



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA-469]

RIN 1117-AB45

Partial Filling of Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 became law. One provision of the Comprehensive Addiction and Recovery Act of 2016 amended the Controlled Substances Act to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. The Drug Enforcement Administration is hereby proposing to amend its regulations to conform to this new statutory provision and to set forth the corresponding regulatory requirements.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-469” on all correspondence, including any attachments.

DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions to submit comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB45/Docket No. DEA-469.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information

(such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) or confidential business information included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Background and Statutory Authority

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) of 2016 into law as Public Law 114-198. One of the provisions of the

CARA amended the Controlled Substances Act (CSA) to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. Specifically, the CARA amended 21 U.S.C. 829 by adding new subsection (f), which allows a pharmacist to partially fill a prescription for a schedule II controlled substance where requested by the prescribing practitioner or the patient. Subsection (f) further provides that for such partial filling to be lawful under the CSA, all of the following conditions must be satisfied: (1) the partial filling must not be prohibited by State law; (2) the prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and (3) the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. In addition, subsection (f) provides that the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portion, if filled, must be filled no later than 72 hours after it was issued.

This proposed rule would revise DEA regulations to incorporate the foregoing new statutory provisions. In addition, DEA is proposing to further revise its regulations to address certain regulatory requirements not addressed by the CARA. In particular, the CARA does not address how the prescribing practitioner should indicate that a prescription for a schedule II controlled substance must be partially filled. Likewise, the CARA does not specify how a pharmacist should record the partial filling of such a prescription. The CARA provides that partial filling of schedule II prescriptions is permitted if the prescription is written and filled in accordance with, among other things, regulations issued by DEA. 21 U.S.C. 829(f)(1)(B). Accordingly, Congress gave DEA explicit authorization to fill in any gaps in the regulatory scheme not addressed by Congress itself in the CARA. DEA is exercising this authority by issuing this proposed rule, which is intended to give practitioners and pharmacists clear guidance in this area,

and to allow for proper auditing by DEA.

In addition, there is potential for benefit to patients and society as a result of this proposed rule. For patients, partial filling could lower the cost of prescriptions by reducing the quantity of unused schedule II controlled substances due to not needing to continue on drug therapy. For instance, a patient would not have to pay for filling an entire prescription when only a portion of the prescription is filled because there is a likelihood that the patient may not need to consume the maximum number of dosage units prescribed. Similarly, the patient's insurance company or other program paying for or subsidizing the cost of the patient's drugs (*e.g.*, a pharmacy's co-pay plan or a government program such as Medicare or Medicaid), would avoid such unnecessary expense. Reducing the dispensing of schedule II drugs that are ultimately not needed would also help to ameliorate the danger that the patient might become dependent upon or addicted to dangerous opioids or other schedule II drugs. The existence of unused drugs in U.S. households contributes to growing rates of prescription drug abuse among Americans. Keeping and storing unused medications in households pose several dangers related to diversion, accidental overdose, and consumption of spoiled substances.¹ Reducing the quantity of unused schedule II controlled substances would reduce the risk of diversion.

There are a number of reasons unused drugs remain in U.S. households. For example, in one survey of 139 respondents, patients cited the following: condition resolved/symptoms improved (42.4 percent); did not believe I needed to take it (12.9 percent); did not feel it was helping the condition (7.1 percent); experienced side effects (6.5 percent); forgot or did not get around to taking it (5.8 percent); person on medications no longer lives there (5.0 percent); physician asked to stop it (4.3 percent); or

¹ "Safe Disposal of Unused Controlled Substances: Current Challenges and Opportunities for Reform," Avalere, <http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf>.

other reason (15.8 percent).²

In recent years, a number of states have enacted laws placing limits on certain controlled substances that may be prescribed. DEA has received inquiries from pharmacists and others asking whether it is permissible under Federal law to fill a schedule II prescription that is otherwise valid, but which exceeds the quantitative limit under State law. The CARA provides that partial filling of schedule II prescriptions is permitted if the prescription is written and filled in accordance with, among other things, State law. 21 U.S.C. 829(f)(1)(B). DEA interprets a prescription written for a quantity that exceeds the limits of State law to be invalid, and therefore, the prescription may not be filled as written. Because such a prescription is invalid, it also cannot be partially filled as a means of getting around the limits imposed by State law.

Partial Fill Request by Practitioner

How a Practitioner May Request That a Prescription Be Partially Filled Under the Proposed Rule

The proposed rule states that where a practitioner issues a prescription for a schedule II controlled substance and wants the prescription to be partially filled (as the CARA now allows), the practitioner must specify the quantity to be dispensed in the partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. This information would need to be included on the prescription, along with other information required for issuing a prescription under 21 CFR 1306.05, at the time it is signed by the practitioner, and in the case of an emergency oral prescription, when communicated by the prescribing practitioner to the pharmacist. DEA proposes this approach to ensure that the practitioner's intent regarding partial filling is made clear to the pharmacist, and will be

² "Taking Stock of Medication Wastage: Unused Medications in US Households." NeuroImage, Academic Press, 16 Oct. 2014. www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub.

properly memorialized in the dispensing records.

How a Pharmacy Would be Required to Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Prescribing Practitioner

When presented with a prescription on which the prescribing practitioner has properly specified his/her intent that the prescription for a schedule II controlled substance be partially filled, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.³ Specifically, upon each such partial filling requested by a prescribing practitioner, the dispensing pharmacist must make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the prescription). For electronic prescriptions, there must be an electronic prescription record, and the record must be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy must maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications must allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

Partial Fill Request by Patient

³ Longstanding DEA regulations, which would not be changed by this proposed rule, also allow the partial filling of a schedule II prescription where the pharmacist is unable to supply the full quantity called for in the prescription (§ 1306.13(a)) and for a patient in a long-term care facility or with a terminal illness (§ 1306.13(b) and (c)).

How a Patient May Request the Partial Filling of a Schedule II Prescription

As a result of the CARA, 21 U.S.C. 829(f) now provides that a prescription for a schedule II controlled substance may be partially filled at the request of either the prescriber or the patient. Thus, even if the prescribing practitioner does not specify on the prescription his/her intent that the prescription be partially filled, the patient may make such request to the pharmacy. The CARA does not place any limitations on how the patient may make a partial fill request. In addition, DEA recognizes that many post-surgery patients may have a difficult time visiting pharmacy in person. Therefore, this proposed rule would not require an in-person request by the patient in every case and would allow alternative pathways for the patient to make such a request and specify the amount to be filled (*e.g.*, phone call by the patient to the pharmacist, or a signed written note from the patient and delivered by a family member to the pharmacist).

