sometimes by product. These mechanisms include national (or sub-national tendering⁸⁶), therapeutic-level reference pricing, international reference pricing, cost-effectiveness analysis, and negotiation. These mechanisms generally result in lower observed prices in other countries compared to the U.S., and these differences tend to be larger for products that have more competition than in the U.S. (such as more biosimilar competition)

⁸⁶ Tendering is a formal procedure to purchase medications using competitive bidding for a particular contract. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5628685/>

or have only a marginally better clinical profile than a cheaper therapy. Since the U.S. price under this model depends on the prices in other countries, the model will likely result in increased observed prices in other countries. 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. In this analysis, ASPE considered the potential impact at the drug-level because the context of each drug may determine the MFN Price.

ASPE modeled the pricing response to the change in direct drug payment for each of the 50 MFN Model drugs shown in Table 6 of this IFC. ASPE assumed that any changes in international sales prices for included countries would not occur until the beginning of the second performance year of the MFN Model. ASPE modeled the manufacturer pricing response based on available 2019 international drug pricing information, using the sales and volume data that CMS used to calculate the MFN Prices shown in Table 6 of this IFC. ASPE did not model how manufacturers and providers might take into account the changes to the add-on.

If there was only one related brand for the included countries,⁸⁷ then ASPE assumed the MFN Price for a drug will increase to the average price of the drug for the included countries plus 10 percent (with the cap of ASP). ASPE made this assumption because 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. ASPE applied this approach to 34 of the 50 MFN Model drugs. ASPE assumed that the MFN Price will not likely increase by more than this because, even if the net price is constant for purchasers in the included countries, these countries may seek to avoid larger increases in transaction prices. In the case of drugs with no international spending in 2019, ASPE assumed that the model would have no impact. ASPE applied this approach to 2 of the 50 MFN Model drugs. When the MFN Price was calculated based on international drug pricing information for a country with access to biosimilar products or a competitor brand

⁸⁷ For this analysis, we included available sales and volume data for the brand drug manufacturer and any parallel importers of the brand drug.

product that is not one of the MFN Model drugs, ASPE assumed smaller international price increases because the MFN Model would reduce the incentive for the manufacturer of an MFN Model drug to compete in those international markets. This approach applied to 8 of the 50 MFN Model drugs. When the MFN Price was calculated using international drug pricing information for a non-innovator unbranded product, ASPE assumed that the MFN Price would not increase. This assumption applied to 6 of the 50 MFN Model drugs.

After analyzing price changes internationally, ASPE analyzed the potential for beneficiaries to switch to other products with, for example, the same active ingredient within the U.S. and billed with HCPCS codes that are not among the MFN Model drugs. First, ASPE assumed that when a manufacturer has multiple branded products with different indications represented by the same HCPCS code, the manufacturer will work to obtain a new HCPCS code for the product in which Medicare Part B makes up a smaller portion of its overall market. In addition, the manufacturer will restrict the amount of product sold that could be billed under this new HCPCS code so that such products will not become included in the MFN Model. This assumption applied to one of the MFN Model drugs. ASPE also assumed that if an MFN Model drug is available within the U.S. in a formulation that will be covered under Medicare Part D, the manufacturer will work to shift 90 percent of the utilization from Medicare Part B to Medicare Part D. This assumption impacted 2 of the 50 MFN Model drugs.

In addition to these assumptions, ASPE made assumptions about potential generic entry for some of the MFN Model drugs. ASPE assumed that MFN Model drugs with generic drugs approved within the included countries or currently subject to on-going Paragraph 4 patent challenges would have generic competition by performance year 3. This assumption impacted 6 of the 50 MFN Model drugs.

After examining the potential price impacts and other utilization changes described previously, ASPE examined the potential for utilization impacts. In general, economic theory and the experts ASPE interviewed suggested that manufacturers will adjust U.S. prices to

maintain sales as long as price is greater than marginal costs of producing and distributing the drug. ASPE also assumed that manufacturers will have substantial ability to price discriminate—that is, adjust pricing for Medicare-participating providers and suppliers to reflect discounts for their Medicare Part B patient share as opposed to all patients. Nonetheless, ASPE still considered the potential that price discrimination will be less than perfect for some drugs. In these cases, a manufacturer might refuse to negotiate lower prices for MFN beneficiaries if doing so threatens its ability to sell in other segments of the U.S. at a positive margin. That is, would the loss in revenues from selling for all purchasers at a reduced price exceed the loss in revenues from losing the MFN beneficiary share of business for that drug? To examine this issue, ASPE estimated the Medicare Part B share of each MFN Model drug compared with the estimated U.S. market. If it seemed likely that a manufacturer will have higher revenues selling to all purchasers at prices slightly above the MFN Drug Payment Amount than not selling to MFN participants for MFN beneficiary use, ASPE assumed the manufacturer will not restrict MFN beneficiaries' access to an MFN Model drug under Medicare Part B. This included examining if the MFN Model drugs had U.S. competitors. Since MFN participants likely treat both Part B beneficiaries and non-Part B beneficiaries (including individuals with employer, individual market, or Medicaid coverage), an MFN participant may select an alternative therapy marketed by a competitor that can be provided to both types of patients. As a result, manufacturers will have an incentive to work to maintain utilization so long as the MFN Payment Amount is not too low.

In cases where manufacturers might refuse to lower U.S. prices sufficiently to make it financially feasible for MFN participants to furnish the drug and receive the MFN Payment Amount, ASPE examined whether there were products that had similar therapeutic effects to a MFN Model drug. ASPE assumed that Medicare Part B beneficiaries will be switched to the potential alternative products. ASPE made these assessments for each performance year. ASPE assumed that half of Medicare Part B beneficiaries will continue accessing their current drugs

through 340B providers. Such changes in drug utilization or service providers will likely result in additional burdens for patients. ASPE did not quantify these impacts.

Additionally, for biological drugs for which there are licensed biosimilar products, ASPE assumed that there will be at least one biosimilar manufacturer that is willing to provide its product at MFN payment levels if the reference manufacturer would not supply this drug. We note however that if reference manufacturers are willing to sell at MFN payment levels, providers may not have any incentive to use biosimilar products. The extent to which providers may use biosimilar products will depend on whether they are easier to access instead of a product subject to the model. The biosimilar manufacturers will need to balance those considerations with the possibility that sufficiently large sales may also result in that product becoming an MFN Model drug. ASPE assumed any utilization changes that occur will result in zero net changes in spending. ASPE made no assumptions about the potential entry of biosimilar products for reference products that currently do not have biosimilar competition in the U.S. or referenced countries.

The overall utilization impact is the sum of the impacts for each of the 50 MFN Model drugs. These impacts reflect, on a drug by drug basis, the assumptions outlined previously. Specifically, where estimates reduced utilization, it reflects assumptions that either manufacturers will be unwilling to reduce prices to MFN participants, viable substitute drugs are not available for all affected patients, or both. In such cases, ASPE assumed that half of the impacted beneficiaries will be able to still access the MFN Model drug through a 340B provider.

ASPE calculated the potential impacts of the MFN Model by calendar year. ASPE assumed that at the end of the MFN Model, there will be no continued impacts because Medicare Part B payments for MFN Model drugs will immediately be based on non-model payment policies at the end of the MFN Model. Given the predictable 7-year model performance period, ASPE assumed manufacturers and MFN participants will have sufficient time to structure their agreements to ensure a seamless transition after the end of the MFN Model.

Table 15 summarizes the results of the ASPE analysis.

TABLE 15—ASSUMPTIONS REFLECTED IN ASPE ESTIMATE

	2021	2022	2023	2024	2025	2026	2027
<i>Non-340B providers</i>							
Behavior							
Continued Availability	100.0%	100.0%	97.7%	95.9%	96.2%	96.5%	96.7%
Altered Availability							
Shift to other drugs	0.0%	0.0%	1.1%	2.1%	1.9%	1.8%	1.6%
Move to 340B	0.0%	0.0%	1.1%	2.1%	1.9%	1.8%	1.6%
No Access	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	100%	100%	100%	100%	100%	100%	100%
MFN Price impact	-11.4%	-14.3%	-18.1%	-20.5%	-19.4%	-17.9%	-16.5%
<i>340B providers</i>							
Behavior							
Continued Availability	100%	100%	100%	100%	100%	100%	100%
MFN Price impact	0%	0%	0%	0%	0%	0%	0%

ASPE estimated the Medicare FFS program impacts of the change from ASP-based payment to MFN-based payment.⁸⁸ The Medicare FFS impact includes changes in spending for Medicare Parts B and D.

For patients that switch to 340B providers, ASPE estimated the spending change based on the difference in the MFN Model payment for drugs acquired under the 340B program and the current Medicare Part B OPPS payment policy.

These impacts are generally considered transfer impacts of the model. To estimate these impacts, ASPE took an approach similar to OACT. ASPE used the direct reduction in Medicare Part B payments due to lower MFN payment amounts and translated that into transfers from the healthcare system to the government, beneficiaries, and Medicaid. In addition to the direct effects of lower payments and associated cost-sharing, the model results in downstream transfers associated with changes in Part B premiums and government payments to Medicare Advantage Plans. Like OACT, ASPE estimated Medicaid impacts based on changes to federal and state

⁸⁸ An indirect benefit of this IFC may be reduced distortions in the labor markets taxed to support the Medicare Trust Fund. Such distortions are sometimes referred to as marginal excess tax burden (METB), and Circular A-94—OMB’s guidance on cost-benefit analysis of federal programs, available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf>—suggests that METB may be valued at roughly 25 percent of the estimated transfer attributed to a policy change; the Circular goes on to direct the inclusion of estimated METB change in supplementary analyses. If secondary benefits—such as reduced marginal excess tax burden is, in the case of this IFC—are included in regulatory impact analyses, then secondary costs must be as well, in order to avoid inappropriately skewing the net benefits results, and including METB only in supplementary analyses provides some acknowledgement of this potential imbalance.

shares of prescription drug costs for dual eligibles but did not estimate impacts on Medicaid that may result from changes in net payments under the Medicaid Drug Rebate Program.

