that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Particulate matter, Volatile organic compounds.

Dated: July 30, 2021.

Edward H. Chu,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

■ 2. In § 52.1320, the table in paragraph (c) is amended by revising the entry ''10–6.330'' to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.330	Restriction of Emissions From Batch-Type Charcoal Kilns.	7/30/2020	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	
*	*	*	*	*

* * * * *

[FR Doc. 2021–16846 Filed 8–9–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS–5528–P]

RIN 0938–AT91

Most Favored Nation (MFN) Model

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to rescind the Most Favored Nation Model interim final rule with comment period that appeared in the November 27, 2020, **Federal Register**.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by October 12, 2021.

ADDRESSES: In commenting, please refer to file code CMS–5528–P.

Comments, including mass comment submissions, must be submitted in one

of the following three ways (please choose only one of the ways listed):

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: Lara Strawbridge, (410) 786–7400 or *MFN@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm any individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Increases in Part B prescription drug spending significantly outpace the growth in spending on other Medicare Part B services,[1] and prices in the United States (U.S.) for most Medicare Part B drugs with the highest Medicare spending far exceed prices in other countries.[2] [3] Specifically, drugs have consistently been a major contributor to the overall Medicare Part B spending trend. Medicare Part B fee-for-service (FFS) spending for separately payable physician-administered drugs and drugs furnished in a hospital outpatient department represented about 11 percent of Medicare Part B FFS benefit spending in 2015, but accounted for about 37 percent of the change in Medicare Part B FFS benefit spending from 2015 to 2020.[4] In addition to the continued growth in spending, Medicare pays substantially more than other countries for many of the highest-cost Medicare Part B drugs that beneficiaries receive in an outpatient setting for which Medicare Part B allows separate payment.[5] In many instances, Medicare pays more than twice as much for certain drugs as other countries do.[6]

This imbalance in payment arises because Medicare generally establishes the payment for separately payable Medicare Part B drugs using the methodology in section 1847A of the Social Security Act (the Act). In most cases, this means payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, the Medicare program does not get the benefit of the substantial discounts provided in other countries, because ASP is calculated using only the prices that manufacturers charge to certain U.S.-based purchasers. ASP-based payments may also encourage the use of more expensive drugs because the dollar amount of the 6 percent add-on portion is larger for drugs with higher ASPs.[7]

The Most Favored Nation (MFN) Model interim final rule with comment period (85 FR 76180) [8] (hereafter, referred to as ''the November 2020 interim final rule'') was published in the **Federal Register** on November 27, 2020, and was effective the same day, with a 60-day comment period. The 60-day comment period on the November 2020 interim final rule closed on January 26, 2021. The November 2020 interim final rule established a 7-year nationwide, mandatory MFN Model, under section 1115A of the Act, with the model performance period beginning on January 1, 2021. The MFN Model would test an alternative way for Medicare to pay for certain Medicare Part B single source drugs and biologicals (including biosimilar biologicals). For additional information on the MFN Model, see the November 2020 interim final rule and the MFN Model website.[9]

In the November 2020 interim final rule, Waiver of Proposed Rulemaking and Delay in Effective Date, we stated that we found that there was good cause to waive the notice and comment requirements under sections 553(b)(B) of the Administrative Procedure Act and section 1871(b)(2)(C) of the Act because of the particularly acute need for affordable Medicare Part B drugs in the midst of the COVID–19 pandemic (85 FR 76249).

In December 2020, while the comment period was open, four lawsuits were filed related to CMS's waivers of proposed rulemaking and delay in effective date as well as other aspects of the MFN Model and the

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

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

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

[4] 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Accessed via: *https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.*

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

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

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

[8] Available at *https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.*

[9] Available at *https://innovation.cms.gov/innovation-models/most-favored-nation-model.*