However, it should be noted that the CARA only authorizes the “patient” – not a member of the patient’s household – to make such request. Whereas the CSA defines “ultimate user” to include a member of the patient’s household (21 U.S.C. 802(27)), the new section 829(f) refers only to “the patient or the practitioner that wrote the prescription” making the request for the partial fill. Thus, the CARA did not authorize members of the patient’s household to request the partial filling of a prescription on behalf of the patient.

How a Pharmacy Must Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Patient

Under the proposed rule, when partially filling a prescription for a schedule II controlled substance at the request of the patient, the pharmacist must make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner. With an electronic prescription, as discussed above in the section on pharmacy recording requirements, the notation must be linked to an electronic

prescription record. Since the prescription will not contain the partial fill instructions from the prescriber, the pharmacy would also be required under the proposed rule to indicate on the prescription that the patient requested the partial fill. For uniformity and clarity, DEA is proposing that the pharmacy record on all such prescriptions: (1) “patient requested partial fill on [date such request was made],” and (2) the quantity dispensed. In the event the prescribing practitioner already made the request to partially fill the prescription, the pharmacy will not be required to make any notation on the prescription indicating that the patient requested a partial fill, unless the patient requested a smaller amount. However, where a practitioner has requested the partial filling of a prescription, the patient may not request a partial filling in an amount greater than that specified by the practitioner.

Request for Public Comment

Parts of this proposed rule merely restate the provisions of the CARA setting forth the general requirements for partial filling of prescriptions for schedule II controlled substances. Since these provisions are mandated by Congress, DEA is obligated to incorporate them into the agency regulations. However, other parts of the proposed rule would fill in any gaps in the regulatory scheme not addressed by Congress. Accordingly, DEA solicits public comment on the following provisions of the proposed rule: § 1306.13(b)(3), (4), and (5).

Regulatory Analysis

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, Reducing Regulation, and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, public health and safety, and environmental advantages; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. The E.O. classifies a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

DEA expects that this proposed rule will have an annual effect on the economy of \$100 million or more in cost savings and therefore is an economically significant regulatory action. The analysis of benefits and costs is below.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a significant regulatory action under E.O. 12866, and therefore has been submitted to the Office of Management and Budget (OMB) for review.

I. Need for the Rule

As discussed above, the CARA was signed into law on July 22, 2016. One of the provisions of the CARA amended the CSA to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions, providing flexibilities to prescribers and patients. Specifically, the CARA amended 21 U.S.C. 829 by adding new subsection (f), which allows a pharmacist to partially fill a prescription for a schedule II

controlled substance where requested by the prescribing practitioner or the patient.

Subsection (f) further provides that for such partial filling to be lawful under the CSA, all of the following conditions must be satisfied: (1) the partial filling must not be prohibited by State law; (2) the prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and (3) the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. In addition, subsection (f) provides that the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portions, if filled, must be filled no later than 72 hours after it was issued.

II. Alternative Approaches

When the prescriber requests the partial fill, the pharmacy's actions are straightforward. The pharmacist dispenses the prescription according to the prescriber's partial fill instructions and makes the required notations on the prescription, and the pharmacy maintains the required dispensing records. However, DEA considered three regulatory alternatives regarding the required notifications when the partial fill is at the request of the patient. DEA considered whether the pharmacist should 1) notify the prescribing practitioner or the prescribing practitioner's agent of the patient's request to partially fill the prescription, and obtain the prescribing practitioner's consent for the quantity; 2) notify the prescribing practitioner or the prescribing practitioner's agent of the patient's partial fill request, but not require the prescribing practitioner's consent; or 3) simply dispense the partial fill as requested without any notification or consent. As the pharmacist's requirement for notification or consent is the only difference between the alternatives, the alternatives analysis below only examines the estimated cost of notification or consent. A complete discussion of benefits and costs is described in the following section.

Alternative 1: Obtain Prescribing Practitioner's Consent for the Partial Fill Quantity

Prior to Dispensing

The first alternative would require the prescribing practitioner's consent of the quantity to be dispensed before the pharmacist dispenses a partial fill at the patient's request. Upon receiving a patient's request for a partial fill, the pharmacist would contact the prescribing practitioner or the prescribing practitioner's agent, and confirm that the prescribing practitioner concurs with the requested partial fill quantity. After confirmation, the pharmacist would dispense the partial fill and make the required notation on the prescription. The notation includes the method of notification (*e.g.*, telephone, email, voicemail) and the person notified.

DEA estimates obtaining consent would require six minutes from each of the parties involved: the pharmacist to request consent, the prescribing office to review request and for the prescribing practitioner or practitioner's agent to give consent, and the patient to wait while consent is received. To estimate the cost, DEA used the following labor wage and employment cost rates from the U.S. Department of Labor, Bureau of Labor Statistics (BLS). The following occupations' median hourly wages were noted:⁴

- Pharmacist requesting consent: 29-1051 Pharmacists, \$60.64.
- Prescriber's representative to give consent: 43-6033 Medical Secretaries, \$17.19.
- Patient: 00-0000 All Occupations, \$18.54.

Additionally, a load of 42.7 percent for benefits was applied to the median hourly wages to obtain loaded median hourly wages below:⁵

- Pharmacist requesting consent: 29-1051 Pharmacists, \$86.53.

⁴ BLS, May 2018 National Occupational Employment and Wage Estimates, United States. https://www.bls.gov/oes/current/oes_nat.htm. (Accessed 2/6/2020.)

⁵ BLS, "Employer Costs for Employee Compensation – September 2019" (ECEC) reports that average benefits for private industry is 29.9 percent of total compensation. The 29.9 percent of total compensation equates to 42.7 percent (29.9% / 70.1%) load on wages and salaries.

- Prescriber's representative to give consent: 43-6033 Medical Secretaries, \$24.53.
- Patient: 00-0000 All Occupations, \$26.51.

Therefore, the estimated cost of obtaining consent (six minutes per occurrence) would cost the pharmacy \$8.65, the prescriber \$2.45, and the patient \$2.65, for a total \$13.85 per occurrence.

While DEA does not have a strong basis to estimate the number of instances the patient will request partial filling of a prescription for schedule II control substance, in the Cost Savings discussion below, the estimated total prescriptions for potential partial filling is 36,375,279. DEA used the midpoint between 0 and 100 percent – half (18,187,640) – to estimate the cost savings. DEA does not know all the reasons a patient may request a partial fill, but believes a patient requesting a partial filling of a prescription for a schedule II controlled substance may seek a partial fill because: the patient is aware of the potential dangers of excess opioids in the household, the patient does not want excess opioids in the household, the patient believes he or she will not need all the dosages prescribed, and there is no additional cost or logistical burden as a result of the partial fill. DEA further believes that patients are likely to follow the instructions of prescribers, and estimates only a small minority of the estimated 18,187,640 requests for partial fills will be at the request of the patient. For the purposes of this analysis, DEA assumes 10 percent, or 1,818,764 partial fills will be at the request of the patient. Applying the cost per occurrence to the number of occurrences, this alternative is estimated to cost pharmacies approximately \$15.7 million per year for the pharmacists to obtain consent, prescribing practitioners approximately \$4.5 million per year to give consent, and patients \$4.8 million while waiting for the pharmacist to obtain consent from the prescribing practitioner or practitioner's agent for a total \$25.0 million per year. The table below summarizes this calculation.

