Interim Final Rule with Comment Period
Medicare Program: Most Favored Nation (MFN) Model for Part B Drugs
SUMMARY

The Centers for Medicare & Medicaid Services (CMS) released an Interim Final Rule with Comment (IFC) on November 20, 2020 creating an MFN Model for Part B drugs. The IFC will be published in the *Federal Register* on November 27, 2020. **The display copy of the rule indicates that the public comment period will end 60 days from publication in the *Federal Register* which would be January 26, 2021.** The rule is effective upon publication but the MFN Model will not begin until January 1, 2021.

The MFN Model prices Medicare Part B drugs based on international prices in all states and U.S. territories for 7 performance years—from January 1, 2021 to December 30, 2027 for 50 single source drugs and biologicals that encompass a high percentage of Medicare Part B drug spending. Participation is mandatory. Unlike a previously published Advanced Notice of Proposed Rulemaking (ANPRM), the IFC does not change how Part B drugs are acquired by hospitals and physicians (e.g. it does not require hospitals and physicians to obtain drugs from a government contracted vendor that negotiates prices with drug manufacturers and distributors).

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I. Overview

The MFN Model will have the following major features:

- Rather than paying for drugs based on manufacturer report ASP, Medicare will pay no more than the lowest price paid internationally among 22 Organization for Economic Cooperation and Development (OECD) countries with per capita gross domestic product of at least 60 percent of the US. The MFN Model price will be GDP adjusted to make it comparable to purchasing power in the U.S.
- Rather than paying a six percent add-on of the manufacturer reported ASP to the provider or supplier administering the MFN drug, Medicare will instead make a flat-add on payment that is not subject to beneficiary coinsurance.

II. Background on Need for Regulatory Action

CMS recounts the federal government's interest in controlling Medicare Part B drug prices through prior publications including:

- The Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs released on May 11, 2018;
- The ANPRM released on October 25, 2018; and
- Executive Orders (EO) released on July 24, 2020 and September 13, 2020 regarding an MFN and "Lowering Drug Prices by Putting American First."

As noted above, the ANPRM would have changed the acquisition and drug distribution model for Medicare Part B drugs by having the federal government contract with a vendor that would negotiate drug prices with drug manufacturers and distributors. Physicians and hospitals would then obtain Part B drugs from these vendors. Prices would be limited by an index based on prices in several European countries. The MFN Model specifically considered public comments on the ANPRM and has been modified accordingly—most significantly by not adopting the changes to the acquisition and drug distribution networks currently in existence. Further, CMS is adopting the MFN Model at this time in response to the President's September 13, 2020 EO ordering CMS "...to implement…rulemaking…to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price."

A. Medicare Part B Drug Benefit and Average Sales Price (ASP) Methodology

Medicare Part B drugs (typically drugs administered via injection or infusion in a physician's office or a hospital outpatient department but also drugs administered through an item of durable medical equipment (DME) among others) are paid 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. CMS, citing the Medicare Payment Advisory Commission, indicates that the add-on may be needed to account for handling and overhead costs and additional mark-up in distribution channels. The regulation expresses concern

that a percentage add-on provides incentives to use higher cost drugs. These higher costs affect beneficiaries who pay 20 percent of the Medicare payment amount.

B. Medicare and Beneficiary Spending

CMS indicates that 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. It also cites an Issue Brief from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) that Medicare Part B 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). The rule indicates that 77 percent of Medicare Part B drug spending is on biologics that do not have generic substitutes. Generic substitutes in Medicare Part D and in retail pharmacy control spending through competitive market forces that can help keep prices low.

C. Relative High Price of Medicare Part B Drugs

The IFC cites a study that the prices for 27 Part B drugs accounting for 64 percent of spending are higher in the U.S. than in 16 other developed European countries. The U.S. had the highest drug prices for 19 of the 27 products. An ASPE study showed that in 2018 ASP rates were at least 2.05 times the value-weighted average price for these drugs OECD countries with per capita GDP at least 60 percent of the U.S'.

III. Provisions of the Interim Final Rule with Comment

A. Model Performance Period

The performance period will be January 1, 2021 through December 31, 2017. The 7-year performance period will allow a transition to the target price by performance year 4 and adequate duration of the model to understand its impact.

B. Defined Population

The defined population will be all Medicare fee-for-service (FFS) beneficiaries receiving an included model drug from an MFN participant.

C. MFN Participants

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. The following are excluded:

- Children's hospitals;
- PPS-exempt cancer hospitals and Extended Neoplastic Disease Care Hospitals (there is only one);

- Critical Access Hospitals;
- Indian Health Service facilities;
- Rural Health Clinics and Federally Qualified Health Centers;
- Hospitals that are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Social Security Act ("the Act") which will be hospitals in the U.S. territories;
- Drugs that administered through an item of DME;
- Drugs that are administered on an inpatient basis but paid under Medicare Part B; and
- Claims paid under the End Stage Renal Disease Prospective Payment System.

Maryland Total Cost of Care Model and Pennsylvania Rural Health Model participants paid on the basis of global budgets will also be excluded for the first and second quarters of performance year 1. These hospitals will continue to be excluded if they continue to be paid based on global budgets and the budget is adjusted for the difference in payment between the MFN Model and non-MFN Model drug payments.

Table 1 of the IFC (a portion of which is extracted below) shows that more than 85 percent of Medicare Part B drug spending is accounted for by physician offices and hospital outpatient departments.

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	2019 Medicare Part B Allowed Charges	Percent of Total
Office	74,479	$20,847,712,641	51.10%
Outpatient Hospital	3,230	$13,896,570,373	34.06%
DME	8,523	$1,999,151,286	4.90%
Cancer Hospital	11	$1,143,173,710	2.80%
All Other	31,335	$2,913,930,405	7.14%
Total	117,578	$40,800,538,415	100.00%

Participation is mandatory and participants will not have to take any action to be enrolled in the MFN Model. However, model participants will have to adhere to specific beneficiary protection requirements established for the model, billing instructions established by CMS and local Medicare Administrative Contractors (MAC) and participate in monitoring and evaluation activities including reporting of information.

Manufacturer ASP reporting will not include MFN Model drugs. While model participants are not being required to furnish information to drug manufacturers about the number of drug units paid under the MFN, manufacturers may require such information from purchasers which may create burden on model participants.

In response to administrative concerns raised on the ANPRM about testing the model in some parts of the country but not others, CMS is applying the MFN Model nationwide.

D. MFN Model Drugs

CMS is beginning the MFN Model with 50 Medicare Part B drugs with the highest annual spending among approximately 550 HCPCS codes listed on the quarterly ASP pricing files. These drugs account for approximately three-quarters of annual Medicare Part B drug spending. MFN drugs are only those drugs that are separately paid. Packaged or bundled drugs are excluded.

Certain vaccines, radiopharmaceuticals, oral drugs, compounded drugs, intravenous immune globulin products, HCPCS codes that include generic drugs and drugs under an Emergency Use Authorization or approval by the Food and Drug Administration (FDA) to treat patients with suspected or confirmed coronavirus disease 2019 (COVID-19) are excluded. CMS will exclude drugs deemed to be in short supply on a quarterly basis from the MFN Model.

CMS will update the list of drugs included in the MFN Model annually but expects the list to remain stable from year to year. The latest full year of Medicare Part B drug spending will be used to determine included drugs for the 2nd subsequent calendar year (e.g. 2019 spending is being used for 2021 or year 1 of the model.) Drugs will only be added to the list of MFN drugs. None will be removed. CMS believes this approach will have the advantage of adding drugs to the list where spending increases because of switches to using drugs not part of the MFN Model.

The IFC seeks comment on whether to exclude all blood related, plasma derived, and human tissue products. The comment solicitation asks 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. CMS also requests comment on whether to exclude 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 rare diseases or conditions. These products may not have sufficient spending currently to be included among the top 50 drugs but the potential for growth in spending could make them eligible. CMS requests comment on how to identify such drugs for exclusion, identify rare diseases and conditions and determine the appropriate length of such exclusion.