Overall, the model results in changes to federal spending in Medicare (including Part B, and Part D) from the model price and utilization impacts, changes in federal and state spending on Medicaid resulting from changes to the governmental obligation of Medicare cost-sharing for dual eligible beneficiaries, and changes in federal spending associated with add-on payment changes in the model. The model also results in changes to beneficiary spending resulting from changes in cost-sharing for drugs, changes in beneficiary premiums, and changes to cost-sharing associated with the add-on payment. These transfers on net balance out with reduced revenues for healthcare providers (which may be completely or mostly offset by the reduced cost of acquiring drugs), reduced revenues for pharmaceutical manufacturers, and reduced revenues for MA plans.

Based on our estimates of annual impacts on prescription drug pricing and annual add-on payments, ASPE did not model any impacts from the provider hardship payments. Eligibility for the hardship exemption will be based on year-over-year losses above 25 percent of total Medicare Part A and Part B payments, including payments for Medicare Part B drugs outside the model and payments for Medicare Part A and Medicare Part B services other than prescription drugs. 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 compared with the pre-model base year and a 62.7 percent loss of revenue over the seven-year demonstration period, without qualifying for the hardship payments in any year.

Table 16 shows the net transfer impacts resulting from changes in Medicare B, and D. According to the ASPE estimate, this model would result in a net reduction of \$87.8 billion in

beneficiary, federal government, and state government spending over the 7 years of the model.

TABLE 16—ESTIMATED TRANSFER IMPACT OF MFN MODEL- ASPE ESTIMATE

	2021	2022	2023	2024	2025	2026	2027	2021–27
<i>Part B Drug Price Reduction</i>								
Federal Government Spending	-2.4	-3.4	-8.4	-10.0	-10.3	-10.7	-10.8	-56.0
State Government Spending	-0.1	-0.1	-0.4	-0.4	-0.4	-0.5	-0.5	-2.4
Beneficiary Spending*	-1.4	-2.0	-5.0	-5.9	-6.2	-6.4	-6.4	-33.4
MA Plan Revenue	0.0	0.0	-4.8	-5.9	-6.1	-6.5	-6.5	-29.8
Health Care System Revenue**	-4.0	-5.5	-8.9	-10.5	-10.9	-11.1	-11.1	-61.9
<i>Part D Drug Switching</i>								
Federal Government Spending	0.0	0.0	0.3	0.3	0.3	0.3	0.3	1.7
State Government Spending	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Beneficiary Spending*	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.7
Health Care System Revenue**	0.0	0.0	0.5	0.5	0.5	0.5	0.5	2.5
<i>Add-on Payment Impact</i>								
Federal Government Spending	0.2	0.2	0.4	0.3	0.4	0.4	0.4	2.2
State Government Spending	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-0.3
Beneficiary Spending*	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.5
MA Plan Revenue	0.0	0.0	0.2	0.3	0.3	0.3	0.3	1.3
Health Care System Revenue**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
<i>Total Impact</i>								
Federal Government Spending	-2.2	-3.2	-7.7	-9.3	-9.7	-10.0	-10.0	-52.1
State Government Spending	-0.1	-0.2	-0.4	-0.4	-0.5	-0.5	-0.5	-2.5
Beneficiary Spending*	-1.6	-2.1	-4.9	-5.9	-6.1	-6.3	-6.3	-33.2
MA Plan Revenue	0.0	0.0	-4.6	-5.6	-5.8	-6.2	-6.2	-28.5
Health Care System Revenue**	-3.9	-5.5	-8.4	-10.0	-10.3	-10.6	-10.6	-59.3

*Beneficiary spending includes spending by beneficiary Medigap plans.

**Health care system revenue includes revenue accrued by health care providers, hospitals, pharmacies, and pharmaceutical manufacturers.

Based on this analysis, the model has the potential to generate impacts internationally. In particular, this model may result in higher prices or longer launch delays for new products in other OECD countries. ASPE did not attempt to quantify the impact of higher prices on utilization or the impact of these delays. The health effects of such delays depend on which products experience these delays and the potential alternative treatments. In addition, foreign governments may seek to mitigate these impacts by accepting higher prices for the products or pursuing alternative price arrangements that are less transparent.

3. Aggregate Effects on the Market

There may be spillover effects in the non-Medicare market, or even in the Medicare market outside Part B as a result of the MFN Model. Testing changes in Medicare Part B drug payment policy may have implications for non-Medicare payers. During the MFN Model, manufacturers' ASPs may increase or decrease, which may cause the payment limits in the quarterly Medicare ASP payment files to increase or decrease. Other payers that align their

payments for drugs included in the MFN Model with the quarterly Medicare ASP payment files could therefore be impacted. Because the extent to which other payers align with Medicare Part B drug payments is unknown, we are not able to quantify the potential impacts of the MFN Model in this regard.

Private secondary payers that pay for beneficiary cost-sharing, such as Medigap plans and employer retiree coverage, will likely be impacted by the MFN Model. For MFN beneficiaries, cost-sharing on MFN Model drugs would be less than the amount that will apply outside of the model. If manufacturers generally raise drug prices in response to the MFN Model, the amount of cost-sharing paid by beneficiaries and secondary payers may increase; the opposite will occur if manufacturers decrease drug prices. Similarly, private primary insurers may be impacted if manufacturers change drug pricing as a result of the MFN Model. Market-wide changes in drug prices, including drugs not covered by Medicare Part B, will impact any individual who receives such drugs. In addition, to the extent manufacturers lower their overall prices for drugs, manufacturers may realize lower revenue as a result of the MFN Model. It is possible that manufacturers will increase international or domestic drug prices, reduce marketing and other expenses, or implement other efficiency measures to reduce their operating costs. Given the uncertainty of manufacturers' potential behavioral responses to the MFN Model, we are unable to quantify these potential spillover effects of the MFN Model. We welcome comments on these potential impacts and evidence on how this rule could affect other payers, patients, and drug manufacturers.

Some of this final rule's important tradeoffs occur over the long run. We request comment on whether the drug products affected by this IFC are likely to be currently over- or under-incentivized, including evidence from the research literature on optimal patent length, and on the effects of the IFC on drug manufacturers' incentives.

4. Estimated Effect and Burden of MFN Model Changes on Medicare Beneficiaries

We estimate that aggregate beneficiary Medicare Part B cost-sharing within the context

of the MFN Model will decrease as the MFN Drug Payment Amount will not exceed 100 percent of the amount that applies outside the MFN Model (that is, the applicable ASP or WAC or payment limit that applies to drug acquired under the 340B program) and that beneficiaries will not have a cost-sharing liability for the alternative drug add-on payment amount. Coinsurance for most separately payable drugs is set at 20 percent of the payment rates, subject to limitation in the hospital outpatient and ASC settings. To the extent that prescribing patterns shift toward lower cost drugs under the MFN Model, in aggregate, beneficiaries could benefit along with the Medicare program. If prescribing patterns shift toward Part D drugs, beneficiary cost-sharing may increase or decrease depending upon the drugs they take, which phase of the Part D benefit such use occurs in, the beneficiary's eligibility for help with drug costs, and their plan choice. In addition, as a result of the MFN Model, we expect Medicare Part B premiums to decrease. Beneficiaries will benefit from 25 percent of any premium reduction that may result as this is the portion of annual premiums that beneficiaries pay.

If MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies instead, beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment. There is significant uncertainty with these potential effects of the MFN Model. CMS will carefully monitor for evidence of these potential effects and conduct beneficiary surveys to assess impacts of the MFN Model on beneficiaries.

Given the uncertainty of these impacts, we are unable to quantify these potential effects of the MFN Model.

In section III.H. of this IFC, we describe our intention to include quality measures as part of the MFN Model, and our plan to collect one quality measure, focused on patient experience, to help better understand the impact of the MFN Model on beneficiary access and quality of care. This information collection will be one part of robust monitoring activities to ensure that MFN

beneficiaries' access to medications and quality of care is preserved or enhanced. We will use a patient experience survey, which we will field to a sample of MFN beneficiaries, beginning in performance year 1. We will include additional items in the patient experience survey that focus on patient access, to the extent that valid and reliable items are available. The patient experience survey will be administered to these beneficiaries by a third party contractor throughout the model performance period. Beneficiaries will not be required to complete the survey.

The patient experience survey will be based on a standardized instrument, designed to assess patients' experiences with health care providers and staff in an ambulatory setting. We will use the most current version of the instrument plus additional survey questions as applicable to meet CMS's monitoring needs.

Based on drug claims analyses and the scope of the MFN Model, we assume the patient experience survey will be administered to 75,000 beneficiaries and be completed by 30,000 beneficiaries per year. The survey will take approximately 30 minutes to complete. Therefore, the annual total number of hours for this information collection will be 15,000 hours (30,000 beneficiaries times 0.5 hours per beneficiary responding).

To derive average costs for individuals we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for our salary estimate (www.bls.gov/oes/current/oes_nat.htm). We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at \$25.72 per hour since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. We are not adjusting this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment. Therefore, the estimated cost for this information collection will be \$385,800 (15,000 hours x \$25.72). Beneficiaries will have annual costs associated with responding to the patient experience survey, which we estimate will be \$385,800 annually during the model.

5. Estimated Effect and Burden on MFN Participants and Manufacturers

MFN participants and drug manufacturers will have administrative costs related to adjusting to and complying with the regulations. These costs may include adjusting purchasing arrangements, which for some affected businesses may mean substantially changing their pricing models and engaging in negotiations with other businesses; tracking units of MFN Model drugs that are paid under the MFN Model and excluded from manufacturers' ASPs; recordkeeping requirements, which may require acquisition of new tools and information sharing; and adjusting to any spillover effects. Additionally, MFN participants may be subject to site visits for the purposes of monitoring the MFN Model.

During the model performance period, MFN participants must participate in MFN Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), as the Secretary determines is necessary to monitor and evaluate the MFN Model, including without limitation collecting and reporting of information, including "protected health information" as that term is defined at 45 CFR 160.103. These monitoring activities may include a sample of site visits to verify any monitoring concerns. We anticipate that these monitoring and compliance requirements will not diverge from general monitoring requirements for Medicare Part B providers. We believe that these requirements do not add additional burden or impose regulatory impact on participants. The MFN Model monitoring will likely include beneficiaries and eligible providers and suppliers completing surveys. Burden for the patient survey is described previously, and burden for any provider and supplier survey will depend on the length, complexity, and frequency of surveys administered as needed to ensure confidence in the survey findings. We will make an effort to minimize the length, complexity, and frequency of any provider and supplier surveys. A typical survey on average requires about 20 minutes of the respondent's time. In other evaluations of models where a survey is required, the frequency of surveys varies from a minimum of one round of surveys to annual surveys. We estimate the burden for annual surveys from clinicians, assuming one per eligible provider and supplier, will

be 7 surveys [annual] times 1/3 hour [20 min.] times \$200 [median physician/surgeon hourly rate plus fringe benefits] times 22,888 [eligible providers and suppliers] = \$10,702,429.

