physical sheets of paper (as set forth in § 1.821(c)(3)).

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Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–28128 Filed 12–28–21; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS–5528–F]

RIN 0938–AT91

Most Favored Nation (MFN) Model

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

ACTION: Final rule.

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

DATES: This final rule is effective February 28, 2022.

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

I. Background

In the August 10, 2021 **Federal Register** (86 FR 43620), we published a proposed rule (86 FR 43618, hereafter, referred to as ''the August 2021 proposed rule'') that would rescind the Most Favored Nation (MFN) Model interim final rule with comment period (85 FR 76180) that appeared in the November 27, 2020 **Federal Register** (hereafter, referred to as ''the November 2020 MFN Model interim final rule''). The November 2020 MFN Model interim final rule established a 7-year nationwide, mandatory MFN Model to test an alternative way for Medicare to pay for certain Medicare Part B single source drugs and biologicals (including biosimilar biologicals), under section 1115A of the Social Security Act (the Act), with the model performance period beginning on January 1, 2021. The MFN Model was not implemented on January 1, 2021 as contemplated following four lawsuits and a nationwide preliminary injunction. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in *California Life Sciences Ass'n* v. *CMS,* No. 3:20–cv–08603, which preliminarily enjoined HHS from implementing the MFN Model and the November 2020 interim final rule. For additional information on the MFN Model and the related lawsuits, see the August 2021 proposed rule, the November 2020 MFN Model interim final rule, and the MFN Model website.[1]

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

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,[2] in the August 2021 proposed rule (86 FR 43620), we proposed to rescind the November 2020 MFN Model interim final rule and remove the regulations at 42 CFR part 513 (these actions would withdraw the MFN Model), and invited comments on our proposal. We received 34 timely items of correspondence from health care providers (such as health systems, hospitals, physician practices, and infusion centers), physician specialty groups, drug manufacturers, pharmaceutical industry groups, pharmacy benefit managers, patient advocacy groups, and individuals.

The following is a summary of the public comments received as well as our responses.

Comment: In general, the comments on the August 2021 proposed rule closely aligned with the comments we received in response to the November 2020 MFN Model interim final rule. Several commenters expressed general support for lowering drug prices. However, all but one of the commenters supported our proposal to rescind the November 2020 MFN Model interim final rule and remove the associated regulatory text at 42 CFR part 513. A commenter supported advancing the MFN Model, stating that the model ''is a guarantee to every American that we are not overpaying for the life sustaining medications they need. . . . [G]ive Americans the same drugs for the same price as the rest of the world.'' Several commenters urged us not to implement the MFN Model or similar models, such as any model that would test international or domestic reference pricing now or in the future. Many commenters expressed concerns about the potential for beneficiaries to lose access to drugs included in the MFN Model if manufacturers did not lower prices to align with the model payment amount, the potential for an MFN Model start to exacerbate practice struggles during the COVID–19 pandemic, and the potential financial hardship and administrative burden that hospitals, physician practices, and 340B covered entities may experience related to the MFN Model. Some commenters described legal concerns that were raised in the model-related lawsuits.

Response: We appreciate commenters' support for our proposal to rescind the November 2020 MFN Model interim final rule and remove the associated regulatory text at 42 CFR part 513 (these actions would withdraw the MFN Model). We appreciate the commenter's concern that Americans are paying more for drugs than consumers in other countries pay, although we disagree with the commenter that the MFN Model would guarantee that Americans would pay the exact amount that others pay for drugs, as the MFN Model was designed as a 7-year model test that would phase in the MFN Price over time, and further, there is no one international price that others outside the United States pay. We will continue to carefully consider this commenter's feedback and other stakeholders' feedback that we received as we explore all options to incorporate value into payments for Medicare Part B drugs, improve beneficiaries' access to evidence-based care, and reduce drug spending for consumers and throughout the health care system. As stated in the Department of Health and Human Services' (HHS') Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy (September 9, 2021), there are many administrative tools that could be used to promote competition and reduce drug pricing, including testing models in Medicare Part B using value-based payments, in which payment for drugs

[1] See the MFN Model website at *https://innovation.cms.gov/innovation-models/most-favored-nation-model*.

[2] For example, in response to the November 2020 interim final rule, 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 average sales price (ASP) reporting.

is directly linked to the clinical value they provide patients.[3]

Comment: Some commenters offered views on potential policies and alternative payment models that HHS and CMS could consider.

Response: We thank stakeholders for their comments. These topics are outside the scope of this rule, but we may consider the comments in the future.

Final Decision: After considering the comments on our proposal, we are finalizing our proposal as proposed. In this final rule, we rescind the November 2020 MFN Model interim final rule and remove the associated regulatory text at 42 CFR part 513. Thus, as a result of this final rule, the MFN Model is withdrawn, effective on the date specified in the **DATES** section of this final rule.