CMS is also considering whether to except drugs from inclusion in the MFN Model where U.S. pharmaceutical manufacturers do not own the distribution rights outside the U.S. and do not control non-U.S. pricing for the drug product. To avoid a manufacturer engaging in a business arrangement to provide distribution rights to another entity outside the U.S. to avoid participation in the MFN Model, this type of exception could be defined such that only ownership rights that were transferred prior to the October 2018 ANPRM would qualify. The October 2018 NPRM publication date would be selected because that is the date manufacturers were first on notice of CMS' plans to develop an MFN or MFN-like model. The exception could also be limited to those drugs where the U.S. price has grown more slowly than inflation since October, 2018 and where the U.S. manufacturer makes a legally enforceable commitment to future U.S. price increases being slower than inflation.

Table 2 displays the list of MFN Model drugs by HCPCS code for performance year 1, along with the top billing specialties.

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

Rank	HCPCS	Short Descriptor	2019 Allowed Charges	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	Gastroenterology	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

Rank	HCPCS	Short Descriptor	2019 Allowed Charges	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
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
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

CMS will publish this HCPCS code list quarterly on the MFN Model website (https://innovation.cms.gov/initiatives/most-favored-nation-model), in advance of the calendar quarter, along with payment amounts and other relevant information and materials. Table 3 (a portion of which is excerpted below) shows the distribution of these drugs by provider and supplier type.

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	2019 Medicare Part B Allowed Charges	Percent of Total
Office	18,783	$16,896,364,008	56.64%
Outpatient Hospital	2,579	$10,970,275,972	36.77%
All Other	2,327	$1,964,188,568	6.59%
Total	23,689	$29,830,828,548	100.00%

E. Model Payment Methodology

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. 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. Beneficiary cost-sharing will apply to the MFN drug payment amount for included drugs.

CMS will calculate an MFN drug payment amount 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. The MFN drug payment amount cannot exceed non-model payment for the drug excluding any non-model add-on payment amount.

1. Data Sources on International Drug Pricing Information

Rather than requiring manufacturers to report international pricing information, CMS 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. 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.

CMS will use one or more data sources, available to CMS at least 20 business days prior to the start of a calendar quarter. Data sources will utilize a standardized method for identifying drugs

across countries. For instance, the data source will use 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 distinguish among injectable, oral, and other forms of a drug. For example, the data source might use International Nonproprietary Names, as applicable. This process requires mapping between the data source's standardized method for identifying scientific and nonproprietary names and HCPCS codes.

For each MFN Model drug, CMS will identify and use the most comprehensive data source available. Only one data source will be used for an MFN Model drug for a quarter. International drug pricing information from two calendar quarters prior to the calendar quarter to which the MFN drug payment amount will apply in the same way as ASP is used. The hierarchy of data sources CMS will use is as follows:

- A data source with sales and volume data for the applicable ASP calendar quarter from at least one 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 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; or
- A data source with list price data for the applicable ASP calendar quarter from at least one included country.

Levels 4 and 5 of the hierarchy will only apply to MFN Model drugs that are added to the list after performance year 1 and perhaps for Q2043 (Sipuleucel-t auto cd54+) and J2507 (Pegloticase injection). For MFN Model drugs in performance year 1, the first three levels of the hierarchy will always result in an available data source.

CMS will use international sales and volume information from as early as the third calendar quarter in 2020 to minimize the possibility of having no international sales and volume information with which to calculate the MFN price. This process will mitigate the potential effect of manufacturers' limiting the reporting of international drug pricing information during the model performance period. In addition, one or more data sources will have mechanisms in place to maintain, update, and correct, if necessary, the data source on at least a quarterly basis. Data sources 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.

CMS plans to monitor the implementation of a World Health Assembly 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.

Using the hierarchy described above, CMS will prioritize use of data sources that incorporate discounts and rebates to the extent possible in order to minimize a shift to higher prices followed by larger rebates. This addresses a concern raised by commenters on the ANPRM that manufacturers will engage in this type of practice to keep nominal prices high but effective international prices low.

CMS will align the extracted data in accordance with the HCPCS code descriptor for the MFN Model drug. Other adjustments may be made to ensure that extracted data is comparable to ASP data (such as when the international price is adjusted for overfill and the U.S. price is not). Data without both sales and volume data will be excluded as will international data with less than $1,000 in quarterly sales or less than 1,000 units in quarterly volume. Overall, CMS reports that where this approach had more than a 1 percent impact, MFN prices tended to increase.

The international drug pricing information data sources that CMS is using 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 it does with ASP pricing, CMS will recalculate the MFN drug payment amounts for up to four prior quarters when revised international drug pricing information is available. In cases where the MFN drug price is recalculated, CMS will prospectively apply the recalculations in the quarterly update. CMS will not automatically reprocess claims, but reserves the right to do so.

CMS seeks comment on whether there should be a threshold change in a drug's price or the drug's price changes by more than a nominal amount before there is a recalculation. If so, CMS asks commenters to suggest the appropriate amount of the threshold or nominal amount. **CMS also seeks comment on how to proceed with the hierarchy of data sources to use when an error is discovered in an international data source but that error is not corrected within 180 days after the applicable ASP calendar quarter**.

2. International Data Included in the MFN Model

Based on comments on the October 2018 ANPRM, CMS believes it is most appropriate to include available international drug pricing information for OECD countries with a GDP per capita of at least 60 percent of the U.S. GDP per capita. This criterion is intended to ensure comparable pricing power exists between the U.S. and other countries whose drug pricing data is being used for pricing Medicare Part B drugs. CMS will update the list of countries using the CIA World Factbook as its GDP data source as it is issued by a U.S. government agency and includes GDP estimates for all OECD member countries.

To avoid creating a potential incentive for countries to discontinue their membership in the OECD, CMS 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 these criteria, CMS 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. CMS believes its 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.

3. Definition of the MFN Drug Payment Amount

CMS will calculate the MFN drug payment amount for a calendar quarter based on a phased-in blend of the applicable ASP and the MFN price, which will be determined 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

CMS 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 its criteria for at least one included country. To fairly compare country-level prices, CMS will adjust the extracted country-level prices if the country's GDP per capita is lower than that of the U.S.

The following steps will be followed to determine the MFN drug price:

- 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)
- 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;
- Calculate 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;
- 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 describes these steps:

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

CMS will extract the available international drug pricing information for an MFN Model drug for the applicable time period 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 International Nonproprietary Names). Only extracted data from the selected data source that appears complete and represent dosage formulations that could fit the MFN model drug's HCPCS code descriptor will be used. CMS will limit the international drug pricing data for combination drugs that contain multiple active ingredients or biological products to the extent feasible.

If more than one data source is available, CMS will select the data source that is most consistently available across quarters even if another data source includes a higher number of included countries in a particular quarter. 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 20 countries, CMS may use an available with data source with sales and volume data for only 15 countries if that data source was used in a prior quarter.

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

CMS will exclude data without both sales and volume data, or quarterly sales of less than $1,000 (expressed as U.S. currency), or sales of less than 1,000 units in a quarter.

c. Convert the Volume Data to Match the HCPCS Code

CMS will adjust volume data to the same level as the HCPCS billing unit, as applicable. For injectables where the HCPCS code is specified as per dose, CMS will limit the number of billing units in a package to one per vial.

d. Calculate the Unadjusted Country-Level Price

The unadjusted country-level price represents the weighted average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit. If volume is unavailable, the unadjusted country-level price will be unweighted.[1]

If no international data source is available that meets MFN Model criteria, CMS will use the applicable ASP as the MFN Model drug payment amount.

[1] This statement appears to be in conflict with the previous one where CMS says that it will only use an international data source if both price and volume data are available.

e. Calculate and Apply the GDP Adjuster and Select Lowest GDP-Adjusted Price

Each country's GDP adjuster will be a straight ratio of its GDP per capita divided by the U.S. GDP per capita capped at 1.0 so as to only increase an international price, not decrease it. The unadjusted country-level price will be divided by the GDP adjustor. The lowest GDP-adjusted country-level price will be the MFN price for the MFN Model drug. If the MFN price is lower than the applicable ASP, ASP will become the MFN price.

Table 4 of the rule 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. Below is an extract of that table for countries with GDP per capita that is at least 60 percent of the U.S.'s.

OECD Country	GDP Per Capita (2017)	GDP Adjustor Year 1, QTR 1
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

f. Identify the Applicable Phase-in Formula and Adjustments

CMS 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, unless an adjustment accelerates the phase-in (explained further below). Table 5 shows the blend percentages.

