

E. The rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury. Incident data show 284 fatal incidents related to rail entrapment between January 2003 and December 2021. The incident data show that these incidents continue to occur and are likely to increase because APBR manufacturers do not comply with the voluntary standard and the market for ABPRs is forecast to grow. The rule establishes performance requirements to address the risk of entrapments associated with ABPRs. Given the fatal and serious injuries associated with entrapments on APBRs, the Commission finds that the rule and its effective date are necessary to address the unreasonable risk of injury associated with APBRs.

F. Public Interest. The rule addresses an unreasonable risk of entrapments and other hazards associated with APBRs. Adherence to the requirements of the rule would reduce deaths and injuries from APBR entrapment incidents; thus, the rule is in the public interest.

G. Voluntary Standards. If a voluntary standard addressing the risk of injury has been adopted and implemented, then the Commission must find that the voluntary standard is not likely to eliminate or adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely.

(1) The Commission determines that, absent modification, the voluntary standard is not likely to eliminate or adequately reduce the risk of injury of entrapments on APBRs. The Commission also determines that ASTM F3186–17, with the modifications described in § 1270.2, is likely to adequately reduce the risk of injury associated with APBRs. Entrapment is the most prevalent hazard pattern among the deaths and injuries associated with APBRs. The entrapment test methods specified in the voluntary standard require products to be tested to assess the potential for entrapment in four different zones. The four entrapment zones required to be tested each address specific types of entrapment as follows: head-first entry into fully bounded openings within the structure of the bed rail; head-first entry under the rail into any opening between the mattress and the bed rail; entry of the head into a gap between the inside surface along the length of the bed rail and the compressed mattress; and neck-first entrapment between the ends of the bed rail and the compressed mattress. Most of the reported entrapment fatalities involved one of the four zones listed. In 214 out of 284 fatal incidents, the entrapment location was identified and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186–17.

(2) The Commission determines that modifications to the voluntary standard are needed to improve safety. Such modifications include: providing additional definitions for product assembly and installation to ensure their consistent and differentiated use throughout the standard; adding requirements for manufacturers to take into account the range of mattress thicknesses to ensure safe use of the product and provide testers with additional guidance for selecting the mattress thickness during

the test setup; addressing inconsistencies with stated dimensions to ensure consistent dimensional tolerances; and providing additional clarity for Zone 1 and 2 test setup and methods, additional guidance for identifying potential Zone 2 openings, and updated requirements for Zone 3 testing consistency.

(3) The Commission determines that substantial compliance with the voluntary standard is unlikely. CPSC conducted two rounds of market compliance testing to ASTM F3186–17: the first round in 2018 and 2019, the second round in 2021. In both rounds, no APBRs met all requirements of ASTM F3186–17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, and entrapment. All products failed the labeling, warning, and instructional requirements.

H. Reasonable Relationship of Benefits to Costs. (1) The benefits expected from the rule bear a reasonable relationship to its cost. The rule reduces the entrapment hazard and other hazards associated with APBRs, and thereby reduces the societal costs of the resulting injuries and deaths. The rule is expected to address the 92 percent of deaths caused by entrapment, resulting in potential societal benefits of \$298.11 million. Benefits additionally were assessed under three scenarios derived from this expected efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Under these three scenarios, the estimated quantifiable annualized benefits of the rule are approximately \$200.24 million, \$133.49 million, and \$66.75 million, respectively. The costs associated with the rule's requirements to prevent the hazards associated with APBRs are expected to be approximately \$2.01 million per year. On a per product basis, the estimated benefits of the rule are approximately \$331.78, \$221.19, and \$110.59 per APBR when assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively, and the costs are approximately \$3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent.

(2) The requirements of the rule, with modifications, are expected to address 92 percent of deaths caused by entrapment. Even under the most conservative assumption that only 25 percent of the potential benefits are achieved, every \$1 in costs for the market to adopt the rule equates to approximately \$33.15 in benefits to society. The estimated annualized net benefits of the rule are approximately \$198.23 million, \$131.48 million, and \$64.74 million, at when benefits are assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively.

