HFMA
Center for Medicare & Medicaid Innovation Most Favored Nations
Interim Final Rule Executive Summary

On Friday, November 20, 2020, the Center for Medicare & Medicaid Innovation(CMMI) released the "Most Favored Nations" (MFN) interim final rule (IFC) that changes how CMS will pay for selected, separately payable Part B drugs. The MFN will test paying Part B drugs at comparable amounts to the lowest adjusted price paid by any country in the Organisation for Economic Co-operation and Development (OECD) whose gross domestic product (GDP) is comparable to the United States. Initially, the model focuses on a set of 50 separately payable Medicare Part B drugs that encompass a high percentage of Medicare Part B drug spending.

The mandatory model requires the participation of all Medicare providers and suppliers (with limited exclusions) that receive separate Medicare Part B fee-for-service payment for the model's included drugs. The MFN begins nationally January 1, 2021, and will run for seven years, through December 31, 2027. For the MFN, payment will be based on global prices and include a flat add-on amount for each dose. CMS estimates the model will reduce Medicare spending by $85.5 billion over its life. Exhibit 1 in the summary provides an impact estimate by specialty.

1) *Who is required to participate in the MFN*? The Model requires the participation of almost all Medicare providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs. Unlike other CMMI mandatory models, the MFN does not have any geographic limitations.

   MFN participants include Medicare-participating physicians, nonphysician practitioners, supplier groups (such as group practices), hospital outpatient departments (HOPDs) including 340 B covered entities, ambulatory surgical centers (ASCs), and other providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs.

   The MFN payment model does not apply when drugs covered under the MFN are:

   - Provided during an inpatient stay, not covered under Part A.
   - Administered during an inpatient hospital stay or included on an inpatient hospital claim.
   - Administered by the durable medical equipment Medicare Administrative Contractors (DME MACs)
   - Paid for under the End-Stage Renal Disease Prospective Payment System, including claims paid using the transitional drug add-on payment adjustment.

2) *Who is excluded from the MFN*? Providers who are not required to participate are limited to:
   a. Children's hospitals
   b. Prospective payment system-exempt cancer hospitals
   c. Critical access hospitals

d. Indian Health Service facilities
e. Federally qualified health centers
f. Rural health centers,
g. Non-subsection d hospitals paid on reasonable cost
h. Extended neoplastic disease care hospitals
i. Participants in certain CMMI models that make payment for hospital services (including outpatient services using a capitated or global rate[1,2])

3) *What drugs are included*? The IFC defines a process of how CMMI identified the initial 50 drugs that will be included in model year one (starting January 1, 2021). The list will be updated annually with new drugs added using the same criteria. However, CMS states that it will not remove drugs from the list, so over time the list will grow to include more than 50 drugs.

   For the beginning of performance year 1, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges after making certain exclusions to the MFN Model Drug HCPCS Codes List. Excluded drugs include:

   - Vaccines (e.g., influenza, pneumococcal pneumonia, coronavirus disease 2019 (COVID-19), and hepatitis B vaccines)
   - Radiopharmaceuticals
   - Oral anticancer chemotherapeutic agents
   - Oral antiemetic drugs
   - Oral immunosuppressive drugs
   - Compounded drugs
   - Intravenous immune globulin products
   - Drugs billed with HCPCS codes that describe a drug product that was approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act
   - Drugs for which there is an Emergency Use Authorization (EUA) from FDA or FDA approval, to treat patients with suspected or confirmed COVID-19
   - Drugs billed using a not otherwise classified (NOC) or not otherwise specified (NOS) billing and

[1] For the first quarter and second quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of the Act for which payment for outpatient hospital services furnished to Medicare fee-for-service beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act.

[2] Beginning with the third quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of the Act for which payment for outpatient hospital services furnished to Medicare fee-for-service beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act, where the parameters of such model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMMI model's parameters (for example, the annual global budget) for the duration of the MFN Model.

payment code

Additionally, CMMI will exclude the following claims when developing the list of drugs included in the MFN model:

- Professional claims with a place of service code indicating a home setting, including home, homeless shelter, assisted living facility, group home, temporary lodging, and custodial care facilities
- Claims administered by the DME MACs

While CMMI will not add new drugs during a model year, it will update the list to reflect changes in HCPCS codes describing drugs that are currently on the list. Exhibit 2 in the Appendix provides the list of 50 drugs for 2021 and details the top billing specialties.