Table 1: Summary Calculation for Alternative 1

	Loaded Hourly Wage (\$)	Time Required (hours)	Cost per Occurrence (\$)	Number of Occurrences	Total Cost (\$M)
Pharmacy	86.53	0.1	8.65	1,818,764	15.7
Prescriber	24.53	0.1	2.45	1,818,764	4.5
Patient	26.51	0.1	2.65	1,818,764	4.8
Total	N/A	N/A	13.75	N/A	25.0

This alternative was not selected. It is contrary to the plain language of the statutory text which allows a patient to request a partial fill without obtaining the practitioner’s consent. Although this alternative ensures consideration of the partial fill by the prescribing practitioner, DEA believes this alternative is unnecessarily burdensome.

While DEA does not have a basis to estimate the likelihood of the prescribing practitioner denying consent for partial fills, DEA assumes denials would be rare. DEA welcomes public comments regarding this assumption. The patient may request a partial fill for a variety of reasons, and a partial fill request does not necessarily mean that the remaining portions of the prescription will not be filled. While making the prescribing practitioner aware of the partial fill would be helpful, requiring consent prior to the pharmacist’s dispensing the partial fill would be unnecessarily burdensome, and, thus, this alternative was not selected.

Alternative 2: Notify the Prescribing Practitioner of the Partial Fill Quantity After Dispensing

The second alternative would require notification to the prescribing practitioner or the prescribing practitioner’s agent of the quantity dispensed upon the patient’s request for the partial fill. In this scenario, the prescribing practitioner’s consent for the partial fill would not be required. Instead, the pharmacist would partially fill the prescription based on the patient’s request, notify the prescribing practitioner or the prescribing

practitioner’s agent of the quantity dispensed, and make the required notation on the prescription. The notation is the same method as for alternative 1.

DEA estimates notifying the prescribing practitioner will require three minutes from each of the parties involved: the pharmacist to contact the prescribing office to give notice and the prescribing office to receive and review notice. Using the same BLS occupations and loaded median hourly wages as Alternative 1, the estimated cost of each notification (three minutes per occurrence) would cost the pharmacy \$4.33 and the prescriber \$1.23 for a total \$5.56 per occurrence.

Applying the same estimate of 1,818,764 partial fills, as in Alternative 1, this alternative is estimated to cost pharmacies approximately \$7.9 million per year for the pharmacists to give notice and prescribing practitioners approximately \$2.2 million per year to receive and review notice. The table below summarizes this calculation.

Table 2: Summary Calculation for Alternative 2

	Loaded Hourly Wage (\$)	Time Required (hours)	Cost per Occurrence (\$)	Number of Occurrences	Total Cost (\$M)
Pharmacy	86.53	0.05	4.33	1,818,764	7.9
Prescriber	24.53	0.05	1.23	1,818,764	2.2
Total	N/A	N/A	5.56	N/A	10.1

This alternative was not selected. DEA believes that this alternative is also unnecessarily burdensome. Although this alternative would ensure that the prescribing practitioner is made aware of the partial filling of the prescription and could react to this information if needed. However, it would cause an additional compliance-burden on both the pharmacy and prescribing practitioner.

Alternative 3: Dispense Partial Fill as Requested Without Consent of, or Notification to, the Prescribing Practitioner

The third alternative would not require the consent of, or notification to, the prescribing practitioner described in alternative 1 or 2, respectively. In this alternative,

the pharmacist would partially fill the prescription based on the patient's request and make the required notation on the prescription. This alternative results in no notification-related cost to the pharmacy or prescriber.

This alternative was selected. Although a partial fill at the request of the patient may represent a departure from the prescribing practitioner's dispensing instructions, this alternative is the least burdensome to the pharmacy, prescribing practitioner, and the patient. Additionally, a partial fill does not preclude the eventual dispensing of the full amount prescribed. Under the proposed rule, patients requesting a partial fill would be entitled to request that the pharmacist fill the remainder of the prescription within a 30-day window. This alternative would result in no additional consent or notification-related costs and would not impose dispensing delays on patients requesting a partial fill. A further discussion of the benefits and costs of this alternative is described below.

III. Analysis of Benefits and Costs

The proposed rule would allow partial fills of controlled substances in schedule II at the request of the patient or the prescribing practitioner, if not prohibited by State law. The proposed rule also includes time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance, and additional provisions for how a practitioner may request that a prescription for a schedule II controlled substance be partially filled, and how a pharmacy must record the partial filling of a prescription for a schedule II controlled substance.

DEA examined the benefits, costs, and cost savings associated with this proposed rule.

Benefits

DEA does not know all the reasons a prescriber or patient might request a partial fill of a prescription. However, as discussed in the Cost Savings section below, a significant portion of filled opioid prescriptions go unused, leading to the excess opioids being kept

by the patient that could be for improper use, diversion, abuse, or improper disposal. Partial filling is expected to reduce the quantity of unused schedule II controlled substances, which would decrease the risk of diversion, and the danger that patients or others may become dependent upon or addicted to prescribed scheduled II controlled substances.

The supply of unused drugs in U.S. households contributes to demand for opioids and illicit drug use. Keeping and storing unused medications in households poses several dangers related to misuse, diversion, accidental overdose, and consumption of spoiled substances.⁶ Many patients receive their first opioid prescription after a surgical procedure and frequently retain the majority of unused medication, which could potentially be sold illegally or misused by the patient. In addition, unused medication can be diverted and used by other members of the patient’s household, friends of the patient, or sold. According to the National Institute on Drug Abuse, 21 to 29 percent of patients prescribed opioids for chronic pain misuse them, between 8 and 12 percent prescribed opioids for chronic pain develop an opioid use disorder, an estimated 4 to 6 percent who misuse prescription opioids transition to heroin, and about 80 percent of people who use heroin first misused prescription opioids.⁷ According to one journal article, “multiple studies have reported an increased risk of new persistent opioid use after prescription of opioids for acute pain in opioid naïve patients. Even patients who undergo relatively minor low-pain surgery are at increased risk of long term opioid use.”⁸ According to the Substance Abuse and Mental Health Administration (SAMHSA), 51.3 percent of people “who misused pain relievers in the past year obtained the last pain reliever they misused

⁶ “Safe Disposal of Unused Controlled Substances: Current Challenges and Opportunities for Reform,” Avalere, <http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf>.

⁷ “Opioid Overdose Crisis,” National Institute on Drug Abuse, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>. (Accessed 2/12/2020.)