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 MFN Model interim final rule (85 FR 76221, 76222, and 76244, respectively). We are finalizing the provisions of the August 2021 proposed rule, which proposed to rescind requirements related to the information collection described in the November 2020 MFN Model interim final rule. As such, the estimate of the impact of this final rule in section IV.C. of this final rule includes the savings from rescinding the information collection requirements in the November 2020 MFN Model interim final rule. Further, the August 2021 proposed rule and this final rule do 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.*).

We did not receive comments on the discussion of information collection in the proposed rule.

IV. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule is to finalize the rescission of the Most Favored Nation Model interim final rule with comment period that appeared in the November 27, 2020 **Federal Register**, and remove the associated regulatory text at 42 CFR part 513 (these actions will 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.

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, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a regulatory impact analysis 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 withdraws the MFN Model, prevents realization of the annualized/monetized estimates of costs and transfers presented in the November 2020 MFN Model interim final rule (85 FR 76235 through 76248). The RIA of the November 2020 MFN Model 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 a financial hardship exemption.

In the November 2020 MFN Model 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 MFN Model 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 MFN Model interim final rule, such effects have not occurred.

[3] *https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf.*

Nevertheless and notwithstanding the nationwide preliminary injunction, this analysis uses a baseline in which the November 2020 MFN Model interim final rule was implemented on January 1, 2021, to calculate the monetized estimates of the effects of this final rule. We maintain the analytical approach described in the RIA of the November 2020 MFN Model interim final rule and August 2021 proposed rule, and for the purpose of quantifying the effects of this final rule, assume that the regulations added by the November 2020 MFN Model interim final rule would remain in full effect if this final rule was not finalized. By rescinding the regulations added by the November 2020 MFN Model interim final rule, this final rule prevents the occurrence of the estimated costs and transfers presented in the November 2020 MFN Model interim final rule. As presented in the August 2021 proposed rule (86 FR 43621), 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 MFN Model 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 MFN Model interim final rule and in the August 2021 proposed rule. This approach illustrates that this final rule prevents the realization of the annualized/monetized estimates of costs and transfers that were presented in the November 2020 MFN Model interim final rule. Because the MFN Model was not implemented, readers should understand that this final 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 FINAL 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:				
Annualized Monetized ($million/year)	11,502.5	2018	7	January 2021–December 2027.
	11,906.3	2018	3	January 2021–December 2027.
From Whom to Whom	Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	4,087.2	2018	7	January 2021–December 2027.
	4,228.3	2018	3	January 2021–December 2027.
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	577.5	2018	7	January 2021–December 2027.
	596.5	2018	3	January 2021–December 2027.
From Whom to Whom	States to hospitals/physicians and MA plans			

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

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				
Annualized Monetized ($million/year)	−29.4	2018	7	January 2021–December 2028.
	−27.1	2018	3	January 2021–December 2028.
To Whom	Hospital/physicians.			
Annualized Monetized ($million/year)	−0.4	2018	7	January 2021–December 2027.
	−0.4	2018	3	January 2021–December 2027.
Transfers:				
Annualized Monetized ($million/year)	7,058.3	2018	7	January 2021–December 2027.
	7,276.5	2018	3	January 2021–December 2027.
From Whom to Whom	Federal Government 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 FINAL RULE BASED ON THE ASPE ESTIMATE—Continued

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($million/year)	4,504.9	2018	7	January 2021–December 2027.
	4,638.6	2018	3	January 2021–December 2027.
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	342.4	2018	7	January 2021–December 2027.
	351.6	2018	3	January 2021–December 2027.
From Whom to Whom	States to hospitals/physicians and MA plans.			

Comment: A few commenters stated that, based on their own or others' analyses, the OACT and ASPE estimates shown in the November 2020 MFN Model interim final rule underestimate the negative financial impact that certain healthcare providers would likely experience had the MFN Model been implemented. Many commenters expressed concern that some of the estimated savings would be related to reduced access to care. We did not receive comments on our approach to illustrate, inversely, the monetized estimates contained in Table 17 (85 FR 76247) and Table 18 (85 FR 76248) of the November 2020 MFN Model interim final rule in Table 1 and Table 2 of the August 2021 proposed rule, respectively.

Response: We thank stakeholders for their comments. As we noted in the November 2020 MFN Model interim final rule and the August 2021 proposed rule, there is much uncertainty around the assumptions for both the OACT and ASPE estimates that were presented in those rules.

Final Decision: After considering the comments on the RIA of our proposal, and because we are finalizing our proposal as proposed, we are finalizing the RIA without change; that is, as presented in the August 2021 proposed rule.