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

Performance Year	Blend of the ASP and MFN price
Year 1	75% ASP, 25% MFN
Year 2	50% ASP, 50% MFN
Year 3	25% ASP, 75% MFN
Years 4 through 7	100% MFN

g. Calculate the MFN Drug Payment Amount

As the last step, CMS will calculate the MFN drug payment amount using the applicable blend of the ASP and MFN price and any other applicable adjustments.

5. Illustrative MFN Drug Payment Amounts

Below is an extract of Table 6 of the rule for one code showing illustrative data for applicable ASPs, MFN prices and MFN drug payment amounts for one billing unit using the above blend percentages. CMS will publish the quarterly MFN drug payment amounts on a CMS website (such as the MFN Model website), similar to how the ASP drug pricing files are posted online prior to the start of the calendar quarter.

The below is a sample of the information presented in Table 6 for one code.

HCPCS Code	Descriptor	Dosage	2019 Quarter	Illustrative 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	
			Q3	$51.744	$12.862	$42.024	
			Q4	$51.965	$12.883	$42.195	

6. Timing of Data and MFN Drug Payment Amount Calculations

ASP date are currently collected for a calendar quarter and used for Part B pricing in the 2nd subsequent calendar quarter (e.g. 3rd quarter 2020 ASP data is used for the 1st quarter 2021 Part B drug pricing). MFN pricing will reflect the same schedule (if available) in accordance with the hierarchy specified above. Table 7 illustrates this schedule.

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

Performance Year	Performance Year Quarter	ASP and MFN price is from:
1	2021, Q1	2020, Q3
1	2021, Q2	2020, Q4
1	2021, Q3	2021, Q1
1	2021, Q4	2021, Q2

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

In response to comments on the October 2018 ANPRM that manufacturers may increase Part B drug prices outside of the model, CMS adopted the phase-in percentage to MFN prices to allow time for manufacturers to adjust to the MFN Model payment amounts and processes. For this same reason, CMS is excluding 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, CMS will make an adjustment to the phase-in formula for an MFN Model drug if the applicable ASP or monthly U.S. list price[2] 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 ASP 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) 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.

The baseline for measuring the cumulative percentage increase will be the later of the third calendar quarter of 2020 (July 2020 through September 2020) or the first calendar quarter that the drug is on the market. The cumulative percentage change will be calculated from the baseline to the end of the applicable ASP calendar quarter. The adjustment will apply to the phase-in formula similarly for all MFN Model drugs regardless of when the MFN Model drug is added to the MFN Model. Both of the above conditions must be met to trigger a change to the phase-in percentage. If the cumulative percentage change in the CPI-U or MFN price is negative, CMS will use zero as the cumulative percentage increase in the CPI-U or MFN price, as applicable, for the relevant quarter.

For example, if the trigger conditions are met for the second quarter of performance year 1, the phase-in formula would change from 75 percent ASP/25 percent MFN to 70 percent ASP/30 percent MFN. If the trigger conditions are met in either of the subsequent quarters, an additional 5 percentage points (65 percent ASP/35 percent MFN price) will be applied. 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.

[2] 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)

Further, after the full phase-in of the MFN price is reached, if both trigger conditions are met, there will be a further decrease in MFN Model drug price based on the larger of the difference between ASP increase and the CPI-U or the MFN price increase. For example, if a drug's ASP cumulatively increased by 14 percent, the CPI-U cumulatively increased by 12 percent, and the MFN price cumulatively increased by 11 percent, CMS would reduce the MFN price by 3 percent (that is, the difference between 14 and 11). Any such additional adjustment will apply for the duration of the model performance period, unless a larger additional adjustment is triggered.

8. Limitation on MFN Drug Payment Amount to Protect Beneficiaries

To avoid potentially increasing beneficiary cost-sharing or coinsurance, CMS will pay the lower of the actual charge on the claim, the MFN price or the ASP price outside of the model. Beneficiary coinsurance will be based on 20 percent of the amount paid by Medicare. In cases where a hospital acquires the drug under the 340B drug discount program, the Medicare payment amount will be the 340B Medicare drug price amount if that is lower than the MFN Model price.

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

CMS will update the list of drugs included in the MFN Model annually. Any drugs added to the MFN will be paid at the phase-in percent for that program year (e.g. 50 percent ASP/50 percent MFN if the drug is added in program year 2). **For future years, CMS seeks comment on whether there is additional information that could be provided that would be helpful to MFN participants for their planning purposes, for example drug utilization reports developed through the model monitoring activities that could provide insight on the potential for specific drugs to be added to the model**.

10. Payment Exceptions for MFN Model Drugs in Short Supply

Rather than broadly excluding drugs that are in short supply from the model, CMS will keep drugs in shortage in the MFN Model but pay them based on ASP as long as the drug remains on the FDA shortage list.

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

CMS will continue to pay the furnishing fee for blood clotting factor products included in the MFN Model.

F. MFN Model Alternative Add-On Payment

1. Overview of the Alternative Add-on Payment

As required by section 1847A of the Act, Medicare Part B currently pays an add-on payment based on 6 percent of a drug's ASP. In the October 2018 ANPRM, CMS solicited comments on potential alternatives to the current add-on payment system that would remove the percentage-based drug add-on payment. Commenters noted that because of sequestration, the amount of

add-on is 4.3 percent of a drug's ASP.[3] CMS received feedback from a number of stakeholder groups; there was no consensus on the best approach to designing an alternative add-on payment. After considering the comments, CMS decided that any alternative add-on should be straightforward and minimize administrative burden.

CMS will pay MFN participants a single add-on payment amount per dose of an MFN Model drug. For the purposes of the MFN alternative add-on payment, "dose" is defined as the number of HCPCS billing units reported on a claim line[4] except when a claim is billed with the modifier JW, which indicates discarded drug. Thus, 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. CMS will also waive beneficiary cost-sharing for the add-on payment.

As codified at §513.220, CMS will calculate an alternative add-on payment based on 6.1224 percent of historical applicable ASPs for 2019 final action claim lines for the selected MFN Model drugs trended forward using an inflationary adjustment for the start of performance year 1.[5] The per-dose add-on payment amount will be calculated only at the beginning of the model and will not be recalculated as the MFN Model Drug HCPCS Codes List changes. Beginning with the second quarter of performance year 1, CMS will update the per-dose add-on payment amount quarterly using an inflation factor.

CMS selected 6.1224 percent because that amount results in an add-on pool that provides, on average, a 6 percent add-on per dose after sequestration.[6] In the absence of actual drug acquisition costs, CMS believes it is appropriate to use an add-on pool that represents, on average, a 40 percent increase compared to the add-on of 4.3 percent of ASP in use during the baseline period (2019).

2. Per-Dose Add-On Payment Amount Methodology

a. Calculation of the Single Per-Dose Add-On Payment Amount (§513.220(b))

Using 2019 historical claims data, CMS calculated a per-dose add-on payment amount by applying the applicable ASP[7] to the identified 2019 claims lines, based on the calendar quarter in which the claim's date of service falls. This corresponds to the manufacturer-reported ASPs from two calendar quarters prior, with the exception of biosimilar biological products. CMS excluded claims submitted by excluded providers and suppliers such as CAHs and cancer hospitals

[3] Under the OPPS payment for certain drugs acquired under the 340B program is based on ASP -22.5 percent and are not considered to include a drug add-on payment amount. CMS refers readers to the 2021 OPPS/ASC proposed rule for a discussion of CMS' proposals for 2021 (85 FR 48889).
[4] Claim line is also referred to as service line or line item.
[5] To align with the determination of the add-on amount for biosimilar biological products, for these products CMS will use 6.1224 percent of the historical applicable ASPs for the reference biological product. Based on the MFN Model Drug HCPCS Code List for performance year 1, this applies to Q5111 (injection, udenyca 0.5 mg.
[6] Section 3709 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act temporarily suspends Medicare sequestration from May 1, 2020 to December 31, 2020.
[7] The payment amount is determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage.

(§513.100(c)), claims processed by DME MACs (§513.100(d)), and claims where Medicare was not the primary payer. CMS included all relevant claim lines for an MFN Model drug with an allowed charge greater than zero dollars. Because it used nearly all the 2019 claims for drugs on the MFN Model drug list, CMS believes that one calendar year provides sufficient data for calculating the single per-dose add-on payment amount.

