

currently 20 unique registrations authorized to handle *N*-ethylpentylone specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From review of entity names, DEA estimates these 20 registrations represent 16 entities. Some of these entities are likely to be small entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 16 entities are small entities. Therefore, DEA conservatively estimates as many as 16 small entities are affected by this proposed rule.

A review of the 20 registrations indicates that all entities that currently handle *N*-ethylpentylone also handle other schedule I controlled substances, and thus they have established and implemented (or maintain) the systems and processes required to handle *N*-ethylpentylone as a schedule I substance. Therefore, DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the 16 affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

#### *Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year \* \* \*.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

#### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

#### **PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (d)(86) and remove and reserve paragraph (h)(36).

The addition reads as follows:

#### **§ 1308.11 Schedule I.**

\* \* \* \* \*

(d) \* \* \*

(86) *N*-Ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) ..... 7543

\* \* \* \* \*

Dated: August 24, 2020.

**Timothy J. Shea,**

*Acting Administrator.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Centers for Medicare & Medicaid Services**

#### **42 CFR Part 411**

**[CMS-1720-RCN]**

**RIN 0938-AT64**

#### **Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Extension of Timeline for Publication of Final Rule**

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

**ACTION:** Extension of timeline for publication of final rule.

**SUMMARY:** This notice announces an extension of the timeline for publication of a Medicare final rule in accordance with the Social Security Act, which allows us to extend the timeline for publication of the final rule.

**DATES:** As of August 26, 2020, the timeline for publication of the final rule to finalize the provisions of the October 17, 2019 proposed rule (84 FR 55766) is extended until August 31, 2021.

**FOR FURTHER INFORMATION CONTACT:** Lisa O. Wilson, (410) 786-8852.

**SUPPLEMENTARY INFORMATION:** In the October 17, 2019 **Federal Register** (84 FR 55766), we published a proposed rule that addressed undue regulatory impact and burden of the physician self-referral law. The proposed rule was issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. In the proposed rule, we proposed exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers; a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; a new exception for donations of cybersecurity technology and related services; and amendments to the existing exception for electronic health records (EHR) items and services. The proposed rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations. This notice announces an extension of the timeline for publication of the final rule and the continuation of effectiveness of the proposed rule.

Section 1871(a)(3)(A) of the Social Security Act (the Act) requires us to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation. In accordance with section 1871(a)(3)(B) of the Act, the timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but may not be longer than 3 years except under exceptional circumstances. In addition, in accordance with section 1871(a)(3)(B) of the Act, the Secretary may extend the initial targeted publication date of the final regulation if the Secretary, no later than the regulation's previously established proposed publication date, publishes a notice with the new target date, and such notice includes a brief explanation of the justification for the variation.

We announced in the Spring 2020 Unified Agenda (June 30, 2020, [www.reginfo.gov](http://www.reginfo.gov)) that we would issue the final rule in August 2020. However, we are still working through the

complexity of the issues raised by comments received on the proposed rule and therefore we are not able to meet the announced publication target

date. This notice extends the timeline for publication of the final rule until August 31, 2021.

Dated: August 24, 2020.

**Wilma M. Robinson,**

*Deputy Executive Secretary to the Department, Department of Health and Human Services.*

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