⁸ “Prescription of opioids for acute pain in opioid naïve patients,” 2019, Carlos A Pino, MD, Melissa Covington, MD, Uptodate.com, Wolters Kluwer. <https://www.uptodate.com/contents/prescription-of-opioids-for-acute-pain-in-opioid-naive-patients>.

from a friend or relative.”⁹ Also, although opioid medications are effective in managing acute pain after surgery, even short-term use of opioids can lead to long-term dependence.¹⁰

The total U.S. economic burden (healthcare costs, criminal justice costs, and lost productivity costs) of prescription opioid misuse in 2013 was estimated to be \$78.5 billion, based on the 1.935 million Americans estimated to meet the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for opioid use disorder.¹¹ This economic burden equates to approximately \$41,600 per person with opioid use disorder.¹² DEA estimates approximately \$41,600 in societal benefit accrues each time we prevent an individual from developing opioid use disorder. This proposed rule is expected to lower the prevalence of opioid misuse and thereby reduce rates of opioid addiction. While DEA has no basis to quantify the amount of misuse that will be prevented, DEA anticipates that reductions in opioid dispensing will reduce the amount of unused opioid medications in American homes, thereby reducing opportunities for medication sharing and other forms of diversion. This, in turn will have a real and significant benefit by reducing misuse and development of opioid use disorder.

Cost Savings

This proposed rule is estimated to lower the amount of schedule II medications dispensed and, therefore, expenditures on prescriptions. It is also expected to reduce the number of unused schedule II controlled substances requiring disposal. To quantify the

⁹ “Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health,” SAMHSA, <https://www.samhsa.gov/data/report/2018-nsduh-annual-national-report>.

¹⁰ Empowering Post-Surgical Patients to Improve Opioid Disposal: A Before and After Quality Improvement Study Jessica M. Hasak, Carrie L. Roth Bettlach, Katherine B. Santosa, Ellen L. Larson, Jean Stroud, Susan E. Mackinnon Journal of the American College of Surgeons 2017.

¹¹ Florence CS, Zhou C, Luo F & Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 Med Care 901 (2016). DEA’s 2017 National Drug Threat Assessment also references this estimate for total economic burden of prescription drug abuse.

¹² \$78.5 billion / 1.935 million patients = \$40,568 per patient.

cost savings, DEA estimated the cost of excess medicine and calculated the approximate percent cost savings opportunity that may be realized by this proposed rule.

In 2017, 163,683,029 schedule II prescriptions were filled for “acute” pain, with a total retail cost of \$11,807,297,373, or an average retail cost of \$72.14 per prescription.¹³ The prescription data includes a data field that indicates whether the condition being treated is “acute” or “chronic.” The figure excludes schedule II controlled substances generally prescribed for chronic conditions, *i.e.*, amphetamine, lisdexamfetamine, methamphetamine, and methylphenidate. DEA believes prescriptions for “acute” conditions are more likely to be partially filled. Therefore, DEA estimates 163,683,029 prescriptions represent the total number of prescriptions that may be partially filled per year. However, many States have already passed laws or adopted regulations limiting the quantity of schedule II controlled substances that may be dispensed pursuant to a prescription. For example, in 2016, Massachusetts became the first state to pass a law to limit first time opioid prescriptions to seven days.¹⁴ Since 2016, many other States have passed similar laws limiting the prescribing of opioids for acute pain. These limits generally range from a 3 to 14-day supply.¹⁵ As of September 2019, 36 States have placed limits on the amount of opioids that can be prescribed by doctors.¹⁶ The limits in five of those States apply only to Medicaid recipients, and two States have no pill or day limits, but require doctors to prescribe the lowest effective dose.¹⁷ Based on review of state limits for prescribing of opioids, DEA estimates there are 34 states with pill or day

¹³ IQVIA Data 2017. Prescriptions for “acute pain” were used to differentiate from “chronic” conditions, which are limited to prescriptions for amphetamine. $\$11,807,297,373 / 163,683,029 = \72.14 .

¹⁴ “Opioid Prescribing Limits Across the States,” Marilyn Bullock, PharmD, BCPS, FCCM, 2/5/2019, pharmacytimes.com.

¹⁵ *Ibid.*

¹⁶ “Opioid prescription limits and policies by state.”

https://ballotpedia.org/Opioid_prescription_limits_and_policies_by_state. (Accessed 2/3/2020.)

¹⁷ *Ibid.*

limits in place, representing 68.7 percent of the U.S. population.¹⁸ DEA believes partial fill provisions under this proposed rule are likely to have impact on the remaining states without opioid prescription limits, representing 31.3 percent of the U.S. population. Applying this percentage, DEA estimates 51,232,788 (31.3 percent) of the 163,683,029 total prescriptions may be partially filled. According to a 2017 study of post-surgical patients who were prescribed opioids, only 29 percent used the entire prescription, leaving 71 percent of post-surgical patients with excess opioids.¹⁹ The study found that patients prescribed opioids after surgery consumed, on average, only 33 percent of the prescribed medication.²⁰ Based on that finding, DEA estimates 71 percent of patients will not use all controlled substance prescriptions. DEA therefore estimates that 36,375,279 (71 percent) of the estimated 51,232,788 prescriptions in states without controlled substance prescribing or dispensing limits will not be fully utilized, presenting an opportunity for cost savings from partial fills.

Assuming a typical partial fill request is for 50 percent of the prescription, and as discussed above, a patient is not likely to return to fill the remaining portion of the prescription, the estimated savings from the remaining unfilled portions is 50 percent of the average cost per prescription (\$72.14) or \$36.07. Multiplying the estimated savings per prescription of \$36.07 by the number of prescriptions available for cost savings (36,375,279) results in \$1,312,035,331 in potential cost savings per year. However, DEA

¹⁸ For the purposes of this discussion, “State” includes Puerto Rico and the District of Columbia. Population estimates are based on the U.S. Census Bureau’s 2019 population estimates. The 34 States that have pill or day limits are: Alaska, Arizona, Colorado, Connecticut, Delaware, Florida, Hawaii, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia.

¹⁹ Empowering Post-Surgical Patients to Improve Opioid Disposal: A Before and After Quality Improvement Study Jessica M. Hasak, Carrie L. Roth Bettlach, Katherine B. Santosa, Ellen L. Larson, Jean Stroud, Susan E. Mackinnon *Journal of the American College of Surgeons* 2017. The purpose of the study was to determine whether providing an educational brochure would improve disposal methods of excess opioids. The study found 35 of 128 participants not given the educational brochure used the entire prescription, and 40 of 130 participants given the educational brochure used the entire prescription. Combining the two groups, 75 (29%) of 258 participants used the entire prescription.