Specifically, CMS used the following steps to calculate a single per-dose add-on payment:

1. Multiplied the number of HCPCS units billed on each claim line by 6.1224 percent of the applicable ASP 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 the drug.
2. Pooled together the total add-on spending amounts for all drugs on the MFN Model HCPCS Codes List and the total number of claim lines for those drugs (excluding claim lines billed with the JW modifier).
3. 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.

The calculated single per-dose add-on payment amount, prior to application of the inflationary factor, is $146.55.

b. Trending the Single Per-Dose Add-On Payment Amount Forward Each Calendar Quarter During the MFN Model (§513.220(b)(7))

To account for inflation over time, CMS will trend forward the single per-dose add-on payment amount each calendar quarter by using a cumulative inflationary factor. CMS will not use changes in ASP or MFN drug payment amount to trend forward the single per-dose add-on payment amount. Specifically, CMS 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 (July 2019) through the first month of the calendar quarter prior to the start of the model (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, CMS will multiply the performance year, quarter 1 alternative add-on payment amount by a cumulative inflation factor and ensure the amount will remain equal to or greater than the amount calculated for the performance year, quarter 1. Specifically, CMS 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, CMS will use an inflation factor of 1. For example, the cumulative inflation factor for performance year 1, quarter 3 (July 1, 2021 through September 30, 202100 will be the percentage increase in the CPI-U from October 2020 through April 2021.

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

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

CMS discusses the impact of the per-dose add-on payment amount. The single per-dose add-on payment 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 payment for drugs with relatively lower historical applicable ASP-based payment amounts per dose. For the MFN Model drugs, average historical add-on payment amounts per dose 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 after sequestration, represents an increase in the add-on payment amount for 70 percent of doses when compared to the historical add-on amount of 4.3 percent of the applicable ASP after sequestration.

Table 8 (reproduced below at the end of this section) shows the estimated variations in impacts for the top 35 specialties.[8] CMS assigned each provider's or supplier's CMS Certification Number (CCN) or Taxpayer Identification Number (TIN) to only one specialty based on the specialty code with the highest total allowed spending for the entity's claim lines. CMS also assigned each specialty a value based on the percentage of its Medicare revenue that is related to Part B drugs: "high" means the specialty's drug revenue in 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. Each row in the table shows the size of the impact for a given specialty: the 5th percentile will experience the largest negative impact and the 95th percentile with have the largest positive impact. CMS notes that some of the large percentage increases seen in the 95th percentile column are likely driven by the small volume of drugs furnished by entities in this percentile.

Based on the single per-dose add-on payment amount of $146.55 (prior to the application of the inflationary factor) and using 2019 drug utilization, on average, MFN participants will have a 40 percent increase in revenue related to the MFN add-on payment amount compared to their 2019 historical Part B drug claims. Nine specialties will see a decrease in add-on revenue: hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecology/oncology, infectious disease, hematopoietic cell transplantation & cellular therapy, and dermatology. CMS notes that overall, entities with lower add-on revenue furnish more drugs with higher drug add-on payment amounts per dose more frequently than entities that are better off.

4. Beneficiary Cost-Sharing Responsibilities

CMS 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. MFN

[8] The analysis excludes 340B covered entities.

participants will continue to collect beneficiary cost-sharing applicable to the portion of the allowed payment based on the MFN drug payment amount. Medicare will pay the entire allowed payment amount that is based on the alternative add-on payment amount. CMS notes this will ensure that beneficiaries do not experience an increase in cost-sharing under the MFN Model due to the alternative add-on payment amount.

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.

G. Billing and Claims Processing Approach

CMS will issue model-specific claims submission instructions. MFN participants will be required to submit a separate claim line using a 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 units field of the claim line with the HCPCS code M1145 will indicate the number of doses of a separately payable MFN Model drug billed on the claim. CMS states the MFN participant will count the number of claims lines with a HCPCS code that is included on the MFN Model drug list (based on the date of service) and exclude claim lines billed with the JW modifier. MFN participants will continue to bill for wastage using a separate claim line and the JW modifier. CMS acknowledges this may increase the administrative burden for providers submitting claims.

CMS waives program requirements in section 1833(a)(1)(S)[9], section 1833(a)(1)(G)[10], and section 1833(t)[11] of the Act to allow flexibility for claims processing. Waiving these program requirements will allow the total allowable model payment to be calculated as the sum of the MFN Drug payment amount and alternative add-on payment amount and to not apply beneficiary cost-sharing to the alternative add-on payment amount.

H. Quality Measures

CMS describes principles for an MFN Model quality measurement approach, which it believes will allow it to test the MFN Model's alternative drug payment methodology, while safeguarding and monitoring beneficiary access and quality of care. The regulations (§513.400) set forth the policies for quality measurement and specify that quality measures are not used to adjust model payments. The quality measurement principles identified by CMS are:

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 (e.g., use claims-based measures where appropriate); and
3) establish standards for adding quality measures, if necessary, during the model.

After reviewing the comments received on the October 2018 ANPRM, CMS adopts one quality measure for the MFN Model, a survey of patient experience. The survey will be conducted by a CMS contractor (providers will not be involved) and fielded periodically beginning in performance year 1. It will sample beneficiaries receiving an MFN Model drug about their

[9] 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 amount of actual charges or the amount established in section 1842(o) of the Act.
[10] 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 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.
[11] Section 1833(t) of the Act specifies how payment under the OPPS is calculated including beneficiary copayment.

experience of care. Beneficiaries not in the model may also be sampled. The survey is described as asking beneficiaries about their "…experience of care, access, or other issues they experienced under the MFN Model…"

The IFC does not reveal the survey questions or the sampling methodology, and no process or timetable for developing the patient experience survey is discussed. CMS states that results of the survey will be used to monitor the impact of the MFN Model and potentially to inform development of educational materials for participants.

CMS repeatedly mentions its plans for monitoring the impact of the MFN Model, which are discussed in section I immediately below. Activities highlighted are analyzing claims data and using patient survey data and site visits to identify any unintended consequences of the model and to ensure that beneficiary access to medications and quality of care under the MFN Model is preserved or enhanced.

If in the future CMS determines that the quality measure and monitoring activities set forth in this IFC are insufficient, it may add more quality measures. The regulations specify that any additional measures under the MFN Model must meet the following criteria:

- Be among one or more of the following categories: patient experience of care, patient activation, shared decision making, adherence, utilization, and process measures;
- Not add significant burden to MFN participants or beneficiaries; and
- Use an instrument that CMS has used previously in a model to adjust payment or for monitoring or evaluation.

I. Beneficiary Protections and Monitoring Actions

This section of the IFC discusses application of existing Medicare rules regarding beneficiary freedom of choice and claims appeals to the MFN Model, provides for a financial hardship exemption for MFN participants under certain conditions, prohibits MFN participants from engaging in actions to avoid treating at-risk beneficiaries, establishes program monitoring and compliance activities, sets forth authority for enforcement of MFN Model requirements, and enumerates record retention requirements for MFN participants.

1. Beneficiary Freedom of Choice

Beneficiaries participating in the original FFS Medicare program are guaranteed the freedom to choose their providers by statute (section 1802 of the Act). To preserve this right under the MFN Model, the regulations (§513.410(a)) prohibit an MFN participant from restricting beneficiaries' ability to choose to receive care from any Medicare participating provider or supplier or from any provider or supplier who has opted out of Medicare. In addition, an MFN participant may not, through an action, omission, or policy, inhibit a beneficiary from exercising his or her freedom of choice. This does not prohibit an MFN participant from communicating to beneficiaries about the benefits of receiving care from an MFN participant, if otherwise consistent with the beneficiary freedom of choice protection.

2. Appeals Processes and Financial Hardship Exemption

The regulations explicitly state at §513.410(b) that an MFN beneficiary[12] retains the right to access to the existing formal claims appeals process (42 CFR part 405, subpart I). 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.

In addition, at §513.230 the IFC codifies a separate financial hardship exemption for MFN participants that is independent from the normal claims processing and appeals procedures. The exemption provides for additional payments to the participant, and is intended to ensure beneficiary access to MFN Model drugs and financial protections for physicians and other MFN participants who are unable to obtain MFN Model drugs at or below the MFN Model Payment amount and are significantly affected by their participation in the MFN Model. The exemption is provided at the sole discretion of CMS and is not subject to appeal.