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 final rule affects 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 MFN Model interim final rule (85 FR 76246) from being realized. Over 20,000 small entities would have been included or affected by the MFN Model if the model had been implemented. We refer readers to Table 3 and Table 8 in the November 2020 MFN Model 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 most likely would have been impacted by the MFN Model had it been implemented. This final rule withdraws the MFN Model, and therefore likely impacts these same entities. Accordingly, we have determined that a Regulatory Flexibility Analysis 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 believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that the August 2021 proposed rule and this final rule will have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Analysis presented in the November 2020 MFN Model interim final rule (85 FR 76245) describes the potential impact of the MFN Model, if it had been implemented, on small entities. This final rule prevents those impacts from being realized. Specifically, the lower drug payments and alternative add-on payments described in section III.F. of the November 2020 MFN Model interim final rule will not occur. Instead, payment for submitted claims will be made under the applicable Medicare payment methodology. This Regulatory Flexibility Analysis, 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We estimate that this final rule will have a significant impact on small rural hospitals by preventing the impacts described in the November 2020 MFN Model interim final rule (85 FR 76246) from being realized. Specifically, these rural entities will not experience drug payment reductions and overall payment reductions. Instead, payment for submitted claims will be made under the applicable Medicare payment methodology. We estimate that this final rule will have a parallel significant impact on urban entities.

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

Comment: Several commenters stated that our estimate of significantly affected providers and suppliers and the magnitude of estimated effects presented in the November 2020 MFN Model interim final rule underestimated the potential financial losses and operational impacts that health care

providers, such as hospitals, physicians and infusion centers, would have experienced had the MFN Model been implemented as contemplated.

Response: We thank stakeholders for their comments. As we noted in the November 2020 MFN Model interim final rule and the August 2021 proposed rule, there is much uncertainty around the assumptions for both the OACT and ASPE estimates that were presented in those rules.

Final Decision: After considering the comments on the estimate of significantly affected providers and suppliers and the magnitude of estimated effects of our proposal, and because we are finalizing our proposal as proposed, we maintain our analysis, as presented in the August 2021 proposed rule, for this final 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 the August 2021 proposed rule and section IV.C. of this final rule, the financial impacts for States (that is, an estimated overall reduction in State spending) presented in the November 2020 MFN Model interim final rule (85 FR 76235 through 76248) will not be realized. The August 2021 proposed rule and this final rule did 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 the August 2021 proposed rule and section IV.C. of this final rule, the financial impacts for States (that is, an estimated overall reduction in State spending) presented in the November 2020 MFN Model interim final rule (85 FR 76235 through 76248) will not be realized. Since this rule 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 final 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 December 14, 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 removes 42 CFR part 513.

Dated: December 21, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–28225 Filed 12–27–21; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 211221–0265]

RTID 0648–XP016

Pacific Island Pelagic Fisheries; 2022 U.S. Territorial Longline Bigeye Tuna Catch Limits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final specifications.

SUMMARY: NMFS specifies a 2022 limit of 2,000 metric tons (t) of longline-caught bigeye tuna for each U.S. Pacific territory (American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI), the territories). NMFS will allow each territory to allocate up to 1,500 t in 2022 to U.S. longline fishing vessels through specified fishing agreements that meet established criteria. The overall allocation limit among all territories, however, may not exceed 3,000 t. As an accountability measure, NMFS will monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna, including catches made under a specified fishing agreement. These catch limits and accountability measures support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: The final specifications are effective January 28, 2022, through December 31, 2022. The deadline to submit a specified fishing agreement pursuant to 50 CFR 665.819(b)(3) for review is June 27, 2022.

ADDRESSES: Copies of the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP) are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, or *www.wpcouncil.org.*

Pursuant to the National Environmental Policy Act, the Council and NMFS prepared environmental analyses that support this action and are available at *https://www.regulations.gov/docket/NOAA-NMFS-2021-0076.*

FOR FURTHER INFORMATION CONTACT: Lynn Rassel, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: NMFS is specifying a 2022 catch limit of 2,000 t of longline-caught bigeye tuna for each U.S. Pacific territory. NMFS is also authorizing each territory to allocate up to 1,500 t of its 2,000 t bigeye tuna limit, not to exceed a 3,000 t total annual allocation limit among all the territories, to U.S. longline fishing vessels permitted to fish under the FEP. A specified fishing agreement with the applicable territory must identify those vessels.

NMFS will monitor catches of longline-caught bigeye tuna by the longline fisheries of each U.S Pacific territory, including catches made by U.S. longline vessels operating under specified fishing agreements. The criteria that a specified fishing agreement must meet, and the process for attributing longline-caught bigeye tuna, will follow the procedures in 50 CFR 665.819. When NMFS projects that the fishery will reach a territorial catch or allocation limit, NMFS will, as an accountability measure, prohibit the catch and retention of longline-caught bigeye tuna by vessels in the applicable territory (if the territorial catch limit is projected to be reached), and/or vessels in a specified fishing agreement (if the allocation limit is projected to be reached).

You may find additional background information on this action in the preamble to the proposed specifications published on October 27, 2021 (86 FR