²⁰ *Ibid.*

does not have a basis to estimate the actual number or percentage of controlled substances issued in these states that will be partially filled, and therefore cannot estimate likely aggregate savings based on this methodology. For the purposes of this analysis, DEA estimates 50 percent of potential savings, or \$656,028,165 (representing 18,187,640 partially filled prescriptions) will be realized as annual cost savings from reduced schedule II controlled substance dispensing. DEA does not have a basis to estimate the impact of this proposed rule on payments to pharmacies, in terms of price per dosage units, copays, insurance reimbursements, etc., or who would realize the cost savings.

In addition to the cost savings from not dispensing remaining portions of partially filled prescriptions, DEA anticipates cost savings from the reduced need to dispose of unused medications. Patients dispose of unused drugs in a variety of ways, including throwing them in the trash, flushing them down the toilet, pouring them down the sink drain, taking them to the pharmacy or physician's office, or taking them to a drug take back site or event. In a two-phased study using a convenience sample in Southern California, researchers found that only 13 percent of people surveyed either disposed of their medications by taking them to the pharmacy or to the physician's office.²¹ For the purpose of this analysis, DEA assumes that only 13 percent of people with leftover schedule II medications dispose of their unused medications in this way. It is likewise estimated that two-thirds of dispensed medications in the United States are unused by patients.²² Based on DEA's assumption that a typical partial fill represents 50 percent of the prescription, and that the average partially filled prescription represents 67 pills, DEA estimates the average number of excess pills is 34 (50% x 67 pills) per full prescription filled.²³ To calculate the total cost savings for patients not needing to dispose of their

²¹ "Taking Stock of Medication Wastage: Unused Medications in US Households." NeuroImage, Academic Press, 16 Oct. 2014, www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub.

²² Ibid.

²³ IMS Health IQVIA Data 2017. The 67 average number of pills dispensed was determined by dividing the total number of prescriptions in 2017 by the total number of extended units (10,921,740,149/163,683,029).

unused schedule II drugs, DEA first multiplied the estimated number of partial fill prescriptions by the average disposal pill count to get a total of 618,379,760 pills (18,187,640 x 34). To estimate the number of pills being disposed of by patients through pharmacies, physician offices, or take back days, DEA multiplied the total number of pills (618,679,760) by 13 percent to get 80,389,369 pills. Using the average cost per disposal of \$5.60/pound collected,²⁴ and the estimate of pound/pill of .0069,²⁵ the total cost savings for unused pills not needing to be disposed of is \$3,106,245 (80,389,369 x \$5.60 x .0069). The remaining 87 percent of pills that are not properly disposed of are assumed to be either thrown away in the trash (62.7 percent), flushed down the toilet (18 percent), disposed of in the sink (4.3 percent), not disposed of and stored (17.4 percent), and other (8 percent).²⁶ Therefore, the total annual cost savings of this proposed rule is \$659,134,410 (\$656,028,165 + \$3,106,245).

Costs

DEA estimates there is a cost to prescribers associated with the time burden of writing instructions for partial fill prescriptions.

Partial filling of a prescription for a schedule II controlled substance, pursuant to this proposed rule, may be requested by the prescriber or the patient. The prescriber may request a partial fill by specifying the quantity to be dispensed in the partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record, along with other information required in 21 CFR 1306.05. While any additional time to specify the quantity to be dispensed in the partial

²⁴ Siler, S., Duda, S., Brown, R., Gbemudu, J., Weiner, S., & Gludemans, J. (n.d.). Safe Disposal of Unused Controlled Substances. Retrieved September 21, 2018, from <http://www.ncdoj.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf>.

²⁵ <http://michigan-open.org/statewide-drug-takeback-event-nets-900-pounds-of-opioids-more///>.

²⁶“Taking Stock of Medication Wastage: Unused Medications in US Households.” NeuroImage, Academic Press, 16 Oct. 2014, www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub. Percentages are of improper disposal methods only. There were other choices on the survey: take it to the pharmacy (11.2 percent) and take it to the physician’s office (1.8 percent), The percentages do not add to 100 percent because respondents were allow to select more than one method.

filling may be minimal, especially when viewed in relation to the entire duration of the medical interaction between the prescriber and the patient, DEA estimates each partial fill requested by the prescriber will require 10 additional seconds for the prescriber to specify the quantity to be dispensed. Based on BLS' mean hourly wage for "29-1060 Physicians and Surgeons" of \$101.43 and a 42.7 percent load for benefits, the estimated loaded hourly wage for a prescriber is \$144.74.²⁷ Therefore, the 10 additional seconds to specify the quantity to be dispensed equates to \$0.40.²⁸ As discussed in the Cost Savings discussion above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year available for partial filling that would be partially filled pursuant to this proposed rule. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year, will be partially filled at the request of the prescriber at an annual cost of \$7,275,056.

When a prescribing practitioner has properly specified his or her intent to partially fill a prescription for a schedule II controlled substance, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.²⁹ Specifically, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the schedule II prescription).

Also, for each such partial filling, the pharmacy would be required to maintain a record

²⁷ BLS, May 2018 National Occupational Employment and Wage Estimates, United States. https://www.bls.gov/oes/current/oes_nat.htm. (Accessed 2/6/2020.) BLS, "Employer Costs for Employee Compensation – September 2019" (ECEC) reports that average benefits for private industry is 29.9 percent of total compensation. The 29.9 percent of total compensation equates to 42.7 percent (29.9% / 70.1%) load on wages and salaries. $\$101.43 \times 1.427 = \144.74 . The "median" hourly rate is generally preferred. However, the median hourly rate for this occupation code was not available; thus, the "mean" was used. While it is likely some of the partial fill instructions will be written by a mid-level practitioner, *i.e.*, nurse practitioner, physician's assistant, etc., or a nurse (in preparation for the prescriber's signature), DEA believes this loaded hourly rate is a reasonably conservative estimate.

²⁸ $10 \text{ seconds} \times (1 \text{ hour} / 3,600 \text{ seconds}) \times \$144.74/\text{hour} = \$0.40$.

²⁹ See note 2.

with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. DEA believes the most common scenario would be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information would be printed, and subsequently affixed to the prescription container. When partially filling a prescription for a schedule II controlled substance at the patient's request, the pharmacist would need to make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner, along with additional information indicating that the patient requested the partial fill. While DEA believes documenting the quantities dispensed for each filled prescription is a usual and ordinary activity for a pharmacist, DEA estimates that it may require 10 additional seconds for a pharmacist to record a partial fill, pursuant to this proposed rule. Based on an estimated loaded median hourly rate of \$86.53 for a pharmacist, from the alternatives analysis above, the 10 additional seconds to record partial fills equates to \$0.24.³⁰ As discussed above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year that would be partially filled. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled, requiring recording of the partial fill by the pharmacist at an annual cost of \$4,365,034.