Finally, MFN participants may choose to apply for a financial hardship exemption that requires the submission of a timely, complete request for a financial hardship exemption. We think that approximately 900 MFN participants will submit a request for a financial hardship exemption each performance year of the model. We expect that a medical health service manager will need approximately 15 hours to compile the necessary supporting documentation and submit a complete financial hardship exemption request. We estimate the burden for applying for the financial hardship exemption per year for all performance year of the model will be 900 [number of MFN participants that submit hardship exemption requests in each performance year] times 15 hours times \$111 [medical health service manager hourly rate plus fringe benefits]=\$1,498,500. Note, the financial hardship exemption requests for performance year 1 (2021) will be submitted in 2022, and the requests for performance year 7 will occur in 2028.

We expect that manufacturers will need to update their ASP reporting. However, we expect the burden to be de minimis compared to existing ASP reporting requirements and can likely be automated based on existing processes.

6. Regulatory Review Cost Estimation

In order to comply with the regulatory changes in this IFC, affected businesses will need to review the rule and MFN participants will need to review MFN-specific billing guidance on how to bill for the alternative add-on payment. We expect that a medical health service manager reading 250 words per minutes could review the rule in approximately 6 hours [(approximately 300 pages*300 words/per page)/250 words per minute)/60 minutes)]. We estimate 1 hour to review the relevant MLN matters publication and 2 hours to read MFN Model billing guidance for a total of 3 hours of billing specific training. Since all MFN participants have experience billing HCPCS codes to Medicare, we do not expect any additional specific burden related to the alternative add-on payment M code during model implementation after the MFN-specific billing

guidance is reviewed. We estimate the salary of a medical and health service manager is \$111 per hour, using the wage information from the 2019 BLS including overhead and fringe benefits (BLS occupation code 11-9110). For each provider or supplier that reviews the rule and MFN-specific billing guidance, the estimated cost based on the expected time and salary of the person reviewing the rule is \$999 ($\111×9 [6 hours for reviewing the rule and 3 hours for billing training]). We estimate that the cost for providers and suppliers to review this IFC and MFN-specific billing guidance will be approximately \$117.9 million (118,101 entities times \$999).

7. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at <http://www.sba.gov/content/table-smallbusiness-size-standards> (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. The vast majority of MFN participants are considered to be small entities, based upon the SBA standards. There are over twenty thousand MFN model participants that will be included or affected by the MFN Model. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this IFC is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

The RFA requires that a Regulatory Flexibility Analysis (RFA) be prepared if an IFC will have a “significant impact on a substantial number” of small entities. HHS interprets the statute as mandating this analysis only if the impact is adverse, though there are differing interpretations. For purposes of the RFA, most practitioners, hospitals, and other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). For details, see the Small Business Administration’s “Table of Small Business Size Standards” at <https://www.sba.gov/document/support--table-size-standards>. The rule of thumb used by HHS for determining whether an impact is “significant” is an adverse effect equal to 3 percent or more of total annual revenues. Because the majority of providers/suppliers in the U.S. qualify as “small,” and this model includes all eligible providers/suppliers that submit claims for separately payable Medicare Part B drugs, we expect the majority of MFN participants to be small entities. However, some of these small entities may not administer Medicare Part B drugs and will not be MFN participants.

There are a number of providers and suppliers, including various physician specialties, that will see reduced drug component payments of 3 percent or more in performance year 1. Please refer to Table 3 to see the number of entities impacted, as well as the types of providers and suppliers that will be most likely impacted by the rule. Lower MFN Model drug payments will likely be a fraction of these entities’ total revenues, taking into account non-Medicare patients and all other services provided. Moreover, the alternative add-on payments could offset such reductions to some extent, as described in section III.F. of this IFC. We considered potential impacts on small entities; we expect that the model’s impact on an MFN participant’s revenue will be driven by the proportion of Medicare payments to the MFN participant that is related to administering Medicare Part B drugs rather than its size. Further, to provide financial protection for MFN participants, we are including a financial hardship exemption for MFN

participants (regardless of size) that experience significant financial hardship as a result of the model test, as described in section III.I.2. of this IFC. It is likely that many, if not all, included providers and suppliers will see an overall decrease in revenue for MFN Model drugs of 3 percent or more over the course of the model. Accordingly, we have determined that a Regulatory Flexibility Analysis (RFA) is required. This RIA, together with the preamble, constitutes the required analysis.

As a result of the model, we expect total allowed charges for Medicare Part B drugs for small entities to go down commensurate with the phase-in of the MFN Price in the calculation of the MFN Drug Payment Amount (Year 1: 75 percent applicable ASP and 25 percent MFN Price; Year 2: 50 percent applicable ASP and 50 percent MFN Price; etc.). Although the alternative add-on payment was designed to hold MFN participants harmless based on current revenue to the greatest extent possible, as shown in Table 8, 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. We estimate that MFN participants, on average, will see an approximate 40 percent increase in historical revenue related to the alternative add-on portion of the MFN Model payments, which will total approximately \$4.4 billion in the OACT estimate and \$2.2 billion in the ASPE estimate over the 7-year model. In these estimates, the total Medicare FFS impact, as indicated in Tables 12 and 16, would be a reduction of approximately \$85.5 billion in Medicare FFS spending in the OACT estimate and a majority of the \$52.1 billion in reduced federal spending in the ASPE estimate over the 7-year model, and will apply mainly to urban and non-340B MFN participants. We note that there is much uncertainty around the assumptions for these estimates. Finally, we have and will continue to take steps to minimize the impact of this IFC on administrative and reporting burdens for small businesses. We welcome comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects. We also welcome comments on adjustments to the MFN Model that could be considered for future rulemaking while preserving the innovative

approach to payment in the MFN Model.

8. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this IFC will have a significant impact on small rural hospitals.

As described in section III.C. of this IFC, we will exclude CAHs from the types of providers and suppliers that will be MFN participants. Slightly less than 10 percent (\$3.35 billion) of total Medicare Part B drug allowed charges in 2019 are associated with rural providers and suppliers (other than CAHs) based on claims with ZIP codes associated with areas that are not assigned to metropolitan core based statistical areas (CBSA) identified by the Office of Management and Budget; of that amount, less than 0.015 percent (\$4.87 million) is for drugs furnished in the U.S. territories outside of the metropolitan areas of Puerto Rico. These rural entities will experience drug payment reductions and overall payment reductions similar to urban entities under the MFN Model.

9. Unfunded Mandates Reform

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This IFC does not mandate any spending by State, local, or tribal governments, or by the private sector, and hence an UMRA analysis is not required.

10. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts state law, or otherwise has Federalism implications. We have examined the provisions in the MFN Model included in this IFC in accordance with Executive Order 13132, and have determined that they will not have a direct effect on state, local or tribal governments, preempt state law, or otherwise have a Federalism implication.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This IFC is considered an E.O. 13771 regulatory action. Details on the estimated costs of this IFC can be found in the preceding and subsequent analyses.

E. Alternatives Considered

This IFC contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the final policies, and presents rationales for our policies and, where relevant, alternatives that we considered in section III of this IFC.

Several alternatives we considered included: (1) the parameters included in this IFC; (2) variations of certain parameters included in this IFC, such as lengthening the phase-in of the MFN Price (described in section III.E.8. of this IFC) to occur over 5-7 performance years, limiting the model performance period to 5 performance years, expanding or limiting the Medicare Part B drugs that would be eligible for inclusion in the MFN Model and a different geographic area; (3) the parameters in the October 2018 ANPRM for a potential IPI Model for Medicare Part B Drugs⁸⁹; and (4) not implementing the model. In addition, when developing the

⁸⁹ <https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs>

parameters for the October 2018 ANPRM and this IFC, we noted that there are a range of methods to implement external reference pricing, and these different approaches would affect the impact of the model.^{90,91} In examining potential variations of certain parameters included in this IFC, we considered potential differences such variations would have on the impacts presented in sections VI.C.1. and VI.C.2. of this IFC. We note that a potential model design with a longer MFN Price phase-in would have a lower estimate of overall Medicare savings; for example, a 7-year phase-in of the MFN Price over a 7-year model performance period would reduce estimates of Medicare savings in the OACT estimate by approximately 25 percent. As noted in section III.E.5. of this IFC, our policy is to phase-in the MFN Price more quickly during the initial years to allow CMS to test the full phase-in of the MFN Price. In considering the scope of the model, we actively assessed whether to pursue a smaller geographic scope. As we discuss in section III.C.3. of this IFC, we reviewed the comments that we received on the October 2018 ANPRM, where we considered 50 percent of the country in a model. We weighed whether the ability to have a research design where we would compare changes in drug spending and utilization relative to a comparison group, a design that CMS uses frequently in its models, would outweigh the concerns we highlight in section III.C.3. of this IFC. We ultimately concluded that operational concerns such as administrative complexity as well as the risk to model integrity associated with a limited geographic scope, as described in section III.C.3. of this IFC, necessitate a test with a nationwide scope using a different evaluation design.

The estimates for the impact of this IFC show a substantial reduction in Medicare Part B spending over a 7-year model. In comparison, the parameters considered in the October 2018 ANPRM were estimated to result in a less substantial reduction in Medicare Part B spending over a 5-year model.⁹² The alternative of not implementing the model would not have an impact

⁹⁰ https://jasmin.goeg.at/432/1/EURIPID_GuidanceDocument_V8.1_310718.pdf

⁹¹ https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf

⁹² <https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs>

compared to existing policy.

F. Accounting Statements and Tables

As required by OMB Circular A–4 under Executive Order 12866 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/) in Tables 17 and 18 we have prepared two accounting statements, based on the OACT and ASPE estimates respectively, showing the classification of transfers, benefits, and costs associated with the provisions in this IFC. The transfer from beneficiaries to providers and MA plans represents the premium change attributable to the drug price, i.e. the difference between the gross impact and the net impact in the drug price section of Table 12. The accounting statement in Table 17 is based on estimates provided in this regulatory impact analysis in Table 12 and the accounting statement in Table 18 is based on estimates in Table 16. Tables 17 and 18 include the estimated effect and burden estimates on beneficiaries outlined in section VI.C.4. of this IFC and on participants and manufacturers in section VI.C.5. of this IFC. The costs shown in Table C18 reflect additional medical expenses incurred as a result of the potential loss of access to certain drugs for some beneficiaries in the ASPE estimate.