I. Least-Burdensome Requirement that Would Adequately Reduce the Risk of Injury. The Commission considered six alternatives to the rule including: take no regulatory action; continue to conduct recalls of APBRs instead of promulgating a rule; conduct an educational campaign without a rule; ban APBRs from the market entirely; require enhanced safety warnings without other requirements; and implement the rule with a longer effective date. Although most of these

alternatives may be a less burdensome alternative to the rule, the Commission determines that none of the alternatives would adequately reduce the risk of deaths and injuries associated with APBRs that is addressed by the rule while still preserving the product's utility to consumers.

Alberta E. Mills,
Secretary, Consumer Product Safety Commission.

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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: Final rule.

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 (DEA) is amending its regulations to conform to this statutory provision, as well as to provide direction on gaps not addressed by legislation. DEA will also be amending its regulations to update a cross-reference in a paragraph that will be redesignated with this final rule.

DATES: This final rule is effective August 21, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) of 2016 into law as Public Law 114–198. Section 702(a) of the CARA amended 21 U.S.C. 829 of the Controlled Substances Act (CSA) by adding subsection (f) to allow a pharmacist to partially fill a prescription for a schedule II controlled substance under certain conditions.

Specifically, subsection (f)(1) allows such partial filling where requested by the prescribing practitioner or the patient provided that all of the following conditions are 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)(2) provides that the remaining portions of a partially filled prescription for a schedule II controlled substance, 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 final rule is revising DEA regulations to incorporate the foregoing statutory provision. In addition, DEA is further revising its regulations to address regulatory requirements not addressed by section 702(a) of the CARA. This provision does not address how the prescribing practitioner should indicate that a prescription for a schedule II controlled substance must be partially filled. Likewise, it does not specify how a pharmacist should record the partial filling of such a prescription. However, it does provide that partial filling of prescriptions for a schedule II controlled substance 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 section 702(a) of the CARA. DEA is exercising this authority by issuing this rule to give practitioners and pharmacists clear guidance in this area, and to allow for proper auditing by DEA.

II. Background

There is potential for benefit to patients and society as a result of this 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. Reducing the dispensing of schedule II controlled substances that are ultimately not needed would also help to reduce the risk that the patient might develop physical dependence or an addiction to opioids or other schedule II controlled substances. The existence of unused drugs in U.S.

households contributes to growing rates of substance misuse of prescription drugs among Americans. Keeping and storing unused medications in households pose several risks 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.

III. Summary of the Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on December 4, 2020, providing an opportunity for comments to be submitted. 85 FR 78282. The comment period closed February 2, 2021. While DEA invited comments on the entire NPRM, DEA specifically pointed commenters to the then proposed changes to 21 CFR 1306.13(b)(3), (4), and (5), which were filling in gaps not addressed by section 702(a) of the CARA. The other proposed amendments to 21 CFR 1306.13(b)(1) and (2) merely reiterated the statutory requirements of section 702(a) of the CARA, and therefore, cannot be changed.

IV. Discussion of Regulatory Text Comments

DEA received 37 comments on the NPRM. Commenters included a nonprofit organization representing hospitals, a trade association representing chain drug stores, an association representing pharmacy boards, three professional pharmacist associations, practicing nurses and nurse practitioner students, and other individual or anonymous commenters. Most commenters generally supported the rule with some of those supporters also raising issues of concern or desiring clarification. Some commenters who opposed the rule primarily expressed concern about the impact on individuals with chronic pain, mistakenly assuming that the rule, if finalized, would require a prescription for a schedule II controlled substance to be partially filled. In fact, the rule simply proposed amending DEA's regulations to allow an option for a prescription for a schedule II controlled substance to be partially filled, if requested by the prescribing practitioner or patient. The comments are summarized below, along with DEA's responses.

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

General Opposition to Provisions Mandated by Congress

Issue: Several commenters expressed opposition to provisions of the rule that were mandated by Congress, stating that the government should not interfere with the prescribing of medicine.