If a patient received a partial fill pursuant to this proposed rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist would require some additional time to fill the prescription. For example, if filling the remainder of the partial fill required 10 additional minutes, based on the estimated loaded median hourly rate of \$86.53 for a pharmacist, that additional time would equate to a cost of \$14.42. Additionally, there would be a similar cost to the

³⁰ 10 seconds x (1 hour / 3,600 seconds) x \$86.53/hour = \$0.24.

patient to potentially make an additional trip to the pharmacy and waiting for the prescription to be filled. However, DEA estimates these additional interactions will be minimal. As discussed earlier in reference to the 2017 study of post-surgical patients who were prescribed opioids, 71 percent of patients in the study did not use the entire prescription, and on average the patients only used 33 percent of the prescribed opioids. If prescribers and patients randomly asked for partial fills, only a small minority of patients would return for the remainder of the prescription. However, DEA does not anticipate the request for partial fills, at the request of the prescriber or the patient, to be random. Rather, DEA anticipates prescribers will exercise professional judgment and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed medicine. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instruction, based on consultation between the prescriber and the patient. Therefore, DEA believes any increase in the number of patient-pharmacy interactions related to patient-requested partial fills and resulting burden would likely be *de minimis*. DEA estimates the total cost of this proposed rule is \$11,640,090 (\$7,275,056 to prescribers and \$4,365,034 to pharmacies) per year.

Discussion of Uncertainties

This analysis evaluates the economic impact of activities that were previously not permitted. Therefore, DEA does not have a strong basis to estimate the level of participation in these activities, including partial filling of prescriptions for schedule II controlled substances by prescribers and patients, and how insurance companies would react to these partial filling of prescriptions.

This analysis is highly sensitive to the percentage of prescriptions being partially filled, and the percentage of partially filled prescriptions with patients returning for remainder of the partially filled prescription.

For example, if prescribers and patients in States with no opioid prescription pill or day limits requested a partial fill of 50 percent of the prescription amount for all 71 percent of prescriptions where not all drugs are used, the estimated cost savings from not dispensing the full prescriptions increases to \$1,312,035,331 (representing 36,375,279 partially filled prescriptions). Because DEA does not have a good basis to estimate the potential cost savings that will be realized, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or \$656,028,165 (representing 18,187,640 partially filled prescriptions) will be realized as cost savings from not dispensing excess schedule II controlled substances. An estimate of zero percent would result in zero cost savings. As the percentage of cases where partial fills are requested increases, the estimated cost savings increase proportionally.

DEA anticipates prescribers will exercise professional judgment and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed medicine, resulting in a minimal number of patients returning for the remainder of the partially filled prescription. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes of patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instruction, based on consultation between the prescriber and the patient.

Finally, this analysis excluded any anticipated impact of this proposed rule on payments to pharmacies, in terms of price per dosage units, copays, insurance reimbursements, etc., or who would realize the cost savings.

DEA welcomes all comments that would narrow the uncertainties in the presented analysis, and specifically asks prescribers, patients, and health care industry, including insurance companies, the following questions:

1. Why do so many prescriptions for schedule II controlled substances result in unused dosages?
2. Would prescribers start using this proposed regulatory provision and start giving instructions for partial filling of schedule II controlled substances, or are there other factors that are likely not to result in prescribers giving partial filling instructions?
3. How often would a prescriber instruct partial filling of a prescription for a schedule II controlled substance?
4. Is it reasonable to anticipate a prescriber will exercise professional judgment and foresight in determining when partial fill would most appropriate, resulting in minimal number of patients returning for the remainder of the partially filled prescription or experiencing pain because they run out of medication? Would prescribers be likely to use consistent criteria for determining when to give partial refills? Given that the majority of schedule II prescriptions are not fully utilized, should prescribers request partial fills in most cases?
5. How likely are patients to request partial filling at the pharmacy when the prescriber has not given instructions for a partial fill on the prescription?
6. Is it reasonable to assume that a patient interested in a partial filling of a schedule II controlled substance would request the prescriber to provide instructions on the prescription?
7. Is it reasonable to assume that when prescribers do not request a partial fill patients will generally not request a partial fill?
8. (Questions for industry including private and public plans and entitlements)

- a. What are likely requirements for copay in a partial filling?
- b. Would the copay be reduced?
- c. Would there be a copay when a patient returns for filling the remainder of a partially filled prescription (full amount or reduced amount)?
- d. Would a patient likely spend less on a partial fill than on a full prescription?
- e. If so, would requesting two or more partial fills likely cost the patient more than filling the full prescription initially?

Summary

In summary, DEA estimates that the total cost savings of this proposed rule will be \$659 million per year, and the total cost will be \$12 million per year, for a net cost savings of \$647 million per year (rounded to the nearest million dollars). At a three percent discount rate, the net present value of the cost savings over a 5-year period is \$2,965 million. At a seven percent discount rate, the present value of the cost savings is \$2,655 million. Due to the fluid nature of the national opioid crisis and legislative activity in State government, DEA believes using a five-year term for the present value analysis is reasonable. DEA welcomes public comment on the assumptions made in this analysis.

This proposed rule is expected to be an E.O. 13771 deregulatory action. The proposed rule is an enabling rulemaking, which expands the options for filling schedule II prescriptions. OMB's guidance on E.O. 13771 explains that agencies may carry E.O. 13771 deregulatory actions forward to be applied to E.O. 13771 regulatory actions, and to offset incremental regulatory costs in the same or subsequent fiscal years.³¹ Adjusting from 2017 to 2016 dollars, the estimated annual cost savings is \$636 million per year over five years, net present value of \$2,911 million (cost savings) at three percent

³¹ OMB Memorandum M-17-21 at 12.

discount rate, and \$2,606 million (cost savings) at seven percent discount rate to offset future incremental regulatory costs.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard of affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not, if promulgated, have a significant economic impact on a substantial number of small entities.

This proposed rule includes provisions regarding partial fill of prescriptions for schedule II controlled substances. The proposed rule would allow partial fills of prescriptions for controlled substances in schedule II at the request of the patient or the prescribing practitioner, if not prohibited by State law. The proposed rule also includes

time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance and additional provisions for how a practitioner may request that a prescription for a schedule II controlled substance be partially filled, how a patient may request that a prescription for a schedule II controlled substance be partially filled, and how a pharmacy must record the partial filling of a prescription for a schedule II controlled substance. While not all practitioners may write prescriptions with partial fill instructions, and not all pharmacies may receive prescriptions for partial fill, these registrants (or entities that employ these registrants) would still be subject to the partial fill provisions contained in the proposed rule.

This proposed rule primarily affects prescribers of schedule II controlled substances and the pharmacies that fill those prescriptions. While prescribers are generally individual practitioners, for the purposes of this analysis, DEA includes industries that employ prescribers. In Table 3, DEA estimates the industries that would be affected by this proposed rule, as described by the North American Industry Classification System (NAICS). This list is not intended to include an exhaustive list of all employers of prescribers of schedule II controlled substances, but rather a representation of primary industries that employ them.