TABLE 17: ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2027 AS A RESULT OF CHANGES IN THIS IFC BASED ON THE OACT ESTIMATE

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs				
Annualized Monetized (\$million/year)	29.4	2018	7%	January 2021 – December 2028
	27.1	2018	3%	January 2021 – December 2028
From Whom to Whom	Hospital/physicians			
Annualized Monetized (\$million/year)	0.4	2018	7%	January 2021 – December 2027
	0.4	2018	3%	January 2021 – December 2027
Transfers				
Annualized Monetized (\$million/year)	-11, 502.5	2018	7%	January 2021 – December 2027
	-11, 906.3	2018	3%	January 2021 – December 2027
From Whom to Whom	Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized (\$million/year)	-4,087.2	2018	7%	January 2021 – December 2027
	-4, 228.3	2018	3%	January 2021 – December 2027
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans.			
Annualized Monetized (\$million/year)	-577.5	2018	7%	January 2021 – December 2027
	-596.5	2018	3%	January 2021 – December 2027
From Whom to Whom	States to hospitals/physicians and MA plans			

Notes	Price discrimination hinges upon producers being able to separate consumers according to their (and, in the pharmaceutical context, their payers') willingness-to-pay. Because the policy reduces the feasibility of that separation, prices would decrease for the consumers previously paying more (a subset of U.S. patients with the federal government as their payer); prices would increase for the consumers previously paying less (international patients and their payers); and producer surplus would decrease.
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TABLE 18: ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2027 AS A RESULT OF CHANGES IN THIS IFC BASED ON THE ASPE ESTIMATE

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs				
Annualized Monetized (\$million/year)	29.4	2018	7%	January 2021 – December 2028
	27.1	2018	3%	January 2021 – December 2028
From Whom to Whom	Hospital/physicians			
Annualized Monetized (\$million/year)	0.4	2018	7%	January 2021 – December 2027
	0.4	2018	3%	January 2021 – December 2027
Transfers				
Annualized Monetized (\$million/year)	-7,058.3	2018	7%	January 2021 – December 2027
	-7,276.5	2018	3%	January 2021 – December 2027
From Whom to Whom	From Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized (\$million/year)	-4,504.9	2018	7%	January 2021 – December 2027
	-4,638.6	2018	3%	January 2021 – December 2027
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans			
Annualized Monetized (\$million/year)	-342.4	2018	7%	January 2021 – December 2027
	-351.6	2018	3%	January 2021 – December 2027
From Whom to Whom	From states to hospitals/physicians and MA plans			
Notes	Price discrimination hinges upon producers being able to separate consumers according to their (and, in the pharmaceutical context, their payers') willingness-to-pay. Because the policy reduces the feasibility of that separation, prices would decrease for the consumers previously paying more (a subset of U.S. patients with the federal government as their payer); prices would increase for the consumers previously paying less (international patients and their payers); and producer surplus would decrease.			

G. Conclusion

The changes in this IFC will affect providers and suppliers that furnish separately payable Medicare Part B drugs in the outpatient setting for which annual Medicare FFS spending is high. These providers and suppliers are mostly physicians (including physician practices), non-physician practitioners, supplier groups, HOPDs (including on- and off-campus outpatient provider-based departments, but excluding cancer hospitals, children's hospitals and CAHs), and ASCs. We estimate that the effect of the MFN Model on providers and suppliers will vary, depending on their type, location, what drugs they furnish, their clinical patterns, and the

alternative add-on payment for the MFN Model. We estimate that eligible providers and suppliers will experience a decrease in overall payment related to the MFN Model. We estimate that beneficiaries who receive included drugs from MFN participants will experience a decrease in cost-sharing, however, some beneficiaries' providers and suppliers may choose not to offer access to the MFN Model drugs, causing these beneficiaries to seek alternative providers, treatment alternatives, or forgo access. The financial hardship exemption is designed to mitigate this risk.

The changes in this IFC will also affect MA organizations, drug manufacturers, primary and secondary payers, and potentially non-Medicare patients. MA organizations will experience lower payments as a result of the MFN Model because the MA ratebook calculations will reflect changes in actual FFS spending due to the impact of the model. Drug manufacturers may have lower revenue, depending upon their behavioral response to the MFN Model. Other payers, including State Medicaid Programs, and patients who take prescription drugs may experience direct or indirect spillover effects that may increase or decrease their costs. In addition, as shown in Tables 12 and 16, the changes we are adopting in this IFC will reduce state and federal Medicaid spending and beneficiary spending on Medicare premiums.

In accordance with the provisions of E.O. 12866, this IFC was reviewed by the Office of Management and Budget.

VII. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the Federal Register before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act

as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

High drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment. Increasing premiums, out-of-pocket costs in both Part B and Part D, and increases in drug prices are causing beneficiaries to divert scarce resources to pharmaceutical treatments and away from other needs, or prompting them to skip doses of their medications, take less than the recommended doses, or abandon treatment altogether.^{93,94} In Medicare Part B, drug spending increased by over 9 percent between 2009 and 2017. Over two thirds of that increase in spending was based on increases in drug prices alone, and only one third due to increases in utilization.⁹⁵ Prices of certain drugs have increased by double-digit percentages over time.⁹⁶ These dramatic increases are on prices where the U.S. already pays significantly more than other countries.⁹⁷ When CMS announced the 2020 Part B Premiums and Deductibles, we noted that the increases in Part B premiums and deductibles was largely due to rising spending on physician-administered drugs.⁹⁸

With more than 25 million Medicare beneficiaries living at or below 200 percent of the Federal Poverty Line (FPL),⁹⁹ high drug prices could lead to improper medication adherence or

⁹³ Kirzinger A, Neuman T, Cubanski J, Brodie M. Data Note: Prescription Drugs and Older Adults, Aug 09, 2019, Kaiser Family Foundation <https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/>

⁹⁴ Kirzinger A, Lopes L, Wu B, Brodie M. KFF Health Tracking Poll – February 2019: Prescription Drugs, Kaiser Family Foundation, Mar 01, 2019, <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

⁹⁵ Medicare Payment Advisory Commission, Report to Congress “Chapter 3: Medicare payment strategies to improve price competition and value for Part B drugs,” June 2019, http://www.medpac.gov/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf?sfvrsn=0

⁹⁶ Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018. *JAMA*. 2020;323(9):854–862. doi:10.1001/jama.2020.1012

⁹⁷ Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures” <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures>

⁹⁸ CMS Newsroom. 2020 Medicare Parts A & B Premiums and Deductibles. <https://www.cms.gov/newsroom/fact-sheets/2020-medicare-parts-b-premiums-and-deductibles>

⁹⁹ Schoen C, Davis K, Willink A, Medicare Beneficiaries’ High Out of Pocket Costs: Cost Burdens by Income and Health Status, Commonwealth Fund, May 12, 2017, https://www.commonwealthfund.org/publications/issue-briefs/2017/may/medicare-beneficiaries-high-out-pocket-costs-cost-burdens-income?redirect_source=/publications/issue-briefs/2017/may/medicare-out-of-pocket-cost-burdens

skipped treatment. The consequences of these behaviors can result in poor clinical outcomes for chronic disease management.¹⁰⁰ The COVID-19 pandemic has rapidly exacerbated these problems. The risk of severe illness from COVID-19 increases with age and the presence of chronic illnesses, putting many older adults at the highest risk levels.^{101,102} This is of particular concern given that 84 percent of individuals over the age of 65 having at least one chronic health condition, and more than 53 million adults over the age of 65 are enrolled in Medicare.^{103,104} With adults 65 and older comprising 8 out of 10 COVID-19 deaths reported in the U.S., COVID-19 has disproportionately impacted Americans 65 or older.¹⁰⁵

Furthermore, the COVID-19 pandemic has led to historic levels of unemployment in the U. S., with both the unemployment rate and number of unemployed persons remaining nearly twice their February (pre-pandemic) numbers.¹⁰⁶ The COVID-19 pandemic has also led to an increase in food prices, straining budgets for many of America's seniors, particularly those who live on fixed incomes,¹⁰⁷ such as the 6 million Medicare fee-for-service beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid.^{108,109,110} Already facing increased financial burden, this population is in need of urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial instability worsened by the COVID-19 pandemic. This need is exacerbated in

¹⁰⁰ <https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm>

¹⁰¹ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html#:~:text=Risk%20for%20Severe%20Illness%20Increases%20with%20Age&text=The%20greatest%20risk%20for%20severe%20cas%20having%20underlying%20medical%20conditions.>

¹⁰² <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

¹⁰³ National Council on Aging, <https://www.ncoa.org/economic-security/money-management/debt/senior-debt-facts/>

¹⁰⁴ MMCO Statistical & Analytic Reports, Managed Care Enrollment Trends (2006-2018 Data), <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics>

¹⁰⁵ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html#:~:text=Risk%20for%20Severe%20Illness%20Increases%20with%20Age&text=The%20greatest%20risk%20for%20severe%20cas%20having%20underlying%20medical%20conditions.>

¹⁰⁶ U.S. Bureau of Labor Statistics. Economic News Release. The Employment Situation- October 2020. November 06, 2020. <https://www.bls.gov/news.release/empstat.nr0.htm>

¹⁰⁷ 54 million people in America face food insecurity during the pandemic. It could have dire consequences for their health. AAMC. October 15, 2020. <https://www.aamc.org/news-insights/54-million-people-america-face-food-insecurity-during-pandemic-it-could-have-dire-consequences-their>

¹⁰⁸ MMCO Statistical & Analytic Reports, Managed Care Enrollment Trends (2006-2018 Data), <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics>

¹⁰⁹ An Overview of Medicare, Kaiser Family Foundation, Feb 12, 2019, <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/>

¹¹⁰ Note: The number of Medicare beneficiaries without supplemental insurance is from 2016 while the dual eligible numbers are from 2018.

communities of color and among women, wherein Black, Latino, and Hispanic adults face higher economic insecurity than their white counterparts.¹¹¹ The economic disruptions caused by the COVID-19 pandemic have increased the burdens placed on America's seniors and other Medicare Part B beneficiaries and given rise to an urgent need for swift action to reduce drug prices. Though we have seen some positive economic and employment trends since the initial peak in April,¹¹² we are currently seeing a new surge in COVID-19 cases that may lead to additional hardship and requires immediate action.¹¹³ As such, we find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic. Implementation of this model will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment.

