DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2020–0032]

RIN 0651–AD48

Electronic Submission of a Sequence Listing, a Large Table, or a Computer Program Listing Appendix in Patent Applications

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule; correction.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) makes corrections to a final rule published on October 14, 2021, that amended the rules of practice to permit higher-capacity physical media to be submitted to the USPTO. This rule fixes typographical errors.

DATES: This rule is effective on December 29, 2021.

FOR FURTHER INFORMATION CONTACT: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at *Mary.Till@uspto.gov*; or Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at *Ali.Salimi@uspto.gov.*

SUPPLEMENTARY INFORMATION: On October 14, 2021, the USPTO published a final rule amending the rules of practice to permit higher-capacity physical media to be submitted to the USPTO (86 FR 57035). That final rule, which went into effect on November 15, 2021, contained two incorrect cross-references in 37 CFR 1.77 to the methods by which a sequence listing may be submitted to the USPTO. This final rule corrects those cross-references to avoid any confusion.

Section 1.77(b)(13) is revised to reference § 1.821(c)(2) for a ''Sequence Listing'' that is submitted as a Portable Document Format (PDF) file via the USPTO patent electronic filing system and § 1.821(c)(3) for a ''Sequence Listing'' that is submitted on physical sheets of paper. The references published in the October 14, 2021, final rule—§ 1.821(c)(1)(ii) and § 1.821(c)(1)(iii)—do not exist.

Rulemaking Considerations

A. Administrative Procedure Act

This rulemaking corrects typographical errors in a rulemaking permitting higher-capacity physical media to be submitted to the USPTO. The changes in this rulemaking involve a rule of agency practice and procedure and/or an interpretive rule. *See Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199, 1204 (2015) (Interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers.'' (citation and internal quotation marks omitted)); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc'ns Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez,* 135 S. Ct. at 1206 (Notice and comment procedures are required neither when an agency ''issue[s] an initial interpretive rule'' nor ''when it amends or repeals that interpretive rule.''); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))).

In addition, the Director of the USPTO finds good cause under 5 U.S.C. 553(b)(B) to waive the notice and comment requirements of the Administrative Procedure Act. As discussed above, the changes in this rulemaking involve correcting typographical errors in two cross-references in the final rule published on October 14, 2021. These changes are administrative in nature and will have no substantive impact on the evaluation of a patent application. If this rule were delayed to allow for notice and comment, this would lead to confusion as to the sections intended to be cross-referenced.

The Director of the USPTO also finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness. As discussed above, the changes in this rulemaking involve correcting typographical errors in two cross-references in the final rule published on October 14, 2021. These changes are administrative in nature and will have no substantive impact on the evaluation of a patent application. The purpose of a delay in effectiveness is to allow affected parties time to modify their behaviors, businesses, or practices to come into compliance with new regulations. This rule imposes no additional requirements on the affected entities. Therefore, the requirement for a 30-day delay in effectiveness is not applicable, and the rule is made effective immediately upon publication.

B. Regulatory Flexibility Act

As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. *See* 5 U.S.C. 603.

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. The USPTO has determined that there are no new requirements for information collection associated with this final rule.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble and under the authority contained in 35 U.S.C. 2, as amended, the USPTO amends 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

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

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Amend § 1.77 by revising paragraph (b)(13) to read as follows:

§ 1.77 Arrangement of application elements.

* * * * *

(b) * * *

(13) ''Sequence Listing,'' required by § 1.821(c), that is submitted as a Portable Document Format (PDF) file (as set forth in § 1.821(c)(2)) via the USPTO patent electronic filing system or on

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]

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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.