Table 3: Affected Industries, Six-Digit NAICS Code

NAICS	NAICS Description
446110	Pharmacies and Drug Stores
621111	Offices of Physicians (except Mental Health Specialists)
621210	Offices of Dentists
621491	HMO Medical Centers
621493	Freestanding Ambulatory Surgical and Emergency Centers
622110	General Medical and Surgical Hospitals

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) publishes the number of firms, employment, and revenue by firm size and industry. To estimate the number of small businesses affected, DEA compared the 2012 SUSB data, the most recent data

available containing revenue by firm size and industry,³² to the U.S. Small Business Administration (SBA) size standards.³³ DEA estimates a total 326,033 entities, of which 318,362 are small entities, would be affected by this proposed rule. Table 4 details the number of entities, SBA size standard, and estimated number of small entities for each affected industry.³⁴

Table 4: Estimated Number of Affected Small Entities

NAICS	NAICS Description	Firms	SBA Size Standard, Annual Revenue (\$M)	Small Entities
446110	Pharmacies and Drug Stores	18,852	30.0	18,503
621111	Offices of Physicians (except Mental Health Specialists)	174,901	12.0	170,287
621210	Offices of Dentists	125,151	8.0	124,689
621491	HMO Medical Centers	104	35.0	81
621493	Freestanding Ambulatory Surgical and Emergency Centers	4,121	16.5	3,603
622110	General Medical and Surgical Hospitals	2,904	41.5	1,199
Total		326,033	N/A	318,362

Partial filling of a prescription for a schedule II controlled substance, pursuant to this proposed rule, may be requested by the prescriber or the patient. The prescriber may request a partial fill by specifying the quantity to be dispensed in the partial filling on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record, along with other information required in 21 CFR 1306.05. While any additional time to specify the quantity to be dispensed in the partial filling may be minimal, especially when viewed in relation to the entire duration of the medical interaction between the prescriber and the patient, DEA estimates each partial fill

³² “Number of small businesses: Small entity counts, employment, and revenues...number of small entities when the size standard is based on revenue [Link to: https://www2.census.gov/programs-surveys/susb/tables/2012/us_6digitnaics_r_2012.xlsx].” <https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-data-resources-for-federal-agencies>. (Accessed 2/4/2020.)

³³ U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective August 19, 2019. <https://www.sba.gov/document/support--table-size-standards>. (Accessed 2/4/2020.)

³⁴ For the purposes of this analysis, “firms” and “entities” are used synonymously.

requested by the prescriber will require 10 additional seconds for the prescriber to specify the quantity to be dispensed. As discussed in the Costs section above, based on BLS' mean hourly wage for "29-1060 Physicians and Surgeons" of \$101.43 and a 42.7 percent load for benefits, the estimated loaded hourly wage for a prescriber is \$144.74.

Therefore, the 10 additional seconds to specify the quantity to be dispensed equates to \$0.40.³⁵ As discussed in the Cost Savings discussion above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year available for partial filling that would be partially filled pursuant to this proposed rule. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled at the request of the prescriber at a cost of \$7,275,056. This cost of \$7,275,056 equates to an average of \$24 per firm, excluding pharmacies.³⁶

When a prescribing practitioner has properly specified his or her intent to partially fill a prescription for a schedule II controlled substance, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.³⁷ Specifically, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the schedule II prescription). Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and

³⁵ 10 seconds x (1 hour / 3,600 seconds) x (\$101.43/hour x 1.427) = \$0.40.

³⁶ 326,033 total affected firms – 18,852 pharmacies and drug stores = 307,181 firms that employ prescribers. \$7,275,056 / 307,181 = \$24 (rounded to nearest whole dollar).

³⁷ See note 2.

IV prescription refills. DEA believes the most common scenario would be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information would be printed, and subsequently affixed to the prescription container. When partially filling a prescription for a schedule II controlled substance at the patient's request, the pharmacist would need to make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner, along with additional information indicating that the patient requested the partial fill. While DEA believes documenting the quantities dispensed for each filled prescription is a usual and ordinary activity for a pharmacist, DEA estimates that it may require 10 additional seconds for the pharmacist to record a partial fill, pursuant to this proposed rule. Based on an estimated loaded median hourly rate of \$86.53 for a pharmacist, from the alternatives analysis above, the 10 additional seconds to record partial fills equates to \$0.24.³⁸ As discussed in the Cost Savings section above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year that would be partially filled. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled, requiring recording of the partial fill by the pharmacist at an annual cost of \$4,365,034. This cost of \$4,365,034 equates to an average of \$232 per firm for pharmacies.³⁹

The average cost of \$24 per firm for prescribers, and \$232 per firm for pharmacies is a very high estimate for small entities, as small prescribing firms are expected to request less than an average number of partial fills per firm, and small pharmacies are expected to fill less than average partial fills per firm. Although these are high estimates, these costs were compared to the average annual revenue for the smallest of small entities. The

³⁸ 10 seconds x (1 hour / 3,600 seconds) x (\$60.64/hour x 1.427) = \$0.24.

³⁹ \$4,365,034 / 18,852 = \$232 (rounded to nearest whole dollar).

average cost ranges from 0.009 percent of revenue for the smallest of small hospitals, and 0.487 percent for the smallest of small pharmacies. The table below summarizes this analysis for each of the industry codes.

Table 5: Average Cost as Percent of Revenue

NAICS	NAICS Description	Firm Size in Receipts (\$)	Firms	Revenue (\$1,000)	Revenue per Firm (\$)	Cost per Firm (\$)	Cost as Percent of Revenue
446110	Pharmacies and Drug Stores	<100,000	757	36,066	47,643	232	0.487%
621111	Offices of Physicians (except Mental Health Specialists)	<100,000	15,275	771,280	50,493	24	0.048%
621210	Offices of Dentists	<100,000	8,701	452,125	51,962	24	0.046%
621491	HMO Medical Centers	<100,000	24	1,266	52,750	24	0.045%
621493	Freestanding Ambulatory Surgical and Emergency Centers	<100,000	223	11,879	53,269	24	0.045%
622110	General Medical and Surgical Hospitals	100,000-499,999*	14	3,812	272,286	24	0.009%

*Revenue data not available for “<100,000.” Examined smallest size with available revenue data.
Source: SUSB.

After normalizing the cost for revenue size of the affected firms by dividing the total cost by the total revenue for the affected industry, the cost as percent of revenue is much lower. As an industry, the cost as percent of revenue is 0.0005 percent and 0.0018 percent for prescribing firms and pharmacies, respectively. These percentages represent all firms, including small firms. The table below summarizes the normalized cost as percentage of revenue.