We also usually provide for a delay in effective date under section 553(d) of the APA and section 1871(e)(1)(B) of the Act. However, such delay in effective date may be waived for good cause, when such delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and a brief statement of the reasons therefore in the notice. We find that delaying implementation of this IFC is contrary to the public interest for the same reasons that we find good cause to waive prior notice and comment.

List of Subjects in 42 CFR Part 513

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

¹¹¹ Center on Budget and Policy Priorities, Tracking the COVID-19 Recession's Effects on Food, Housing, and Employment Hardships. November 9, 2020. <https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and>

¹¹² U.S. Bureau of Labor Statistics. Economic News Release. The Employment Situation- October 2020. November 06, 2020. <https://www.bls.gov/news.release/empisit.nr0.htm>

¹¹³ Center for Disease Control. COVID-19 Forecasts: Cases. <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/forecasts-cases.html>

For the reasons set forth in the preamble and under the authority at 5 U.S.C. 301, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV by adding part 513 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513—Most Favored Nation (MFN) MODEL

Sec.

Subpart A—General Provisions

513.1 Basis, scope, and duration.

513.2 Definitions.

Subpart B—Inclusion in the Model

513.100 MFN Model payments and MFN participants.

513.120 MFN Model geographic area.

513.130 MFN Model drugs, updates, categories and exclusions.

513.140 Included international data.

Subpart C—Payment Process and Methodology

513.200 Payment process and beneficiary cost-sharing.

513.210 Model payment methodology for MFN Model drugs.

513.220 Model alternative add-on payment.

513.230 Financial Hardship Exemptions, Request Process, and Reconciliation Payment.

Subpart D—[Reserved]

Subpart E—Quality Strategy, Beneficiary Protections, and Compliance Activities

- 513.400 Quality measures.
- 513.410 Beneficiary protections.
- 513.420 Monitoring and compliance activities.
- 513.430 Audits and record retention.
- 513.440 Enforcement authority.
- 513.450 Limitations on review.

Subpart F—Waivers

- 513.500 Waivers of Medicare program requirements for purposes of testing the MFN Model.

Subparts G through J — [Reserved]

Subpart K--Model Termination

- 513.1000 Termination of the MFN Model.

Authority: 42 U.S.C.1302, 1315(a), and 1395hh.

Subpart A—General Provisions

§ 513.1 Basis, scope, and duration.

(a) *Basis.* This part implements the test of the Most Favored Nation (MFN) Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

- (1) The types of providers and suppliers required to participate in the MFN Model and applicable requirements.
- (2) The beneficiaries included in the MFN Model.
- (3) The drugs included in the MFN Model.
- (4) The methodologies for establishing Medicare payment amounts for and making payments for MFN Model drugs, including an alternative add-on payment.

(5) Beneficiary protections.

(6) Beneficiary cost-sharing.

(c) *Duration.* The MFN Model has a performance period of 7 performance years. The first performance year (performance year 1) begins on January 1, 2021, and the final performance year ends on December 31, 2027, unless sooner terminated in accordance with § 513.1000.

§ 513.2 Definitions.

For the purpose of this part the following definitions are applicable unless otherwise stated:

Add-on percentage means the percentage above 100 percent.

Alternative add-on payment means the payment described in § 513.220.

Applicable ASP means the payment amount determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage.

ASP stands for average sales price.

ASP calendar quarter means the period that is two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply.

CCN stands for CMS Certification Number.

Country-level price means the unadjusted country-level price for an MFN Model drug at the HCPCS code level as calculated in accordance with § 513.210(b)(2).

CPI-U stands for Consumer Price Index for All Urban Consumers based on all items in U.S. city average and not seasonally adjusted.

Days means calendar days.

DME stands for Durable Medical Equipment.

FDA stands for Food and Drug Administration.

GDP stands for gross domestic product.

GDP-adjusted country-level price means the country-level price adjusted by the GDP

adjuster as calculated in accordance with § 513.210(b)(4).

GDP adjuster means the country-specific adjuster as calculated in accordance with § 513.210(b)(3).

HCPCS stands for Healthcare Common Procedure Coding System.

HCPCS code level means the specified drug and amount described in the HCPCS code long descriptor.

MAC stands for Medicare Administrative Contractor.

Manufacturer's average sales price has the same meaning as under 42 CFR Subpart J.

MFN stands for most favored nation.

MFN beneficiary means an individual who is furnished an MFN Model drug by an MFN participant and who, on the date of service, is enrolled in Medicare Part B, has Medicare as his or her primary payer, and is not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan.

MFN Drug Payment Amount means the portion of the total allowed payment amount for an MFN Model drug determined in accordance with § 513.210.

MFN Model drug means a separately payable Medicare Part B drug or biological described by a HCPCS code included on the MFN Model Drug HCPCS Codes List.

MFN Model Drug HCPCS Codes List means the list of drugs included in the MFN Model for a given calendar quarter of a performance year established under § 513.130.

MFN participant means a Medicare participating provider or supplier, identified by its CCN or TIN, that is required to participate in the MFN Model in accordance with § 513.100(b).

MFN Model Payment means the total payment to an MFN participant for an MFN Model drug in accordance with subpart C of this part, inclusive of the MFN Drug Payment Amount and the Alternative Add-on Payment.

MFN Price means the lowest GDP-adjusted country-level price of the countries specified in § 513.140(b) for an MFN Model drug.

Model performance period means the 7-year period of time beginning on January 1, 2021, through December 31, 2027.

NOC stands for not otherwise classified.

OIG stands for the Department of Health and Human Services Office of Inspector General.

Outpatient prospective payment system (OPPS) means the payment system for designated hospital outpatient items and services and certain Medicare Part B services furnished to hospital inpatients when Part A payment cannot be made as defined by section 1833(t) of the Act.

Performance year means each 12-month period beginning on January 1 and ending on December 31 during the performance period for the MFN Model specified in § 513.1(c).

Provider means a “provider of services” as defined under section 1861(u) of the Act and codified at § 400.202 of this chapter.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

TIN stands for taxpayer identification number.

WAC means wholesale acquisition cost as defined at section 1847A(c)(6)(B) of the Act.

Subpart B-- Inclusion in the Model

§ 513.100 MFN Model payments and MFN participants.

(a) *General.* Subject to the exceptions specified in paragraph (d) of this section, the MFN Model payments specified under this part apply only to claims for an MFN Model drug furnished to an MFN beneficiary by an MFN participant.

(b) *MFN participants.* Subject to the exclusions specified in paragraph (c) of this section, the MFN Model requires participation by each Medicare participating provider and supplier that submits a claim (except for claims specified in paragraph (d) of this section) for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary.

(c) *Excluded providers and suppliers.* The following are excluded from participation in

the MFN Model:

- (1) Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act).
- (2) PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act).
- (3) Critical access hospitals (CAHs) (defined under section 1820 of the Act).
- (4) Indian Health Service (IHS) facilities (as described in section 1880 of the Act),

except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act.

(5) Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act).

(6) Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act).

(7) Hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act.

(8) Extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act).

(9) For the first quarter and second quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act.

(10) Beginning with the third quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act, where the parameters of such model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings

under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model.

(d) *Exceptions.* The MFN Model payments specified under this part do not apply to any of the following:

(1) Claims for MFN Model drugs furnished in the inpatient hospital setting under those circumstances where Part A would not pay for hospital services.

(2) Claims for MFN Model drugs administered during an inpatient hospital stay or included on an inpatient hospital claim.

(3) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.

(4) Claims paid under the End-Stage Renal Disease Prospective Payment System, including claims paid using the transitional drug add-on payment adjustment.

(e) *MFN participant requirements during the MFN Model.* During the model performance period described in § 513.1(c), MFN participants must do all of the following:

(1) Adhere to the beneficiary protections requirements under § 513.410.

(2) Adhere to the MFN Model-specific billing instructions requirements established by CMS and the MAC responsible for processing the MFN participant's claims, including without limitation those described in § 513.200.

(3) Participate in MFN Model monitoring and evaluation activities in accordance with § 403.1110(b) of this chapter, including collecting and reporting information as the Secretary determines is necessary to monitor and evaluate the MFN Model, including without limitation "protected health information" as that term is defined at 45 CFR 160.103.

(f) *MFN participant requirements after the MFN Model.* For 2 years after termination of the MFN Model, MFN participants must participate in MFN Model monitoring activities as described in § 513.420.

§ 513.120 MFN Model geographic area.

The MFN Model geographic area is all states and U.S. territories.

§ 513.130 MFN Model drugs, updates, categories and excluded drugs.

(a) *MFN Model drugs.* CMS creates and periodically updates the MFN Model Drug HCPCS Codes List as described in this section. The MFN Model Drug HCPCS Codes List designates the MFN Model drugs, which are subject to the MFN Model payments specified in subpart C of this part.

(1) *Initial MFN Model Drug HCPCS Codes List.* For the beginning of performance year 1, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, and adds the remaining HCPCS codes, after updating such HCPCS codes for any applicable changes, to the MFN Model Drug HCPCS Codes List. Final action claims with dates of service within calendar year 2019 and allowed charges greater than \$0 are used to determine aggregate 2019 Medicare Part B total allowed charges.

(2) *Annual Update of the MFN Model Drug HCPCS Codes List.* For the start of each subsequent performance year, using Medicare Part B total allowed charge from the next subsequent calendar year, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate Medicare Part B total allowed charges, after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, for the most recent full calendar year, and adds any remaining HCPCS codes not already on the MFN Model Drug HCPCS Codes List to the MFN Model Drug HCPCS Codes List, after updating such HCPCS codes for any applicable changes, effective on the first day of the performance year.

(3) *Removal.* No more frequently than quarterly, CMS removes HCPCS codes from the MFN Model Drug HCPCS Codes List when CMS becomes aware that all of the National Drug Codes assigned to the HCPCS code have been permanently withdrawn from the U.S. market and the drug has been permanently withdrawn from the U.S. market, the specific HCPCS code included on the MFN Model Drug HCPCS Codes List is terminated with no replacement code

available or planned, or an exclusion in paragraph (b)(1) of this section applies.