In order to obtain a financial hardship exemption, an MFN participant must submit a request with in 60 days of the end of the performance year for which the exemption is sought. The request must be made in accordance with instructions on the MFN Model website and at a minimum must include all of the following content:

- 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- and off-invoice discounts or adjustments, and any other price concessions) that was furnished by the participant during the performance year to MFN beneficiaries.
- Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts and adjustments, and any other price concessions) that was furnished by the 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 participant's average net acquisition costs, with a justification of why such remuneration should not be treated as a price concession.
- Administrative information, including participant's name, TIN or CCN (as applicable), contact name, phone number, and email address.
- 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

[12] An MFN beneficiary is defined as one who is furnished an MFN Model drug by an MFN participant and who, on the date of service, is (1) enrolled in Medicare Part B, (2) has Medicare as his or her primary payer, and (3) is not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan.

to 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;
    - It has not 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 participant during the performance year that is not reflected in the participant's submission; and
    - The submission is true, accurate and complete.

CMS will post a template on the MFN Model website for participants to use in submitting the net acquisition costs and administrative information. It says this will be similar to the template used for the 2020 Hospital Survey for Specified Covered Outpatient Drugs Average Acquisition Cost for purposes of the 340B program.[13]

In reviewing requests for exemption, CMS will use its sole discretion to grant the request of an MFN participant who (1) submits a timely and complete request that demonstrates all of the conditions listed below, and (2) has an *excess reduction amount per beneficiary* that is greater than zero. Incomplete financial hardship exemption requests will not be considered by CMS. The request must demonstrate all of the following:

- The participant exhausted all reasonable methods to obtain MFN Model drugs at or below the MFN Model Payment for such drugs during the performance year.
- The participant's average net acquisition cost for each MFN Model drug (including invoices and off-invoice discounts or adjustments) furnished during the performance year to patients who were <u>not</u> MFN beneficiaries was not less than its average net acquisition costs for the same drug furnished to MFN beneficiaries.
- Any remuneration the 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.

The *excess reduction amount per beneficiary* is greater than zero if compared to the prior year, during the performance year the participant experienced a reduction in per beneficiary Medicare FFS allowed charges for separately payable Medicare Part B drugs that is greater than 25 percent of the prior year's allowed charges per beneficiary. CMS believes that the 25 percent threshold represents a significant year-to-year reduction and will protect participants from significant financial hardship under the MFN Model while also preserving the model's test of aligning payment for Medicare Part B drugs with the lowest international prices.

The *excess reduction amount per beneficiary* is calculated by CMS using available final action claims data where Medicare was the primary payer that is estimated to be more than 90 percent complete using the following steps. (CMS notes that claims are generally complete within 2

[13] This is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index under "Related Links."

months; non-claims-based payment payments such as performance adjustments and repayments are not included.)

1) For dates of service within the performance year and separately for the prior year, calculate the 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 participant with a Medicare Part A or Part B allowed charge greater than $0.
2) Calculate the participant's *average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year* by dividing the participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year as calculated in step 1 by the total number of beneficiaries calculated in step 1.
3) Similarly calculate the participant's *average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year*.
4) Subtract the participant's *average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year* (Step 2) from the participant's *average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year* (Step 3).
5) Calculate 25 percent of the 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) The MFN participant's *excess reduction amount per beneficiary* equals the difference calculated in Step 4 less the 25 percent share calculated in Step 5. If this amount is greater than zero, the threshold is met.

If a financial hardship exemption is granted for a performance year, as soon as practical CMS will make a reconciliation payment to the participant for that year equal to the *excess reduction amount per beneficiary* times the total number of beneficiaries with at least one claim for a service furnished by the participant with a Medicare Part A or Part B allowed charge greater than $0. The reconciliation payment amount is not subject to appeal.

The regulations specify that beneficiary cost sharing will not apply to the reconciliation payment amounts. CMS believes that because beneficiaries will have paid cost sharing based on the allowed payment amounts for the Part B drugs they received during the performance year, it would be confusing and burdensome for beneficiaries and participants to take steps to seek additional cost sharing amounts.

For performance year 1, CMS does not expect many MFN participants to quality for a reconciliation payment. That expectation reflects CMS' estimate that the overall reduction in Medicare Part B drug payments for that year will average 7 percent under the MFN Model's phase-in approach. CMS observes that 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. It notes further that hospital participants will likely have Medicare Part A revenues and purchasing abilities that

lessen the likelihood of qualifying for a financial hardship exemption. Non-hospital MFN participants will be more likely to potentially qualify in later performance years.

For future years, CMS seeks comment on whether an alternative threshold might better protect beneficiary access to MFN Model drugs or mitigate impacts on physicians and other MFN Model participants. CMS asks whether, for example, 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**. CMS also seeks comment on how to 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 the confidentiality of individual financial hardship exemption requests to the extent provided by law. However, it 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 amount. CMS does not intend to make such information available in an individually identifiable manner.

3. Availability of Services

The regulations prohibit MFN participants from taking 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 defined for purposes of the Medicare Shared Savings Program.[14] (These actions are sometimes referred to as "lemon dropping"). CMS commits to monitor participants' compliance with this requirement. It states 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

CMS establishes a monitoring program for the MFN Model at §513.420 that it says is consistent with other Innovation Center models. The regulations require that MFN participants agree to comply with all applicable laws and regulations, and participants must notify CMS within 15 days after becoming aware they are under investigation or have been sanctioned by the federal, state or local government or any licensing authority. If during its monitoring efforts CMS

[14] From 42 CFR 425.20: *At-risk beneficiary* means, but is not limited to, a beneficiary who—
(1) Has a high-risk score on the CMS-HCC risk adjustment model;
(2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;
(3) Is dually eligible for Medicare and Medicaid;
(4) Has a high utilization pattern;
(5) Has one or more chronic conditions.
(6) Has had a recent diagnosis that is expected to result in increased cost.
(7) Is entitled to Medicaid because of disability; or
(8) Is diagnosed with a mental health or substance abuse disorder

discovers that it has made or received an incorrect model-specific payment, it may make payment to, or demand payment from, the MFN participant.

Monitoring activities will be undertaken by CMS to ensure participant compliance and to obtain information about the effects of the MFN Model on beneficiaries, providers, suppliers, and the Medicare program. The goal is to facilitate real time identification of issues and timely response. The monitoring activities will include requests for documentation from participants including surveys and questionnaires; audits of claims data, medical records, and other participant data; interviews including with members of the MFN participant's leadership, management, and staff; interviews with beneficiaries and their caregivers; site visits; and tracking patient complaints and appeals.

CMS expects that monitoring of the MFN Model will include gathering and analyzing data captured through the Ombudsman's service, the evaluation of the MFN Model's patient experience survey, and audits of charts, claims data, medical records, and other data as available. The regulations stipulate that CMS or its designees may use any relevant data or information including all Medicare claims submitted for items or services furnished to beneficiaries in the MFN Model. MFN participants must cooperate with evaluation and monitoring 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.

With respect to scheduling site visits, the regulations require that to the extent practicable, CMS or its designee must provide the MFN participant with at least 15 days advance notice and attempt to accommodate the participant's request for particular dates. The participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS. The participant must ensure that personnel with the appropriate responsibilities and knowledge are available during all site visits. At any time, CMS may perform unannounced site visits at all physical locations of the MFN participant to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.
CMS identifies several subject areas that it intends to target in its monitoring and compliance efforts regarding the MFN Model. In some cases, this involves longer-term analyses.

- *Inappropriate billing.* Participants will be monitored (e.g., through documentation requests and audits of claims and medical records) to ensure that MFN Model drugs are not being inappropriately billed (for example, excessive doses or units). It expects this monitoring activity to discourage participants from furnishing smaller and more frequent doses of MFN Model drugs to beneficiaries in order to maximize the model's alternative add-on payments. If CMS finds that an MFN participant has been engaged in inappropriate billing, it will take remedial actions as discussed in section I.5 immediately below.
- *Reduced Access to Drugs.* Claims data and patient surveys will be analyzed to determine whether MFN beneficiaries continue to be able to access the right drug at the right time. For example, CMS will compare participants' case mix under the MFN Model to a pre-model historical baseline to determine whether complex patients are being systematically

excluded. Participants will be audited if CMS has reason to believe that they are compromising beneficiary access to care. In addition, CMS plans to analyze monthly claims data updates and make historic comparisons of trends including drug utilization, program spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and other indicators present in claims data. Prescribing pattern review will include observing for any shift to compounded drugs or other categories of drugs that are not included in the MFN Model. Physician visits, days in a hospital, and other services will be monitored to determine whether any treatment patterns are changing systematically, to detect issues with beneficiary access or potential provider and supplier payment issues.