November 2020 interim final rule: *Association of Community Cancer Centers* v. *Azar,* No. 8:20–cv–03531 (D. Md.); *California Life Sciences Ass'n* v. *CMS,* No. 3:20–cv–08603 (N.D. Ca); *Regeneron Pharmaceuticals* v. *HHS,* No. 7:20–cv–10488 (S.D.N.Y.); and *Community Oncology Alliance, Inc.* v. *HHS,* No.1:20–cv–03604 (D.D.C.). On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in *California Life Sciences,* which preliminarily enjoined HHS from implementing the MFN Model and the November 2020 interim final rule. The lawsuits in the U.S. District Court for the District of Maryland and the U.S. District Court for the District of Columbia were stayed based on the nationwide preliminary injunction. On December 30, 2020, the U.S. District Court for the Southern District of New York issued a preliminary injunction in *Regeneron Pharmaceuticals* v. *HHS,* which preliminarily enjoined HHS from applying the November 2020 interim final rule to Regeneron's drug EYLEA® (aflibercept).

On January 8, 2021, the Solicitor General determined not to appeal the preliminary injunction issued in *California Life Sciences.* On January 19, 2021, at the parties' request, the U.S. Northern District of California stayed the case until at least April 23, 2021. Subsequently, on April 26, 2021, another stay was granted until July 26, 2021. On July 29, 2021, another stay was granted until September 27, 2021.

In *Regeneron Pharmaceuticals,* on February 2, 2021, the plaintiff filed a letter seeking leave to file a motion for summary judgment, and HHS filed a letter seeking leave to file a motion for a stay. On February 10, 2021, the U.S. District Court for the Southern District of New York granted HHS's request and stayed the case for 90 days (that is, through May 11, 2021). On May 10, 2021, the stay in this case was extended for an additional 90 days, until August 9, 2021, to give HHS time to consider how to proceed with the rule in light of the ''unanimous'' court decisions to date. In its order, the court noted that HHS should ''not assume that another stay will be granted,'' as the stays gave HHS ''a half-year to reach a conclusion regarding how to proceed[.]''

As a result of the nationwide preliminary injunction, the MFN Model was not implemented on January 1, 2021, as contemplated in the November 2020 interim final rule. While the nationwide preliminary injunction has been in place, CMS considered how to proceed given stakeholders' concerns about potential impacts of the MFN Model.

II. Provisions of the Proposed Regulations

We received approximately 1,166 timely pieces of correspondence in response to the November 2020 interim final rule. We appreciate the comments that we received. We note that many commenters agreed with HHS about the urgency of addressing high prescription drug prices, but nearly all of the commenters expressed concern about beginning the model on January 1, 2021, including starting the model during the COVID–19 pandemic. Given that the nationwide preliminary injunction precluded implementation of the MFN Model on January 1, 2021, as contemplated, that multiple courts found procedural issues with the November 2020 interim final rule, and that stakeholders expressed concern about the model start date,[10] we are proposing to rescind regulations added by the November 2020 interim final rule and remove the associated regulatory text at 42 CFR part 513. We believe this proposed rule communicates how we wish to proceed with the November 2020 interim final rule to the courts and the public. Since the preliminary injunctions prevented the November 2020 interim final rule from taking effect, we do not believe there would be any disruption to reliance interests or Medicare program administration if this proposed rule were to take effect. If finalized, our proposal would allow us to take time to further consider the issues identified by commenters and would address the November 2020 interim final rule's procedural deficiencies by rescinding it. We note that this proposed rule (that is, our proposal to effectively withdraw an interim final rule with comment period) is limited to the codification of the November 2020 interim final rule, and does not reflect any judgment by HHS regarding future policy.

On July 9, 2021, President Biden signed an Executive Order on Promoting Competition in the American Economy that, in part, directs the Secretary of HHS to take steps to lower the prices of and improve access to prescription drugs and biologicals. HHS is exploring opportunities to promote value-based care for our beneficiaries; to address the high cost of Medicare Part B drugs, manufacturers' pricing, and the resulting growth in Medicare Part B drug spending; and to modernize the Medicare program to improve the quality and cost of care for beneficiaries. We will continue to carefully consider the comments we received on the November 2020 interim final rule as we explore all options to incorporate value into payments for Medicare Part B drugs and improve beneficiaries' access to evidence-based care.