(4) *Maintenance.* No more frequently than quarterly, CMS revises HCPCS codes on the MFN Model Drug HCPCS Codes List as necessary to reflect quarterly HCPCS code updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, including adding replacement codes for HCPCS codes that were terminated.

(b) *Exclusions.* (1) The following are excluded from the MFN Model:

(i) Vaccines specified in section 1861(s)(10) of the Act (influenza, pneumococcal pneumonia, coronavirus disease 2019 (COVID-19), and Hepatitis B vaccines).

(ii) Radiopharmaceuticals.

(iii) Oral anticancer chemotherapeutic agents described in section 1861(s)(2)(Q) of the Act.

(iv) Oral anti-emetic drugs described in 1861(s)(2)(T) of the Act.

(v) Oral immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

(vi) Compounded drugs.

(vii) Intravenous immune globulin products.

(viii) Drugs billed with HCPCS codes that describe a drug product that was approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act;

(ix) Drugs for which there is an Emergency Use Authorization (EUA) from FDA, or FDA approval, to treat patients with suspected or confirmed COVID-19; or

(x) Drugs billed using a not otherwise classified (NOC) or not otherwise specified (NOS) billing and payment code.

(2) The following claims are excluded from the determination of whether a drug is to be included on the MFN Model Drug HCPCS Codes List:

(i) Professional claims with a place of service code indicating a home setting, including home, homeless shelter, assisted living facility, group home, temporary lodging, and custodial

care facilities.

(ii) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.

§ 513.140 Included international data.

(a) *General.* (1) CMS uses drug pricing information from international data sources, available to CMS at least 20 business days prior to the start of a calendar quarter, meeting the requirements in paragraph (c) of this section for MFN Model drugs from countries included in paragraph (b) of this section.

(2) For purposes of selecting a data source for each MFN Model drug for a calendar quarter, CMS identifies available international drug pricing information data sources for the MFN Model drug, by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable.

(b) *Non-U.S. member countries of the Organisation for Economic Co-operation and Development (OECD).* (1) CMS uses available international sales, volume, and pricing data for countries that were non-U.S. OECD member countries as of October 1, 2020 with a GDP per capita that is at least 60 percent of the U.S. GDP per capita as determined by CMS in accordance with this paragraph (b).

(2) Each country's GDP per capita is assessed using data available at the end of the applicable ASP calendar quarter.

(3) Subject to the limitation specified in paragraph (b)(4) of this section, the GDP per capita for a country is the the most recent estimate of GDP per capita based on purchasing power parity for that country available in the U.S. Central Intelligence Agency (CIA) World Factbook.

(4) The country's GDP per capita and U.S. GDP per capita selected from the CIA World Factbook must be for the same year.

(5) CMS identifies countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the GDP per capita for a country by the U.S. GDP per capita and assessing the results.

(c) *Identification of international data sources.* (1) CMS obtains data from one or more international drug pricing information data sources for purposes of identifying available international drug pricing information for the countries specified in paragraph (b) of this section.

(2) Such data sources must, as determined by CMS--

(i) Utilize a standardized method for identifying drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names;

(ii) Utilize a standard method for identifying drug forms that at a minimum distinguishes among injectable, oral, and other forms of a drug; and

(iii) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 180 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the database.

(iv) Contains international drug pricing information stated in U.S. currency, such as the following:

(A) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, or retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels.

(B) Volume data (for example, number of packages or units sold).

(C) List prices.

(v) Have mechanisms in place to maintain, update, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(3) For each MFN Model drug for a calendar quarter, CMS selects a data source using the following hierarchy.

(i) The data source contains sales and volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) The data source does not have sales and volume data for the applicable ASP calendar quarter, but contains sales and volume data for any prior ASP calendar quarter beginning on or after October 1, 2019 from at least one country described in paragraph (b) of this section. If sales and volume data from a prior ASP calendar quarter are used, CMS uses sales and volume data from the most recent ASP calendar quarter for which both sales and volume data are available.

(iii) The extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website.

(iv) The data source contains ex-manufacturer price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(v) The data source contains list price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(vi) If there is more than one data source for an ASP calendar quarter, for each MFN Model drug, CMS selects the data source at the highest level of the hierarchy that contains information from the highest number of countries described in paragraph (b) of this section and, if available, incorporates discounts and rebates into its drug pricing information, and uses this data source to calculate the MFN Price as described in § 513.210(b).

Subpart C— Payment Process and Methodology

§ 513.200 Payment process and beneficiary cost-sharing.

(a) *General.* For purposes of the MFN Model, the allowed MFN Drug Payment Amount does not exceed the billed amount on the claim for the MFN Model drug.

(b) *Model-specific billing instructions.* MFN participants submit claims for MFN Model drugs to the applicable MAC in the form and manner specified by CMS in model-specific billing instructions.

(c) *Beneficiary cost-sharing.* Beneficiary coinsurance does not apply to the portion of the allowed payment amount for an MFN Model drug that is determined under § 513.220.

§ 513.210 Model payment methodology for MFN Model drugs.

(a) *Payment amount.* The total allowed payment amount for an MFN Model drug furnished to an MFN beneficiary by an MFN participant on a given date of service within a calendar quarter is determined in accordance with this section. The total allowed payment equals

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(1) For each billing unit in the HCPCS code descriptor of the MFN Model drug, the MFN Drug Payment Amount determined in accordance with paragraphs (b), (c) and (d) of this section, as applicable, where the allowed MFN Drug Payment Amount does not exceed the billed amount on the claim for the MFN Model drug as described in § 513.200(a); and

(2) The alternative add-on payment determined under § 513.220.

(b) *Calculation of the MFN Drug Payment Amount with Available International Drug Pricing Data.* CMS selects an available international drug pricing information data source described in § 513.140(c) for at least one country specified in § 513.140(b) for an MFN Model drug, and calculates, in advance of each calendar quarter for a performance year, the applicable MFN Drug Payment Amount for one billing unit of an MFN Model drug using the following steps:

(1) *Available international drug pricing data.* (i) For the MFN Model drug, using the data source selected in accordance with § 513.140(c)(3) (except for a data source described in § 513.140(c)(3)(iii)), CMS identifies available international drug pricing data for the MFN Model drug, by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable. CMS extracts available drug pricing data for the countries specified in § 513.140(b) from the selected international drug pricing information data source. CMS uses the extracted data that have complete package size

information and only for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor, as determined by CMS. If a data source described in § 513.140(c)(3)(iii) is selected, CMS uses such extracted data.

(ii) When international drug pricing data with sales and volume data are available, CMS excludes from the calculation of the unadjusted country-level price under paragraph (b)(2) of this section international drug pricing data without both sales and volume data, with less than \$1,000 in quarterly sales (expressed as U.S. currency), or with less than 1,000 units in quarterly volume.

(iii) CMS converts the extracted volume data to the MFN Model drug's HCPCS code billing unit level, as applicable.

(iv) CMS adjusts the extracted volume data, as applicable, before converting the extracted volume data to the MFN Model drug's HCPCS code billing unit level when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product, as determined by CMS.

(v) CMS limits the number of HCPCS code billing units when –

(A) The package labeling indicates a limited amount of drug is to be used from the package; and

(B) The HCPCS code dosage is per dose.

(2) *Calculate the unadjusted country-level price for the MFN Model drug by country.*

(i) Using the drug pricing data extracted and adjusted in accordance with paragraph (b)(1) of this section, CMS calculates the unadjusted country-level price for the MFN Model drug by country, using the calculation that is applicable.

(ii) If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows:

(A) CMS sums the adjusted volume data (as specified in paragraph (b)(1)(iii) of this section) for the drug.

(B) CMS sums the total sales for the drug (that remain after performing the exclusions in

paragraph (b)(1)(ii) of this section).

(C) CMS divides the sum determined in paragraph (b)(2)(ii)(B) of the section by the sum determined in paragraph (b)(2)(ii)(A) of this section, resulting in an average price per unit of drug, where the unit of drug is the same as the HCPCS code billing unit.

(iii) If an international drug pricing information data source with ex-manufacturer or list prices is used, the applicable calculation is as follows:

(A) For each extracted ex-manufacturer or list price, CMS calculates the number of HCPCS billing units in the package by dividing the amount of drug in the package by the amount of drug represented in one HCPCS billing unit.

(B) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the package, resulting in a price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(C) CMS sums the price per unit of drug calculated in paragraph (c)(3)(iii)(B) of this section.

(D) CMS divides the sum calculated in paragraph (c)(3)(iii)(C) of this section by the number of ex-manufacturer or list prices that were summed in paragraph (c)(3)(iii)(C) of this section, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(iv) CMS performs the applicable calculation for each country specified in § 513.140(b) for which international drug pricing information is available in the selected data source.

(3) *Calculate the GDP adjuster for each country.* (i) CMS calculates the GDP adjuster by dividing the country's GDP per capita by the U.S. GDP per capita for the same year.

(ii) In cases where the resulting ratio exceeds 1.0, the GDP adjuster is set to 1.0.

(iii) Subject to the limitations specified in paragraph (b)(3)(iv) of this section, the GDP per capita for a country is the most recent estimate of GDP per capita based on purchasing power

parity for that country available in the CIA World Factbook at the end of the applicable ASP calendar quarter.

(iv) *Limitations.* (A) The country's GDP per capita and U.S. GDP per capita must be for the same year.

(B) The GDP per capita used must be for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

(4) *Apply the GDP adjuster to calculate the GDP-adjusted country-level price.* CMS applies the applicable GDP adjuster identified in paragraph (b)(3) of this section to each unadjusted country-level price identified in paragraph (b)(2) of this section to calculate the GDP-adjusted country-level price by dividing each unadjusted country-level price by the applicable GDP adjuster.

(5) *Identify the lowest GDP-adjusted country-level price.* CMS identifies the lowest GDP-adjusted country-level price for the MFN Model drug. Except as provided in paragraph (b)(7) of this section, the price identified is the MFN Model drug's MFN Price.

(6) *Identify Applicable ASP.* CMS identifies the applicable ASP for the applicable quarter.

(7) *Compare the MFN Price to the applicable ASP.* CMS compares the price determined in paragraph (b)(5) of this section to the applicable ASP identified in paragraph (b)(6) of this section. The MFN Price equals the applicable ASP if the applicable ASP is less than the price determined in paragraph (b)(5) of this section.