Table 5: Average Cost as Percent of Revenue, Normalized

NAICS	NAICS Description	Firm Size in Receipts	Firms	Revenue (\$1,000)	Cost (\$)	Cost as Percent of Revenue
446110	Pharmacies and Drug Stores	All firms	18,852	236,277,373	4,365,034	0.0018%
621111	Offices of Physicians (except Mental Health Specialists)	All firms	174,901	402,159,295		
621210	Offices of Dentists	All firms	125,151	104,740,291		
621491	HMO Medical Centers	All firms	104	7,124,698		
621493	Freestanding Ambulatory Surgical and Emergency Centers	All firms	4,121	24,084,457		
622110	General Medical and Surgical Hospitals	All firms	2,904	826,654,913		

Source: SUSB.

If a patient received a partial fill pursuant to this proposed rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist would require some additional time to fill the prescription. For example, if filling the remainder of the partial fill required ten additional minutes, based on the estimated loaded median hourly rate of \$86.53 for a pharmacist, that additional time would equate to a cost of \$14.42. However, DEA estimates these additional interactions will be minimal. As discussed earlier in reference to the 2017 study of post-surgical patients who were prescribed opioids, 71 percent of patients in the study did not use the entire prescription, and on average the patients only used 33 percent of the prescribed opioids. If prescribers and patients randomly asked for partial fills, only a small minority of patients would return for the remainder of the prescription. However, DEA does not anticipate the request for partial fills, at the request of the prescriber or the patient, to be random. Rather, DEA anticipates prescribers will exercise professional judgement and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed medicine. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instructions, based on consultation between the prescriber and the patient. Therefore, DEA believes any increase in the number of patient-pharmacy interactions related to patient-requested partial fills and resulting burden is *de minimis*.

Therefore, DEA's evaluation of economic impact by size category indicates that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of these 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 the UMRA of 1995.

Congressional Review Act

This proposed rule is a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This proposed rule will result in an annual effect on the economy of \$100,000,000 or more; DEA estimates this rule will result in a cost savings of \$659 million per year over five years. However, it will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), DEA has identified the following collections of information related to this proposed rule. If adopted, this proposed rule would create additional recordkeeping requirements for pharmacies regarding partial fills. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

A. Collections of Information Associated with the Proposed Rule

Title: Recordkeeping Requirements for Partial Fills of Prescriptions for Schedule II Controlled Substances

OMB Control Number: 1117-NEW

DEA Form Number: N/A

DEA is proposing to require pharmacies to create and maintain certain records relating to partial fills of prescriptions for schedule II controlled substances. When presented with a prescription for a schedule II controlled substance, on which the prescribing practitioner has properly specified his/her intent that the prescription be partially filled, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations (for other circumstances).⁴⁰ Specifically, upon each such partial filling requested by the prescribing practitioner, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the prescription). For electronic prescriptions, there would need to be an electronic prescription record and the record would need to be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications would need to allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

⁴⁰ Longstanding DEA regulations, which would not be changed by this proposed rule, also allow the partial filling of a schedule II prescription where the pharmacist is unable to supply the full quantity called for in the prescription (§ 1306.13(a)) and for a patient in a long-term care facility or with a terminal illness (§ 1306.13(b) and (c)).

As proposed, upon partially filling a prescription for a schedule II controlled substance at the request of a patient, dispensing pharmacists would need to make a notation on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record of the following: (1) “patient requested partial fill on [date such request was made]” and (2) the quantity dispensed. In addition, for each such partial filling, the pharmacy would need to maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser would need to be linked to each electronic controlled substance prescription record.

DEA estimates the following number of respondents and burden associated with this collection of information:

- Number of respondents: 68,676
- Frequency of response: Per occurrence (264.83255 per year, calculated)
- Number of responses: 18,187,640 per year
- Burden per response: 0.002777778 hour (10 seconds)
- Total annual hour burden: 50,521 hours

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

B. Request for Comments Regarding the Proposed Collections of Information

DEA is soliciting comment on the following issues related to these information collections:

- The need for the information collection and its usefulness in carrying out the proper functions of DEA.

- The accuracy of DEA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB45/Docket No. DEA-469. All comments must be submitted to OMB on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, DEA proposes to amend 21 CFR part 1306 as follows:

PART 1306— PRESCRIPTIONS

1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829a, 831, 871(b) unless otherwise noted.

2. In § 1306.13, redesignate paragraphs (b) and (c) as paragraphs (c) and (d), and add a new paragraph (b) to read as follows:

§ 1306.13 Partial filling of prescriptions.

* * * * *

(b) Partial filling of a prescription for a schedule II controlled substance at the request of the prescribing practitioner or patient:

- (1) *General requirements.* A prescription for a controlled substance in schedule II

may be partially filled if all of the following conditions are satisfied:

(i) It is not prohibited by State law;

(ii) The prescription is written and filled in accordance with the Act, this chapter, and State law. A prescription written for a quantity that exceeds the limits of State law is not a valid prescription, therefore, the prescription may not be filled as written. Because such a prescription is not valid, it also cannot be partially filled;

(iii) The partial fill is requested by the patient or by the practitioner who wrote the prescription; and

(iv) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) Time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance. If all the conditions of paragraph (b)(1) of this section are satisfied, and the prescription is partially filled, remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled not later than 30 days after the date on which the prescription is written, except that in the case of an emergency oral prescription, as described in subsection 309(a) of the Act (21 U.S.C. 829(a)), the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled not later than 72 hours after the prescription is issued.

(3) How a practitioner may request that a prescription for a schedule II controlled substance be partially filled. Where a practitioner issues a prescription for a schedule II controlled substance and wants the prescription to be partially filled, the practitioner must specify the quantity to be dispensed in each partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. This information must be included on the prescription, along with the other information required by § 1306.05, at the time the practitioner signs the

prescription or, in the case of an emergency oral prescription, this information must be communicated by the prescribing practitioner to the pharmacist.

(4) How a patient may request that a prescription for a schedule II controlled substance be partially filled. A patient may request that his/her prescription for a schedule II controlled substance be partially filled. Such a request by the patient may be made: in person, in writing if signed by the patient, or by a phone call from the patient to the pharmacist. Where a practitioner has requested the partial filling of a prescription in accordance with paragraph (b)(3) of this section, the patient may not request a partial filling in an amount greater than that specified by the practitioner.

(5) How a pharmacy must record the partial filling of a prescription for a schedule II controlled substance. (i) Upon partially filling a prescription at the request of the prescribing practitioner in accordance with paragraph (b)(3) of this section, the pharmacist must make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. In addition, for each such partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

(ii) Upon partially filling a prescription at the request of the patient in accordance with paragraph (b)(4) of this section, the pharmacist must make a notation on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record of the following: (I) “patient requested partial fill on [date such request was made]” and (II) the quantity dispensed. In addition, for each such

partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

* * * * *

Timothy J. Shea,

Acting Administrator.

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