4) *How much will MFN participants be paid for drugs covered under the model*? In general, the MFN Model will test paying Part B drugs at comparable amounts to the lowest adjusted price (adjusted for purchasing power parity) paid by any OECD country that has a GDP per capita that is at least 60% of the U.S. GDP per capita. If the current average sales price (ASP) price is lower than the lowest OCED price, then the MFN price will be the ASP price. Additionally, the MFN Drug Payment Amount for covered drugs acquired under the 340B program cannot exceed the non-model drug payment amount for claim lines submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

The MFN price will be phased in over the first four years of the model as described in the table below.

Phase-In of MFN Prices By Performance Year

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

- *What happens if prices for selected drugs grow faster than anticipated*? CMS will accelerate the

phase-in of the MFN Price by 5 percentage points at the next quarterly update to calculate the MFN Drug Payment Amount for the MFN Model drug where both of the conditions in Exhibit 3 are met. The accelerated phase-in price will not be reversed but will remain in place for the duration of the model.

If the conditions described in Exhibit 3 are met after the full phase-in of the MFN Price for a qualifying drug, for each calendar quarter thereafter, CMS decreases the MFN Drug Payment Amount equal to the largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the national drug codes (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) and in the MFN Price, respectively, determined quarterly.

- *What if no international pricing data is available for selected drugs*? If, as of the first calendar quarter during which an MFN Model drug has been included on the list, no international sales, volume or pricing information is available to determine the MFN Price, the MFN Drug Payment Amount is the applicable ASP.

- *What happens if a selected drug is in short supply?* If an MFN Model drug is reported as "Currently in Shortage" by the Food and Drug Administration (FDA), beginning with the first day of the next calendar quarter after the date on which it is reported in shortage, the MFN Drug Payment Amount is the applicable ASP.

CMS will update the MFN Drug Payment Amounts on a calendar quarter basis. CMS publishes the quarterly MFN Drug Payment Amounts on the MFN Model website in advance of the calendar quarter in which the MFN Drug Payment Amounts apply, along with any recalculated MFN Drug Payment Amounts for prior quarters.

5) *How does the model change drug add-on payments for covered drugs*? The model uses a flat amount to pay for handling and storage of covered drugs. This amount is updated on a quarterly basis.

Initially, the 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. CMS updates the alternative add-on payment by applying a cumulative inflation factor based on the cumulative percentage change in CPI-U from October 2020 through the first month of the prior calendar quarter. If the cumulative percentage change in the CPI-U is negative, CMS uses an inflation factor of 1.

The alternate add-on payment is not payable for claim lines billed with a JW modifier (indicating

drugs discarded, not administered to any patient) or if the participant is engaged in a CMMI model that also tests an alternative approach to the Part B drug add-on payment. A discussion of how to bill for the new add-on payment is provided in the discussion of billing issues in this document.

Based on a CMS 2019 claims analysis, on average, the single per-dose add-on payment amount included in the IFC, after sequestration is applied, represents an increase in the add-on payment amount for 70% of doses on average compared to the effective historical add-on amount of 4.3% of the applicable ASP after sequestration. In general, according to CMS's analysis, physician practices will be better off under the per-dose add-on payment approach than HOPDs, and single specialty practices will be better off than multispecialty practices.

CMS is waiving beneficiary cost-sharing (coinsurance and deductible amounts) on the portion of the allowed MFN Model Payment amount that is based on the alternative add-on payment. Under the MFN Model, the drug payment amount will continue to be subject to beneficiary coinsurance and the annual deductible amount. However, for the alternative add-on, CMS is waiving beneficiary cost sharing. Medicare will pay the entire allowed payment amount that is based on the alternative add-on payment to ensure that beneficiaries do not experience an increase in cost-sharing under the MFN Model as a result of testing an alternative add-on amount

6) *How do billing requirements change*? MFN participants must submit claims for MFN Model drugs to the applicable MAC in the form and manner specified by CMS in model-specific billing instructions that may be provided in sub-regulatory guidance. The IFC provides makes one change and provides a clarification to billing instructions for providers.