We invite comments on our proposal to rescind and remove the regulations at 42 CFR part 513, which also would withdraw the MFN Model.

III. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of CMS Innovation Center Models. However, costs incurred through information collections were described in sections III.H., III.I.b., and VI.C.5. of the November 2020 interim final rule (85 FR 76221, 76222, and 76244, respectively) . If this proposed rule is finalized, requirements related to the information collection described in the November 2020 interim final rule would not continue. As such, resulting savings are included in the estimate of the impact of our proposal to withdraw the MFN Model in section V.C. of this proposed rule. Further, this proposed rule does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this proposed rule is to propose the rescission of the Most Favored Nation Model, codified by an interim final rule with comment period

[10] For example, commenters stated that the MFN Model should not start during the COVID–19 pandemic, and in addition that the model should not begin on January 1, 2021, while the public comment period for the November 2020 interim final rule was ongoing (until January 26, 2021). Further, commenters stated that CMS failed to allow MFN participants sufficient time to prepare for model start and to develop and deploy new systems with distributors and customers to exclude model sales from ASP reporting.

that appeared in the November 27, 2020 **Federal Register**, and remove the associated regulatory text at 42 CFR part 513, which also would withdraw the MFN Model.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory actions or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

Removing the regulatory text at 42 CFR part 513, which also would withdraw the MFN Model, would mean that the annualized/monetarized estimates of costs and transfers presented in the November 2020 interim final rule (85 FR 76235 through 76248) would not be realized. The regulatory impact analysis of the November 2020 interim final rule estimated that the MFN Model would result in substantial overall savings for the Medicare program, the Medicaid program, and beneficiaries, and that model participants would experience costs associated with complying with the regulations, survey completion, and potential requests for financial hardship exemption.

In the November 2020 interim final rule, we presented estimates from the CMS Office of the Actuary (OACT) (85 FR 76236) and the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) (85 FR 76240). We noted that there is much uncertainty around the assumptions for both the OACT and ASPE estimates, and refer readers to section VI.C. of the November 2020 interim final rule for a more complete discussion of the estimated impacts of the MFN Model. These potential impacts were estimated to occur beginning January 2021 through December 2028, in alignment with a January 1, 2021 model start. However, because the MFN Model was not implemented on January 1, 2021, as contemplated in the November 2020 interim final rule, such effects have not occurred.

Nevertheless and notwithstanding the nationwide preliminary injunction, this analysis uses a baseline in which the November 2020 interim final rule was implemented on January 1, 2021, to calculate the monetized estimates of the effects of this proposed rule. We maintain the analytical approach described in the regulatory impact analysis of the November 2020 interim final rule, and for the purpose of quantifying the effects of this proposed rule, assume that the regulations added by the November 2020 interim final rule will be in full effect if this proposed rule is not finalized. As a result of the rescission of the regulations added by the November 2020 interim final rule, this proposed rule would, if finalized, prevent the occurrence of the estimated costs and transfers presented in the November 2020 interim final rule. We summarize this result in Tables 1 and 2, which illustrate, inversely, the monetized estimates contained in Table 17 (85 FR 76247) and Table 18 (85 FR 76248) of the November 2020 interim final rule. The period covered shown in Tables 1 and 2 begins January 2021 in alignment with the accounting statements and tables presented in the November 2020 interim final rule. This approach illustrates that this proposed rule, if finalized, would prevent the realization of the annualized/monetarized estimates of costs and transfers that were presented in the November 2020 interim final rule. Because the MFN Model was not implemented, readers should understand that this proposed rule does not affect conditions in the past.

TABLE 1—ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2028 AS A RESULT OF PROVISIONS OF THIS PROPOSED RULE BASED ON THE OACT ESTIMATE

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				
Annualized Monetized ($million/year)	−29.4	2018	7	January 2021—December 2028.
	−27.1	2018	3	January 2021—December 2028.
To Whom	Hospital/physicians.			
Annualized Monetized ($million/year)	−0.4	2018	7	January 2021—December 2027.
	−0.4	2018	3	January 2021—December 2027.
Transfers:				

TABLE 1—ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2028 AS A RESULT OF PROVISIONS OF THIS PROPOSED RULE BASED ON THE OACT ESTIMATE—Continued

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($million/year)	11,502.5 11,906.3	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	4,087.2 4,228.3	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	577.5 596.5	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	States to hospitals/physicians and MA plans.			