- *Quality of Care Monitoring.* CMS does not describe specific quality of care monitoring activities, but anticipates that these may include claims and survey data analytics, site visits, medical record review, and tracking patient complaints and appeals. It will use claims data to track beneficiary utilization and outcomes under the MFN Model. CMS believes that these types of monitoring activities will allow it to promptly identify any unintended consequences of the MFN Model, and determine methods to address them.

5. Enforcement Authority and Remedial Action

The IFC provides that nothing in the terms of the MFN Model or new 42 CFR 513 limits or restricts 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 an MFN participant. Further, the IFC provides for remedial actions that CMS may take to address noncompliance with requirements of the MFN Model.

The regulations specify the grounds for when CMS, at its sole discretion, may take remedial actions with respect to an MFN participant. In addition to failure to comply with Medicare program requirements or the terms of the MFN Model, these grounds include systematically engaging in the under delivery or over delivery of an MFN Model drug; taking actions that threaten the health or safety of a beneficiary or other patient; undergoing a change in control that presents a program integrity risk; submitting false data or making false representations in connection with the MFN Model; avoiding at-risk beneficiaries; or avoiding patients on the basis of payer status. Additional grounds include a participant being subject to sanctions of an accrediting organization or a federal, state or local government agency; being the subject of a fraud or misconduct investigation by HHS or the Department of Justice; being the subject of a CMS enforcement action; being subject to a CMS determination that for program integrity reasons an action taken or not taken by the participant is not in the best interests of the MFN Model or the Medicare program; or failing to demonstrate improved performance following a remedial action.

When CMS determines that one or more of these grounds for remedial action are met, it may notify the MFN participant of the violation, require the participant to provide additional information, require the participant to develop and implement a corrective action plan by a specified deadline, subject the participant to additional monitoring or auditing; remove the

participant from the MFN Model, recoup model-specific payments, or take other actions. CMS may take one or more of the actions listed.

6. Audits and Record Retention

Because MFN participants will receive model-specific payments and access to payment rule waivers, CMS believes it is appropriate that it have the ability to audit, inspect, investigate, and evaluate records and other materials related to participation in the MFN Model. It notes that there are audit and record retention requirements under the Medicare Shared Savings Program and in current models being tested under section 1115A, such as the CMS Innovation Center's Comprehensive Care for Joint Replacement Model.

In §513.430 MFN participants are required to give the federal government (including CMS, HHS, and the Comptroller General, or their designees) access to all documents and evidence to enable the audit, evaluation, inspection, or investigation of the implementation of the MFN Model. Without limitation, this includes documents and other evidence regarding the participant's compliance with the terms of the MFN Model; quality measure information and the quality of services performed under the terms of the model; patient safety; the accuracy of model-specific payments made under the model; use of items and services furnished under the model; and other program integrity issues.

In general, the MFN participant must maintain the documents and evidence for a period of 6 years from the later of (1) the last payment received under the MFN Model or (2) the date of completion of any audit, evaluation, inspection, or investigation, whichever is later. Exceptions apply if CMS determines there is a special need to retain a particular records for a longer period and notifies the MFN participant at least 30 days before the normal disposition date, or if there has been a termination, dispute, allegation of fraud or a 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.

J. Interaction with Other Models and Programs

Based on its review, CMS expects Medicare beneficiaries who receive an MFN Model drug will also be assigned, aligned, or attributed to another Innovation Center model or CMS program. CMS does 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 the model test is an alternative approach to the add-on payment for Part B drugs. CMS does acknowledge that some models and programs will require adjustments to account for the payment changes under the MFN Model.

CMS does not expect the MFN Model to have significant impact on shared savings, total cost of care, or other benchmarks and measures for models or programs that focus on total cost of care, such as the Medicare Shared Savings Program. CMS will determine whether changes to benchmarks, targets, and reconciliation methodologies are necessary for other specific models or programs. CMS acknowledges that the design of some other models and programs could create

overlaps including potential overlaps resulting in overpayment of savings due to double counting the interventions from two different models.

CMS notes that Oncology Care Model (OCM) practices have the opportunity to receive a performance-based payment if they reduce the total cost of care in the OCM episodes compared to a target. Based on the performance year 1 MFN Model drug list, CMS anticipates substantial overlap between MFN participants and OCM practices. To avoid paying performance-based payments in OCM that are due simply to the drug payment changes under the MFN Model and not to changes in care delivery, CMS will adjust reconciliation calculations such that the drug payments in the OCM episode expenditures will be calculated as if the MFN Model were not occurring. CMS will provide additional information to OCM participants.

CMMI waived section 1833(t) of the Act for certain acute care hospitals participating in models under section 1115A of the Act for which payment for outpatient hospital services provided to Medicare FFS beneficiaries, including the MFN Model, is made under a fully capitated or global budget basis (discussed above in Section C). CMS will exclude these entities for the first and second quarters of performance year 1 from the MFN model; these entities include the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model. Beginning with the third quarter of performance year 1, these entities will only by excluded from the MFN Model if the parameters of the other Innovation Center model adjusts for the difference in payment for MFN Model drugs such that savings under the MFN Model are incorporated into the other model's parameters (e.g., the annual global budget). These exclusions will apply only during the period the hospital participates in a model in which it is paid on a fully capitated or global budget basis.

Quality Payment Program. The MFN Model will not qualify as either an Advanced APM or a MIPS APM under the Quality Payment Program. The MFN Model does not require participating health providers to meet all the requirements for an Advanced APM (such as using CEHRT) and does not meet the MIPS APM requirement for providers to be financially accountable for both the cost and quality of care provided to beneficiaries.

K. Interaction with Other Federal Programs

1. Impact on Medicaid

a. Impact on Medicaid "Best Price"

Medicaid Best Price is the lowest price of a drug (single source or innovator multiple source drug including biologicals) from the manufacturer during a rebate quarter to best price eligible entities or purchasers in the U.S. The MFN Drug Payment Amount is a Medicaid payment and will not be included in the manufacturer's best price determination.

CMS expects that the MFN Drug Payment Amounts will result in a decrease in drug prices to make drugs competitive with the MFN Drug Payment Amounts and reduce the risk of financial loss for MFN participants. If these market forces result in manufacturers reducing prices

available to MFN participants, these reduced prices will be considered in the manufacturer's best price determination and potentially lower best price and increase Medicaid rebates.

b. Impact on Average Manufacturer Price (AMP)

In general, AMP is the price wholesalers pay to purchase drugs from the pharmaceutical manufacturer for an outpatient drug distributed to retail community pharmacies and retail community pharmacies.[15] A separate AMP must be calculation for 5i drugs; 5i drugs are inhalation, infusion, instilled, implanted or injectable drugs not generally dispensed through a retail community pharmacies but are sold to physicians, pharmacy benefit managers, and hospitals.

Because the MFN Model includes certain Part B drugs that are infused in the outpatient setting, the price paid by an MFN participant to a manufacturer will be included in the AMP or 5i AMP calculation. If the manufacturer lowers prices to an MFN participant at or below the MFN Drug Payment Amount, the manufacturer's AMP for an MFN Model drug may be lower. Since the Medicaid drug rebate is partially based on a percentage of the AMP, a decrease in a drug's AMP may lower the applicable Medicaid drug rebate. CMS notes the resulting effect on the Medicaid drug rebate will depend upon any changes in both the AMP and best price.

CMS notes that if the APM for an MFN Model drug is lowered, the Inspector General, may find that the ASP for the drug exceeds the AMP for the drug and determine that CMS' non-model payment allowance for the drug should be 103 percent of AMP instead of the ASP.[16]

2. Interaction with 340B Program

The 340B Drug Pricing Program allows covered entities (certain hospitals and other health care providers) to obtain discounted prices on "covered outpatient drugs"[17] from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug which is the maximum price a manufacturer can charge a covered entity for the drug provided to an eligible patient. [18]

Covered entities will be included in the MFN Model and as MFN participants will receive the MFN Drug Payment Amount and the alternative add-on payment. As discussed above (section E), 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 OPPS for the MFN Model drug for the corresponding calendar quarter. The MFN alternative add-on payment is the same for all MFN participants, including 340B covered entities.