MFN participants will be required to submit a separate claim line using a new model-specific HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim. The MFN participant will indicate in the units field of the claim line with HCPCS code M1145 the number of doses of a separately payable MFN Model drug that are billed on the claim.

To calculate the number of add-on payment units, the MFN participant will count the number of claim lines with a HCPCS code that is included on the applicable MFN Model Drug HCPCS Codes List (based on the date of service), including all claim lines when the number of billing units necessary to indicate the dosage given exceeds the character size of the units field and the claim has more than one claim line for such MFN Model drug (we note that this is expected to be a rare situation). Claim lines with the JW modifier should be excluded from this calculation. MFN participants will need to submit an appropriate billed charge for the JW modifier as CMS still is applying their "lesser of" policy.

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

7) *What role do quality measures play in the model*? Quality measures are only used to monitor the MFN model's impact to beneficiaries. They are not used to adjust payments to providers. CMS will administer a patient experience survey to a sample of beneficiaries who receive an MFN Model drug. A sample of non-MFN beneficiaries may also be surveyed.

8) *Is the MFN an Advanced Alternative Payment Model*? No

9) *Is there a hardship exemption from the MFN model*? Yes, the model includes a hardship exemption to qualifying participants. The IFC states that CMS will grant exemptions at "its sole discretion." Details on the time and application process are included in Exhibit 4.

   If CMS grants a financial hardship exemption to an MFN participant for a performance year, CMS provides the participant a reconciliation payment for the performance year that equals the amount calculated by multiplying the excess reduction amount per beneficiary by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the performance year.

Appendix

Exhibit 1: Estimated Impact by Specialty for the Per-Dose Add-on Amount (Based on 2019 Claims Data)

Specially*	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)
Hematology/Oncology	2,083	29.2%	High	-8%
Ophthalmology	3,175	18.0%	Medium	140%
Internal Medicine	5,249	14.1%	Low	4%
Rheumatology	2,020	10.9%	High	9%
Medical Oncology	624	8.3%	High	-13%
Neurology	2,681	3.7%	Low	-21%
Nurse Practitioner	2,763	1.9%	Low	32%

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Specially*	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)
Hematology	509	1.5%	High	-6%
Urology	2,385	1.5%	Low	143%
Gastroenterology	1,778	1.5%	Low	-20%
Family Practice	3,595	1.0%	Low	115%
Allergy/Immunology	1,325	1.0%	Medium	46%
Physician Assistant	2,079	0.6%	Low	222%
Cardiology	2,567	0.5%	Low	1284%
Pulmonary Disease	905	0.5%	Low	37%
Orthopedic Surgery	1,678	0.4%	Low	794%
Obstetrics/Gynecology	1,285	0.4%	Low	55%
Radiation Oncology	724	0.3%	Low	1%
Endocrinology	1,032	0.3%	Low	194%
Gynecological/Oncology	119	0.3%	High	-33%
Infectious Disease	152	0.3%	Medium	-10%
Physical Medicine and Rehabilitation	1,215	0.3%	Low	159%
Nephrology	1,068	0.2%	Low	634%
Hematopoietic Cell Transplantation & Cellular Therapy	48	0.1%	Low	-15%
Hospitalist	398	0.1%	Low	8%
Dermatology	529	0.1%	Low	-31%
Interventional Cardiology	546	0.1%	Low	1383%
General Practice	525	0.1%	Low	62%
Interventional Pain Management	374	0.1%	Low	149%
Pediatric Medicine	172	0.1%	Low	1%
Sleep Medicine	304	0.1%	Low	20%
General Surgery	589	0.1%	Low	23%

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Exhibit 2: Performance Year 1 MFN Model Drug HCPCS Codes List with Top Billing Specialties