TABLE 2—ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2028 AS A RESULT OF THE PROVISIONS OF THIS PROPOSED RULE BASED ON THE ASPE ESTIMATE

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs: Annualized Monetized ($million/year)	−29.4 −27.1	2018 2018	7 3	January 2021—December 2028. January 2021—December 2028.
To Whom	Hospital/physicians			
Annualized Monetized ($million/year)	−0.4 −0.4	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
Transfers: Annualized Monetized ($million/year)	7,058.3 7,276.5	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	Federal Government to hospitals/physicians and MA plans			
Annualized Monetized ($million/year)	4,504.9 4,638.6	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans			
Annualized Monetized ($million/year)	342.4 351.6	2018 2018	7 3	January 2021—December 2027. January 2021—December 2027.
From Whom to Whom	States to hospitals/physicians and MA plans			

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *https://www.sba.gov/document/support--table-size-standards.* The rule of thumb used by HHS for determining whether an impact is ''significant'' is an adverse effect equal to 3 percent or more of total annual revenues.

This proposed rule, if finalized, would impact the vast majority of Medicare-participating providers and suppliers that submit claims for separately payable Medicare Part B drugs by preventing the impacts described in the November 2020 interim final rule (85 FR 76246) from being realized. There are over 20,000 small entities that would be included or affected by the MFN Model if the model was implemented. We refer readers to Table 3 and Table 8 in the November 2020 interim final rule (85 FR 76195 and 76219, respectively) to see the number of entities, as well as the types of providers and suppliers, that would be most likely impacted by the MFN Model. This proposed rule proposes to withdraw the MFN Model, and therefore would likely impact these same entities. Accordingly, we have determined that a Regulatory Flexibility Analysis (RFA) is required. As its measure of significant economic impact on a substantial number of small entities, HHS uses a

change in revenue of more than 3 to 5 percent. We do believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed will have a significant economic impact on a substantial number of small entities. The RFA presented in the November 2020 interim final rule (85 FR 76245) describes the potential impact of the MFN Model, if it was implemented, on small entities. If finalized, this proposed rule would prevent those impacts from being realized. Specifically, the lower drug payments and alternative add-on payments described in section III.F. of the November 2020 interim final rule would not occur. Instead, payment for submitted claims would be made under the applicable Medicare payment methodology. This RFA, together with the preamble, constitutes the required analysis.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Similar to urban entities, we estimate that this proposed rule, if finalized, would have a significant impact on small rural hospitals by preventing the impacts described in the November 2020 interim final rule (85 FR 76246) from being realized. Specifically, if the MFN Model was implemented, these rural entities would experience drug payment reductions and overall payment reductions similar to urban entities. Instead, if this proposed rule is finalized, payment for submitted claims would be made under the applicable Medicare payment methodology.

We welcome comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects for this proposed rule.

E. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. As discussed in section V.C. of this proposed rule, the financial impacts for States (that is, an estimated overall reduction in State spending) presented in the November 2020 interim final rule (85 FR 76235 through 76248) would not be realized. This proposed rule does not mandate any spending by State, local, or tribal governments, or by the private sector, and hence an UMRA analysis is not required.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As discussed in section V.C. of this proposed rule, the financial impacts for States (that is, an estimated overall reduction in State spending) presented in the November 2020 interim final rule (85 FR 76235 through 76248) would not be realized. Since this regulation does not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 21, 2021.

List of Subjects for 42 CFR 513

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

PART 513—[REMOVED]

■ For the reasons set forth in the preamble and under the authority at 5 U.S.C. 301, the Centers for Medicare & Medicaid Services proposes to remove 42 CFR part 513.

Dated: August 3, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–16886 Filed 8–6–21; 4:15 pm]

BILLING CODE 4120–01–P