[15] AMP is defined at section 1927(k)(1) of the Act.
[16] Inspector General review is in accordance with section 1847A of the Act.
[17] Defined at 1927(k)(2) of the Act.
[18] The ceiling price is calculated as AMP minus Medicaid unit rebate amount. Since the Medicaid unit rebate amount is based partly on AMP minus best price, if the MFN Model affects a drug's AMP and best price, the 340B prices will be affected.

CMS notes that 340B covered entities may need to work with manufacturers to obtain MFN Model drugs within the MFN Drug Payment Amount. CMS estimates that 340B covered entities will realize a total add-on percentage amount of 4.5 percent in the first year of the model but this modest increase in add-on revenue might be offset through higher facility costs for acquiring MFN Model drugs. CMS estimates that 340B providers will have no impact to their costs for the first year of the MFN model. In the Regulatory Impact Analysis of this IFC, CMS discusses further potential impacts to 340B providers based on a variety of changes in drug prices, including international prices (discussed below in this summary).

3. Interaction with Medicare

Medicare Part B. CMS is excluding from the ASP calculation any units of an MFN Model drug provided to MFN beneficiaries and billed by MFN participants. Thus, ASPs for MFN Model drugs could be higher or lower resulting in Medicare payments to providers and suppliers that are not MFN participants that could be higher or lower than payments would have been absent the model.

Medicare Advantage. Medicare Advantage (MA) plans will not be MFN participants. MA payment to non-contracted, out-of-network providers for administration of an MFN Model drug will be based on the non-model Medicare FFS payment amount.

CMS expects the MFN Model will lower Medicare FFS expenditures which will impact the historical FFS claims experience for calculating the rates for plan services. As a result, CMS anticipates payments to MA organizations will be lower than they would be absent the model. CMS estimates 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. Because of uncertainties around the assumptions for these estimates, 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. This analysis is discussed in greater detail in the Regulatory Impact Analysis of this IFC (discussed below in this summary).

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

Reported ASP data is used to establish the Medicare payment amounts. In general, Medicare's payment for most separately payable Part B drugs is 106 percent of the volume-weighted average of manufacturers' ASP for a drug and is updated quarterly.[19] For purposes of testing the MFN Model, CMS will waive the payment requirements in section 1847A of the Act for MFN Model payments; these payment requirements will continue to apply to payments outside of the model.

CMS discusses the options it considered to mitigate potential impacts on manufacturers' ASPs because of potential price concessions given to MFN participants for both MFN Model drugs and drugs not subject to the MFN Model. CMS notes that sales to MFN participants may include price concessions that result in lower net sales prices as compared to what net sales price would be absent the MFN Model which in turn may lower the manufacturer's ASP and reduce payment

[19] In accordance with sections 1847A and 1927(b)(3) of the Act.

to providers that are not MFN participants. To minimize this potential, CMS will exclude from the calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants when the MFN Drug Payment Amount is based on available international drug pricing information and Medicare Part B is the primary payer. This policy will not apply when there is no available international drug pricing information and the MFN price is equal to the applicable ASP. CMS will indicate the MFN Drug Payment Amounts that are based on available international drug pricing information in the MFN Model drug pricing files posted on a CMS website. CMS will issue program instructions to describe how the waiver will impact manufacturers' calculation of the manufacturer's ASP.

CMS believes this approach is responsive to comments received in response to the October 2018 ANPRM. Based on stakeholder feedback, CMS acknowledges that all MFN participants will not have distribution management systems to provide information to manufacturers about the number of units and payment of MFN Model drugs that were furnished to MFN beneficiaries. CMS will allow manufacturers to establish mechanisms with MFN participants to obtain this information. CMS will not collect the number of units that manufacturers exclude from ASP.

CMS also wants to minimize the potential for excessive increases in non-model Medicare drug payments. CMS discusses how manufacturers' ASP may increase and cause a concomitant increase in non-model Medicare drug payment amounts. CMS notes that manufacturers could raise prices for MFN Model drugs in the U.S. to make up for price concessions that may be given to model participants. CMS believes its policy for manufacturers to exclude from the calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants when the MFN Drug Payment Amount is based on available international drug pricing information and Medicare Part B is the primary payer and the MFN price phase-in (discussed above in section E) will minimize the potential for manufacturers to increase prices for non-model participants and non-model purchases.

M. Program Waivers and Model Termination

CMS is testing the MFN Model under the authority of section 1115A of the Act and waives certain Medicare program requirements necessary for testing models described in section 1115A (b) of the Act.[20]

CMS waives the following program requirements that are necessary solely for 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 OPPS;
- Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and biologicals;

[20] 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 carry out section 1115 of the Act with respect to testing models described in section 1115A(b) of the Act.

- Sections 1847A(b) and 1847(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;
- Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug;
- 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 to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC 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 OPPS is calculated 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 for OPPS budget neutrality. CMS intends to use the applicable payment amount for each separately payable drug instead of using the MFN Drug Payment Amount and alternative add-on payment amount. Beginning in 2022, for purposes of the budget neutrality calculations, CMS may consider using drug volume for drugs included in the MFN Model but would utilize the applicable OPPS payment amount and not the MFN Drug Payment Amount. CMS believes a waiver of the OPPS budget neutrality requirement for Part B drugs furnished under the MFN Model is necessary to prevent redistribution of the reductions in Part B drug expenditures to non-drug Part B services under the OPPS. The MFN Model is not designed to change pricing for services that are not related to Part B drugs.

CMS states that to the extent that MFN participants receive separate payment for MFN Model drugs under program requirements that it has not listed, it waives such requirements as necessary to effectuate the MFN Model.

CMS may terminate the MFN Model for reasons including, but not limited to, the following: (1) CMS determines it no longer has the funds to support the model; or (2) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act which is not subject to administrative or judicial review.

N. Evaluation

CMS' evaluation of the MFN Model will include an analysis of the quality of care furnished under the model and the changes in Medicare spending related to the model.[21] Evaluation reports will be publicly posted on the CMS website. CMS will use the evaluation of the early performance years of the MFN Model for decisions related to performance years 5 to 7.

[21] An evaluation of the MFN Model is required under section 1115A(b)(4) of the Act.

CMS will evaluate several populations including Medicare beneficiaries who are likely to receive one of the MFN Model drugs based on recent diagnoses and/or prior treatment. CMS notes this population analysis will allow evaluation of possible prescriber behavior changes due to the MFN Model from prescribing MFN Model drugs to other alternative Part B or Part D drugs or vice versa. Other population evaluations could include MFN Model drug users and subgroups of particular patient populations such as cancer patients.

For each evaluation, CMS will create separate impact estimates for Medicare spending and drug/other health care utilization. Medicare spending will include 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 settings (e.g., inpatient hospital spending). The quality of care evaluation will examine drug access as measured by utilization of both Part B and Part D drugs and non-drug health care utilization that may change as a result of the MFN Model.

CMS discusses the evaluation design, interrupted time series (ITS), that it will use to evaluate this nationwide, mandatory model which lacks an independent comparison group. CMS notes that ITS is employed with and without comparison groups and the design can be used when data are available both for the pre-intervention period and the post-intervention period and the intervention occurs at a specific, identifiable point in time.[22] The pre-intervention period establishes a baseline that it used to project what would be expected in the absence of the intervention. Intervention effects are demonstrated when observations after the intervention start period deviate from the baseline projections.

CMS notes the most common statistical method for analyzing ITS data is segmental regression and the IFC includes a detailed discussion of the specifications for the analysis. The IFC also includes an illustration of a potential subgroup analysis and the expected changes that could be detected in the MFN Model evaluation of two groups of Medicare cancer patients. CMS states it is also interested in evaluating the model's impact on the Medicaid program and commercial insurance, including MA.

CMS also plans to evaluate the experiences of MFN participants (beneficiaries and providers) and other stakeholders affected by the changes in payment included in the model. To assess the model's impact on access to and quality of care, CMS will interview MFN participants either by focus groups, surveys, or one-on-one stakeholder interviews. CMS also plans to ask beneficiaries about their total out-of-pocket costs under the MFN Model. CMS will use the results of the qualitative analysis to provide additional context for the results of the quantitative analysis on health care spending.