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges	First Top Specialty	Second Top Specialty	Third 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 biosimilar 10mg	$1,010,328,165	Rheumatology	Gastroenterology	Internal Medicine
10	J0129	Abatacept injection	$968,556,135	Rheumatology	Internal Medicine	Hematology/ Oncology
11	J9355	Inj trastuzumab excl biosimi	$851,042,669	Hematology/ Oncology	Internal Medicine	Medical Oncology
12	J9145	Injection, daratumumab 10 mg	$843,712,153	Hematology/ Oncology	Internal Medicine	Medical Oncology
13	J2350	Injection, ocrelizumab, 1 mg	$703,104,359	Neurology	Hematology/ Oncology	Internal Medicine
14	J1300	Eculizumab injection	$562,413,430	Neurology	Hematology/ Oncology	Internal Medicine
15	J9305	Pemetrexed injection	$539,680,121	Hematology/ Oncology	Internal Medicine	Medical Oncology
16	J9022	Inj, atezolizumab,10 mg	$486,551,001	Hematology/ Oncology	Internal Medicine	Medical Oncology
17	J9173	Inj., durvalumab, 10 mg	$476,638,073	Hematology/ Oncology	Internal Medicine	Medical Oncology
18	J2353	Octreotide injection, depot	$466,969,222	Hematology/ Oncology	Internal Medicine	Medical Oncology
19	J0717	Certolizumab pegol	$458,757,878	Rheumatology	Internal Medicine	Nurse Practitioner

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Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges	First Top Specialty	Second Top Specialty	Third Top Specialty
		inj 1mg				
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 suspension	$331,012,840	Urology	Hematology/ Oncology	Internal Medicine
28	J9306	Injection, pertuzumab, 1 mg	$318,023,592	Hematology/ Oncology	Internal Medicine	Medical Oncology
29	J9047	Injection, carfilzomib, 1 mg	$296,821,394	Hematology/ Oncology	Internal Medicine	Medical Oncology
30	J3262	Tocilizumab injection	$279,068,051	Rheumatology	Internal Medicine	Hematology/Oncology
31	J1930	Lanreotide injection	$278,600,806	Hematology/ Oncology	Internal Medicine	Medical Oncology
32	J3357	Ustekinumab sub cu inj, 1 mg	$264,386,412	Rheumatology	Gastroenterology	Dermatology
33	J0881	Darbepoetin alfa, non-ESRD	$258,409,215	Hematology/ Oncology	Internal Medicine	Medical Oncology
34	J2323	Natalizumab injection	$255,449,074	Neurology	Hematology/ Oncology	Internal Medicine
35	J2796	Romiplostim injection	$248,212,119	Hematology/ Oncology	Internal Medicine	Medical Oncology
36	J9034	Inj., bendeka 1 mg	$219,156,831	Hematology/ Oncology	Internal Medicine	Medical Oncology
37	J0885	Epoetin alfa, non-ESRD	$187,518,352	Hematology/ Oncology	Internal Medicine	Nephrology
38	Q2043	Sipuleucel-t auto cd54+	$182,158,187	Urology	Hematology/ Oncology	Internal Medicine

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Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges	First Top Specialty	Second Top Specialty	Third Top Specialty
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

Exhibit 3: Rapidly Increasing MFN Covered Drug Costs: Accelerating Model Pricing Criteria

1) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U.

2) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the MFN Price.

Exhibit 4: MFN Hardship Exemption Application Process

The MFN participant must submit its request for a financial hardship exemption to CMS in accordance with the submission process posted on the MFN Model website and such request must be submitted

within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption. The MFN participant's request for a financial hardship exemption must include, at a minimum, all of the following:

- 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 related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries.
- Average net acquisition cost for each MFN Model drug (inclusive of all on- and off- invoice discounts and adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries.
- Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug.
- Administrative information, including: MFN participant's name, Taxpayer Identification Number or CMS Certification number (CCN) (as applicable), contact name, phone number, and email address.
- The MFN participant's attestation that:
    - The MFN participant experienced a reduction in Medicare Part B fee-for-service payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;
    - The MFN participant has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and
    - The MFN participant submission is true, accurate and complete.

- CMS grants a financial hardship exemption to an MFN participant for a performance year, if the MFN participant submits a timely, complete request for financial hardship exemption in accordance with the requirements of this section which, in the sole discretion of CMS, demonstrates all of the following:

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