(8) *Phase-in.* CMS identifies the applicable phase-in formula based on the applicable performance year as follows:

- (i) Performance year 1: 75 percent applicable ASP and 25 percent MFN Price.
- (ii) Performance year 2: 50 percent applicable ASP and 50 percent MFN Price.
- (iii) Performance year 3: 25 percent applicable ASP and 75 percent MFN Price.
- (iv) Performance year 4: 100 percent MFN Price.

(v) Performance year 5: 100 percent MFN Price.

(vi) Performance year 6: 100 percent MFN Price.

(vii) Performance year 7: 100 percent MFN Price.

(9) *Final calculation steps.* (i) CMS applies the applicable phase-in formula to the applicable ASP and the MFN Price. Subject to any applicable adjustments as provided in paragraph (d) of this section, the amount determined in this paragraph is the MFN Drug Payment Amount.

(ii) Subject to the limitation in paragraph (b)(iii) in this section, CMS recalculates the MFN Drug Payment Amounts for prior quarters when revised international drug pricing information is available in the data source that was used to calculate the MFN Price and applicable ASP updates are available from CMS. CMS prospectively applies the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates.

(iii) MFN Drug Payment Amounts may be recalculated for the prior four calendar quarters of the model.

(c) *Frequency of MFN Drug Payment Amount updates.* CMS updates the MFN Drug Payment Amounts on a calendar quarter basis. CMS publishes the quarterly MFN Drug Payment Amounts on the MFN Model website in advance of the calendar quarter in which the MFN Drug Payment Amounts apply, along with any recalculated MFN Drug Payment Amounts for prior quarters.

(d) *Exceptions.* (1) *Payment for MFN Model drugs for which no international drug pricing data are available.* If, as of the first calendar quarter during which an MFN Model drug has been included in the MFN Model Drug HCPCS Codes List in accordance with § 513.130, no international sales, volume or pricing information meeting the requirements described in § 513.140(c)—including data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website— is available from

any country described in § 513.120(b) for any calendar quarter beginning on or after October 1, 2019 through the applicable quarter, the MFN Drug Payment Amount is the applicable ASP.

(2) *Payment for MFN Model drugs that are in short supply.* If an MFN Model drug is reported as “Currently in Shortage” by FDA, beginning with the first day of the next calendar quarter after the date on which it is reported in shortage, the MFN Drug Payment Amount is the applicable ASP. CMS calculates payment in accordance with paragraph (b) of this section as of the first day of the calendar quarter after the date upon which the drug is no longer reported as “Currently in Shortage” by FDA.

(3) *Adjustment to phase-in formula.* (i) CMS accelerates the phase-in of the MFN Price by 5 percentage points at the next quarterly update to calculate the MFN Drug Payment Amount for the MFN Model drug where both of the following conditions are met:

(A) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug’s HCPCS code compared to the cumulative percentage increase in the CPI-U.

(B) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug’s HCPCS code compared to the cumulative percentage increase in the MFN Price.

(C) For purposes of paragraphs (d)(3)(i)(A) and (B) of this section, the cumulative percentage increase means the cumulative percentage change from the end of the baseline to the end of the applicable ASP calendar quarter.

(D) The baseline in paragraph (d)(3)(i)(C) of this section for an MFN Model drug is the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1. If there is not an applicable ASP for the first quarter of performance year 1 for an MFN Model drug, the baseline for that MFN Model drug is the ASP calendar quarter for the first applicable ASP based

on the manufacturer's average sales price for that MFN Model drug that occurs after the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1.

(ii) For purposes of paragraph (d)(3)(i) of this section, if the cumulative percentage increase in CPI-U or MFN Price is negative, CMS uses zero as the cumulative percentage increase in CPI-U or MFN Price, as applicable.

(iii) The application of an acceleration of the phase-in formula continues for the duration of the model performance period.

(iv) CMS applies an additional acceleration of the phase-in formula for each calendar quarter where the conditions specified in paragraph (i) are met.

(4) *Adjustment for rapid increases in the applicable ASP or any monthly U.S. list prices beyond inflation and MFN Price after the full phase-in of the MFN Price.* If the conditions described in paragraphs (d)(3)(i)(A) and (B) of this section are met after the full phase-in of the MFN Price for an MFN Model drug, for each calendar quarter thereafter, CMS decreases the MFN Drug Payment Amount equal to largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U and in the MFN Price, respectively, determined quarterly.

(5) *Limitation on MFN Drug Payment Amount.* The MFN Drug Payment Amount cannot exceed the non-model drug payment amount for claim lines submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

(e) *Blood clotting factor furnishing fee.* When applicable, the blood clotting furnishing fee under §410.63(c) of this chapter is payable along with the MFN Drug Payment Amount.

§ 513.220 Model alternative add-on payment.

(a) *Payment amount.* (1) The total allowed alternative add-on payment amount for a separately payable dose of an MFN Model drug furnished to an MFN beneficiary by an MFN

participant on a given date of service within a calendar quarter is determined in accordance with this section.

(2) The total allowed alternative add-on payment amount for a claim line does not exceed the billed amount on that claim line.

(b) *Calculation of the per-dose alternative add-on payment amount.* CMS calculates the per-dose alternative add-on payment for performance year 1, quarter 1 for MFN Model drugs using the following steps:

(1) CMS identifies available Medicare Part B fee-for-service final action claims lines, with dates of service in 2019, for drugs on the initial MFN Model HCPCS Codes List described in § 513.130(a)(1), excluding claims for providers and suppliers specified in § 513.100(c), and claims specified in § 513.100(d), that were furnished by Medicare-participating providers and suppliers, have a separately paid allowed charge greater than \$0, and for which Medicare Part B was the primary payer. If a HCPCS code on the initial MFN Model HCPCS Codes List was not in use during any calendar quarter in 2019, CMS uses the HCPCS code that was applicable for the MFN Model drug during 2019.

(2) CMS identifies the applicable ASP for each calendar quarter of 2019 for the drugs (by HCPCS code as specified in paragraph (b)(1) of this section) included on the initial MFN Model HCPCS Codes List. In the case of a biosimilar biological product, the applicable ASP for the reference biological product is identified and used in paragraph (b)(3) of this section.

(3) CMS multiplies the number of units billed for each claim line described in paragraph (b)(1) of this section by 6.1224 percent of the applicable ASP identified in paragraph (b)(2) of this section for the HCPCS code on the claim line and date of service.

(4) CMS sums the products calculated in paragraph (b)(3) of this section for all claim lines for each MFN Model drug to calculate the total add-on spending amount for each MFN Model drug.

(5) CMS sums the amounts calculated in paragraph (b)(4) of this section to calculate the

total pooled add-on spending amount for all MFN Model drugs.

(6) CMS divides the amount calculated in paragraph (b)(5) of this section by the total number of claim lines retained in paragraph (b)(1) of this section, excluding claim lines billed with the JW modifier.

(7) CMS trends the amount calculated in paragraph (b)(6) of this section forward to the applicable ASP calendar quarter for quarter 1 of performance year 1 using the percentage change in CPI-U from July 2019 through October 2020.

(c) *Frequency of alternative add-on payment amount updates.* For each calendar quarter after quarter 1 of performance year 1, CMS updates the alternative add-on payment by applying a cumulative inflation factor based on the cumulative percentage change in CPI-U from October 2020 through the first month of the prior calendar quarter. If the cumulative percentage change in the CPI-U is negative, CMS uses an inflation factor of 1.

(d) *Limitation on the alternative add-on payment.* The alternate add-on payment is not payable for claim lines billed –

(1) With the JW modifier; or

(2) By MFN participants that receive an alternative add-on payment for an MFN Model drug under any other model authorized by section 1115A of the Act that tests an alternative approach to the add-on portion of payment for Medicare Part B drugs.

§ 513.230 Financial hardship exemptions, request process, and reconciliation payment.

(a) *General.* For purposes of the MFN Model, a financial hardship exemption for a performance year may be granted to an MFN participant by CMS, in its sole discretion and not subject to appeal, when the provisions in this section are met.

(b) *Request for financial hardship exemption.* To be eligible for a financial hardship exemption, the MFN participant must submit a request for financial hardship exemption in the form and manner and with the content specified by CMS, including without limitation the requirements of this paragraph (b).

(1) *Timing and form of request.* The MFN participant must submit its request for a financial hardship exemption to CMS in accordance the submission process posted on the MFN Model website and such request must be submitted within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption.

(2) *Request content.* The MFN participant's request a financial hardship exemption must include, at a minimum, all of the following:

(i) Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient.

(ii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts or adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(iii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts and adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries.

(iv) Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug.

(v) Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address.

(vi) The MFN participant's attestation that:

(A) The MFN participant experienced a reduction in Medicare Part B FFS payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year)

due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;

(B) The MFN participant has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers, and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and

(C) The MFN participant submission is true, accurate and complete.

(c) *Standard of review.* (1) Incomplete requests for a financial hardship exemption, as determined by CMS, are not reviewed.

(2) CMS grants a financial hardship exemption to an MFN participant for a performance year, if the agency in its sole discretion determines the following requirements have been met:

(i) The MFN participant submits a timely, complete request for financial hardship exemption in accordance with the requirements of this section which in the sole discretion of CMS demonstrates all of the following:

(A) The MFN participant exhausted all reasonable methods to obtain MFN Model drugs at or below the MFN Model Payment for such drugs during the performance year.

(B) The MFN participant's average net acquisition cost for each MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries was not less than the MFN participant's average net acquisition costs for such MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(C) Any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug.

(ii) The MFN participant's excess reduction amount per beneficiary (as determined in paragraph (d)(6) of this section), is greater than zero.

(d) *Excess reduction amount per beneficiary.* CMS calculates the MFN participant's excess reduction amount per beneficiary using available final action claims data where Medicare was the primary payer that is estimated to be more than 90 percent complete in accordance with the following steps:

(1) CMS calculates, separately for dates of service within the performance year and prior year, the MFN participant's total allowed charges for separately payable Medicare Part B drugs, and the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0.

(2) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year.

(3) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the prior year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the prior year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year.

(4) CMS subtracts the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year (as calculated in paragraph (d)(2) of this section) from the MFN participant's average per beneficiary total

allowed charges for separately payable Medicare Part B drugs for the prior year (as calculated in paragraph (d)(3) of this section).