CMS states the evaluation may require MFN participants to collect and submit additional data. These requirements will be incompliance with 42 CFR 403.1110(b) which requires entities

[22] 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, MNo.1: 348-355, doi:10.1093/ije/dyw098.

participating in a model under section 1115A to collect and report information as the Secretary determines is necessary to monitor and evaluate the model.[23]

O. Limitations on Review

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 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 the above authority, CMS is precluding administrative and judicial review of:

- CMS' selection of an MFN participant, as well as CMS' decision to terminate an MFN participant;
- The selection of the geographic area for the MFN Model;
- The selection of MFN Model drugs;
- The selection of included international data, including selection of countries, international drug pricing databases, and international drug pricing information; and
- The methodology for determining MFN prices, drug payment amounts, alternative add-on amounts, and reconciliation payments related to financial hardship exemptions.

IV. Regulatory Impact Analysis

The phased-in MFN price discount relative to applicable ASP is shown in Table 9 assuming current pricing relationships remain constant:

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

Year	2021	2022	2023	2024	2025	2026	2027
Price Impact	-16%	-33%	-49%	-65%	-65%	-65%	-65%

The IFC then presents impacts from CMS' Office of the Actuary (OACT) and the Assistant Secretary for Planning and Evaluation (ASPE).

[23] Collecting and reporting information includes protected health information as defined at 45 CFR 160.103.

1. OACT Estimate

Manufacturers could adopt several strategies in response to the model, such as:

- Charging a lower price to providers and suppliers inside the model;
- Refusing to adjust their price from the non-model amounts; or
- Altering the availability and terms of their international prices.

OACT expects the challenge to U.S. market revenues will lead manufacturers to devote considerable resources to the third option making OACT's assumption of the effects on pricing different than presented in Table 9. There will also be beneficiary reactions. OACT describes the following possibilities: accessing the drugs by traveling to a provider or supplier not participating in the model, accessing the drugs through a 340B provider in the model, or forgoing access.

There is not a reliable precedent upon which to base assumptions about responses to the pricing effects of the MFN Model. Given the high degree of uncertainty, OACT presented 3 scenarios:

1. An OACT estimate reflecting reasonable assumptions for potential changes in manufacturer, provider, and supplier behavior;
2. A Pricing-Effects Only scenario where all currently projected utilization is assumed to be retained; and
3. An extreme disruption scenario where non-340B utilization of affected drugs drops to zero percent.

Other estimates outside the range of the three scenarios could be reasonable as well, due to the wide range of potential responses. Among these are manufacturers increasing prices for non-Part B drugs, which would affect both private market and Part D expenditures. This possibility was not quantified.

a. OACT "Reasonable Assumptions" Estimate

The IFC provides the detail underlying OACT's assumptions for scenario 1 including strong resistance to the model from manufacturers and limited ability of beneficiaries to switch to non-MFN Model participants to obtain Part B drugs. Under these assumptions, some manufacturers will adhere to their current pricing instead of lowering sales prices in response to the model. Beneficiaries will have limited ability to obtain drugs outside of the model as the model encompasses all geographic areas. However, as the impact on 340B providers will be less than on other hospitals because of the large pricing reductions already being adopted, beneficiaries may have some limited ability to seek out Part B drugs at 340B hospitals. Table 11 below shows the OACT assumptions reflected for scenario 1:

TABLE 11—ASSUMPTIONS REFLECTED IN OACT ESTIMATE

	2021	2022	2023	2024	2025	2026	2027
Non-340B Providers							
Behavior							
Continued Availability	80%	75%	70%	70%	70%	70%	70%
Altered Availability							
Move to non-MFN	1%	1%	1%	1%	1%	1%	1%
Move to 340B	10%	10%	10%	10%	10%	10%	10%
No Access	9%	14%	19%	19%	19%	19%	19%
Total	100%	100%	100%	100%	100%	100%	100%
MFN price Impact	-16%	-25%	-25%	-25%	-25%	-25%	-25%
340B Providers							
Behavior							
Continued Availability	100%	100%	100%	100%	100%	100%	100%
MFN price Impact	0%	-3%	-3%	-3%	-3%	-3%	-3%

OACT estimates Medicare savings under this scenario at $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 or secondary market effects. This estimate is on a pre-COVID-19 basis, and is not adjusted for the effects of the pandemic.

b. Pricing Effects Only Illustration

To show the effects of the model absent any provider or beneficiary behavioral responses, OACT calculated the impacts of the payment changes alone. These values reflect the pricing changes inside the model, as shown in Table 9, and the assumption that manufacturers and MFN participants are able to continue to provide access to all drugs. Again, because 340B providers will receive the lesser of the model payment amount or the amount outside the model for the drug, no impact to their costs is expected for the first year. The net impact on Medicare after the premium offset is a savings of $155.6 billion over the 7-year period, and none of the impact would be due to lost utilization.

c. Extreme Disruption Illustration

Under this scenario, OACT 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 beneficiaries 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 goes below the baseline 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 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.

2. ASPE Estimate

ASPE made a number of assumptions based on published literature and expert consensus that they applied on a drug-by-drug basis. 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. 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 rule details other assumptions as well including that manufacturers will increase prices for non-MFN Model drugs but not so much that they will enter the top 50 Medicare Part B drugs and become part of the model. ASPE also considered that other countries will try to find ways to prevent spending increases while limiting disruption in their drug markets. Other detailed complex assumptions about substitution and utilization impacts were based on the availability of alternatives to MFN Model participants, beneficiary and behavioral changes occurring in other countries.

Table 15 summarizes the results of the ASPE analysis.

TABLE 15—ASSUMPTIONS REFLECTED IN ASPE ESTIMATE

	2021	2022	2023	2024	2025	2026	2027
Non-340B Providers							
Behavior							
Continued Availability	100%	100%	97.7%	95.9%	96.2%	96.5%	96.7%
Altered Availability							
Move to non-MFN	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%
340B Providers							
Behavior	100%	100%	100%	100%	100%	100%	100%
Continued Availability							
MFN price Impact	0%	0%	0%	0%	0%	0%	0%

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.

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 quantify these impacts.

3. Aggregate Effects on the Market

CMS notes that 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 including on Medigap plans and employee retiree coverage. 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.

Given the uncertainty of manufacturers' potential behavioral responses to the MFN Model, CMS is unable to quantify these potential spillover effects of the MFN Model but requests comments on these issues.

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

CMS estimates 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. Part B premiums are also estimated to decrease.

However, beneficiaries may be affected in other ways if MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies or there are problems with access to care. 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.

CMS also provides estimates of the burden on beneficiaries of completing these surveys.

5. Estimated Effect and Burden on MFN Participants and Manufacturers

CMS estimates modest compliance costs associated with the MFN Model that will not diverge from general monitoring requirements for Medicare Part B providers. However, there will be regulatory burden associated with answering surveys that will be administered as part of evaluating the demonstration project. CMS quantifies the estimates of the amount of burden associated with participating in these surveys.

6. Regulatory Flexibility Act Analysis

CMS expects total allowed charges for Medicare Part B drugs for MFN Model participants to go down commensurate with the phase-in of the MFN price. Although the alternative add-on payment was designed to hold MFN participants harmless based on current revenue to the greatest extent possible, some specialties will benefit from a higher aggregate add-on payment amount, while some portion of other specialties will have a decrease in aggregate add-on payments.

On average, CMS estimates that MFN participants 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. The total Medicare FFS impact would be a reduction of approximately $85.5 billion in Medicare spending in the OACT estimate and $52.1 billion in in the ASPE estimate over the 7-year model period. The majority of these reductions affect urban and non-340B MFN participants.

V. Waiver of Proposed Rulemaking and Delay in Effective Date

Under the Administrative Procedures Act and section 1871 of the Act, an agency is required to go through notice and comment rulemaking before a rule can take effect. These laws also require a delay in the effective date of final rules. However, there are provisions for waiving notice and comment rulemaking for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

CMS cites the high drug prices in the U.S. and their consequences for Medicare beneficiaries as the good cause reason to waive notice and comment rulemaking procedures for MFN IFC and any delay in the effective date. The IFC cites a number of studies reporting on the serious economic and health consequences for beneficiaries in need of treatment as well as the effect on Medicare premiums and out-of-pocket costs in both Part B and Part D of high drugs prices. CMS indicates the urgency for addressing high Part B drug prices is particularly acute because of the COVID-19 public health emergency.