(5) CMS calculates 25 percent of the MFN participant's total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year and divides that amount by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the prior year, to calculate 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year.

(6) CMS subtracts 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year (as calculated in paragraph (d)(5) of this section) from the difference calculated in paragraph (d)(4) of this section, to calculate the MFN participant's excess reduction amount per beneficiary.

(e) *Reconciliation payment.* (1) If CMS in its sole discretion grants a financial hardship exemption to an MFN participant for a performance year, CMS provides such MFN participant a reconciliation payment for the performance year that equals the amount calculated by multiplying the excess reduction amount per beneficiary specified in paragraph (d)(6) of this section by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than \$0 with a service date within the performance year.

(2) The amount of a reconciliation payment provided in accordance with this section is--

- (i) Not subject to appeal;
- (ii) Not subject to beneficiary cost-sharing, including any deductible or coinsurance; and
- (iii) Made by CMS (or a CMS contractor) as soon as practical.

Subpart D—[RESERVED]

Subpart E—Quality Strategy, Beneficiary Protections, and Compliance Activities

§ 513.400 Quality measures.

(a) *General.* Quality measures do not adjust model payments to MFN participants and are used for monitoring purposes.

(b) *Collection of quality measures.* (1) CMS administers a patient experience survey to a sample of beneficiaries who receive an MFN Model drug. A sample of non-MFN beneficiaries may also be surveyed.

(2) If during the MFN Model CMS determines that the quality measures specified in paragraph (b) of this section are not sufficient to adequately monitor the quality of care that MFN beneficiaries are receiving from MFN participants or that MFN participants are providing, CMS may specify additional measures. CMS applies the following criteria when specifying additional quality measures:

(i) Additional measures are among one or more of the following categories:

(A) Patient experience of care.

(B) Patient activation

(C) Shared decision making.

(D) Adherence.

(E) Utilization.

(F) Process measures.

(ii) Additional measures will not add significant burden to MFN participants or beneficiaries.

(iii) Additional measures utilize an instrument that CMS has used previously in a model to adjust payment or for monitoring or evaluation.

§ 513.410 Beneficiary protections.

(a) *Beneficiary choice.*

(1) MFN participants must not restrict beneficiaries' ability to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare.

(2) The MFN participant must not commit any act or omission, nor adopt any policy that inhibits a beneficiary from exercising his or her freedom to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare. Notwithstanding the foregoing, MFN participants may communicate to beneficiaries the benefits of receiving care from an MFN participant, if otherwise consistent with the requirements of this part and applicable law.

(b) *Appeals.* An MFN beneficiary and his or her assignees retain their right to appeal claims in accordance with part 405 subpart I of this chapter.

(c) *Availability of services.* MFN participants must not take any action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels or other factors that would render the beneficiary an "at-risk beneficiary" as defined at § 425.20 of this chapter.

§ 513.420 Monitoring and compliance activities.

(a) *Compliance with laws.* (1) *Agreement to comply.* The MFN participant must comply with all applicable laws and regulations.

(2) *Notification.* The MFN participant must notify CMS within 15 days after becoming aware that the MFN participant is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).

(b) *CMS monitoring and compliance activities.* (1) CMS conducts monitoring activities to ensure compliance by MFN participants with the terms of the MFN Model, to obtain timely information about the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and

on the Medicare program and to facilitate real time identification and response to potential issues. Such monitoring activities may include, without limitation, the following:

(i) Documentation requests sent to the MFN participant including, without limitation, surveys and questionnaires.

(ii) Audits of claims data, medical records, and other data from the MFN participant.

(iii) Interviews with any individual or entity participating in the MFN Model including members of the MFN participant's leadership, management, and staff.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the MFN participants, performed in a manner consistent with § 513.420(c).

(vi) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation, all Medicare claims submitted for items or services furnished to beneficiaries in the MFN Model.

(3) The MFN participant must cooperate with evaluation and monitoring activities as may be necessary to enable CMS to evaluate the MFN Model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under this section.

(c) *Site visits.* (1) To the extent practicable, CMS or its designee provides the MFN participant with no less than 15 days advance notice of any site visit. To the extent practicable, CMS attempts to accommodate a request for particular dates in scheduling site visits. However, the MFN participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

(2) The MFN participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(3) Notwithstanding the foregoing, CMS may perform unannounced site visits at all physical locations of the MFN participant at any time to investigate concerns about the health or

safety of beneficiaries or other patients or other program integrity issues.

(4) Nothing in this part must be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Right to correct.* If CMS discovers that it has made or received an incorrect model-specific payment under the terms of the MFN Model, CMS may make payment to, or demand payment from, the MFN participant.

§ 513.430 Audits and record retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the MFN Model.

(b) *Access to records.* MFN participants must maintain and give the Federal Government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the MFN Model, including without limitation, documents and other evidence regarding the following:

(1) The MFN participant's compliance with the terms of the MFN Model, including this subpart.

(2) Quality measure information and the quality of services performed under the terms of the MFN Model, including this subpart.

(3) Patient safety.

(4) The accuracy of model-specific payments made under the MFN Model.

(5) Utilization of items and services furnished under the MFN Model.

(6) Other program integrity issues.

(c) *Record retention.* The MFN participant must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment received by the MFN participant under the MFN Model or from the date

of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless--

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MFN participant at least 30 days before the normal disposition date; or

(2) There has been a termination, dispute, or allegation of fraud or similar fault against the MFN participant, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

§ 513.440 Enforcement authority.

(a) *Remedial action*—(1) *Grounds for remedial action.* In addition to any other grounds for remedial action that are permitted under the terms of this part, CMS may take one or more of the remedial actions set forth in paragraph (a)(2) of this section if CMS determines, in CMS' sole discretion, that an MFN participant:

(i) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(ii) Has failed to comply with any of the terms of the MFN Model, including applicable requirements of this part.

(iii) Has systematically engaged in the under delivery or over delivery of an MFN Model drug.

(iv) Has taken any action that threatens the health or safety of an MFN beneficiary or other patient.

(v) Has undergone a change of control that presents a program integrity risk.

(vi) Has submitted false data or made false representations, warranties, certifications or attestations in connection with any aspect of the MFN Model.

(vii) Has avoided at-risk beneficiaries, as this term is defined in § 425.20 of this chapter.

(viii) Has avoided patients on the basis of payer status.

(ix) Is subject to sanctions or final actions of an accrediting organization or Federal, State, or local government agency.

(x) Takes any action that CMS determines for program integrity reasons is not in the best interests of the MFN Model or the Medicare program, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the MFN Model or Medicare program.

(xi) Is subject to investigation by HHS (including the HHS Office of Inspector General (OIG)) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act *qui tam* matter in which the Federal Government has intervened, or similar action;

(xii) Is the subject of administration enforcement action imposed by CMS; or

(xiii) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(2) *Taking remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a)(1) of this section exist, CMS make take one or more of the following remedial actions:

(i) Notifying the MFN participant of the violation.

(ii) Requiring the MFN participant to provide additional information to CMS or its designees.

(iii) Requiring the MFN participant to develop and implement a corrective action plan in a form and manner and by a deadline specified by CMS.

(iv) Subjecting the MFN participant to additional monitoring, auditing, or both.

(v) Removing the MFN participant from the MFN Model.

(vi) Recouping model-specific payments.

(vii) Other action as may be permitted under the terms of this part.

(b) *OIG authority.* Nothing contained in the terms of the MFN Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal Government authority or agency, including its authority to audit, evaluate, investigate, or inspect model participant for violations of any statutes, rules, or regulations administered by the Federal Government.

§ 513.450 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for any of the following:

- (a) The selection of models for testing or expansion under section 1115A of the Act.
- (b) The selection of organizations, sites, or participants, including MFN participants, to test the MFN Model, including a decision by CMS to remove an MFN participant from the MFN Model.
- (c) The elements, parameters, scope, and duration of such MFN Model for testing or dissemination, including without limitation all of the following:
 - (1) The selection of the model geographic area for the MFN Model by CMS.
 - (2) The selection of MFN Model drugs by CMS.
 - (3) The selection of included international data, including selection of countries, international drug pricing databases, and international drug pricing data.
- (d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- (e) The termination or modification of the design and implementation of an MFN Model under section 1115A(b)(3)(B) of the Act.
- (f) Determinations about expansion of the duration and scope of the MFN Model under section 1115A(c) of the Act, including the determination that the MFN Model is not expected to meet criteria described in paragraphs (c)(1) or (2) of such section.

Subpart F—Waivers

§ 513.500 Waivers of Medicare program requirements for purposes of testing the MFN Model.

CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the MFN Model:

(a) Sections 1833(t)(6) and 1833(t)(14) of the Act and §§ 419.62 and 419.64 of this chapter related to Medicare payment amounts for drugs and biologicals under the hospital outpatient prospective payment system (OPPS) as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(b) Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and biologicals as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(c) Sections 1847A(b) and 1847A(c) of the Act and §§ 414.904 and 414.802 of this chapter related to use of the ASP-based, WAC-based, or other applicable payment methodology and calculation of manufacturers' ASP as necessary to permit testing of an alternative payment for MFN Model drugs and to exclude certain units of MFN Model drugs from manufacturers' ASPs.

(d) Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug that is determined under § 513.220 as necessary to permit testing of an innovative payment approach for the alternative add-on payment amount.

(e) Section 1833(a)(1)(S) of the Act related to Medicare payment for drugs and biologicals is 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) of the Act as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(f) Section 1833(a)(1)(G) of the Act related to the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services

furnished to an individual in an ASC must be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(g) Section 1833(t) of the Act related to how beneficiary copayment is calculated under the OPSS as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C of this part.

(h) Section 1833(t)(9)(B) of the Act related to the requirement that Medicare account for adjustments to ensure that the amount of expenditures under the OPSS for the year does not increase or decrease from the estimated amount of expenditures under the OPSS that would have been made if the adjustments had not been made.

Subparts G through J — [Reserved]

Subpart K--Model Termination

§ 513.1000 Termination of the MFN Model.

(a) CMS may terminate the MFN Model for reasons including, but not limited to, the following:

- (1) CMS determines that it no longer has the funds to support the MFN Model.
- (2) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act.

(b) As specified in section 1115A(d)(2) of the Act, termination of the model in accordance with section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

Dated: November 18, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 18, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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