Response: As discussed in the NPRM, the provisions which are directly from the CARA cannot be modified. DEA has to allow both the patient and the practitioner to request partial fills. However, because DEA was granted the authority to fill in gaps not addressed by the CARA, DEA is able to create regulations to direct the manner which the partial fill is to be requested and recorded. Also, the government may be involved in the prescribing of medicine, as agencies such as Indian Health Services, Department of Veterans Affairs, Department of Defense, and Bureau of Prisons can serve as the healthcare provider.

General Requirements for Partial Filling

Issue: Commenters expressed concern over DEA's stance in the proposed rule's preamble and in the proposed amendment at 21 CFR 1306.13(b)(1)(ii) regarding the validity of a prescription. Specifically, commenters urged DEA to reconsider its position, expressed in the proposed rule, of interpreting a prescription to be invalid if the quantity exceeds the limits of state law. An association asked for clarification and guidance when the partial fill is the result of limitations set by state or local law. One association stated that this is inconsistent with DEA policy that was set forth in a DEA policy letter dated August 24, 2011, and that DEA will cause confusion amongst healthcare providers. The association's comment included a quote from this DEA policy letter, which stated "DEA expects that when information is missing from or needs to be changed on a Schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and Federal laws and policies to decide whether it is appropriate to make changes to that prescription." Commenters stated that this conflicts with the position taken in the proposed rule and that it also is inconsistent with many state laws, which allow a prescription written in excess of state limits to still be considered valid. Furthermore, commenters stated that multiple State Boards of Pharmacy have also issued guidance saying that state laws do not require pharmacists to confirm the validity of higher quantity prescriptions for schedule II controlled substances with the prescribing

pharmacist, due to states having exceptions to their quantity limits. Finally, multiple commenters asked DEA to clarify the actions that pharmacists will be allowed to do regarding the partial filling of a prescription for a schedule II controlled substance and to revise the proposed regulatory text to ensure pharmacists can continue changing the partial fill quantities when prescriptions are written in excess of state limits.

DEA Response: In the NPRM's preamble, DEA acknowledged that many states have begun enacting partial fill laws and limiting the amounts allowed to be prescribed for initial prescriptions.² DEA referenced the CARA which states that a prescription for a schedule II controlled substance may be partially filled if the act of doing so is not prohibited by state law, and the prescription is written and filled in accordance with DEA regulations and state law. 21 U.S.C. 829(f)(1).

DEA wishes to clarify that where state law provides exceptions or exemptions for prescriptions for schedule II controlled substances which exceed the state limit for quantity, the prescription is not considered in violation of the CARA. DEA notes that in the NPRM, the stance was taken that a prescription written in excess of state law would be considered invalid. However, in light of information received from commenters, DEA has learned that states have begun implementing laws and issuing guidance to address prescriptions written in excess of state law quantity limits.

In acknowledgement of those states' actions, DEA will not consider a prescription for a schedule II controlled substance to be invalid when written in excess of the state limit, when the state has provided an exception or exemption. In light of the comments discussed above, DEA is not adopting the final two sentences of the proposed regulatory language for 21 CFR 1306.13(b)(1)(ii), which had proposed to provide that, "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."

Regarding the commenters' request to change the regulatory text to allow pharmacists the authority to modify prescriptions by fixing the amount of the partial fill so that it is not in excess of a state's limit, DEA declines to make such a change. DEA considers the August 2011 policy letter—referenced

by several commenters—to be a guidance document which is no longer in effect. The only guidance documents currently in effect are those which are located on DEA's website in the guidance portal.³ This policy letter is not in the guidance portal. DEA's regulations do not provide for a pharmacist to modify a prescription for a schedule II controlled substance. Where a pharmacist knows that a modification is needed to address the amount being in excess of the state's limit (and the state does not have an exception or exemption in place), the pharmacist should use their knowledge of state laws and state guidance and return the prescription to the prescribing practitioner.

Request of Partial Fill by a Practitioner

Issue: There were twenty-two comments received discussing the proposed amendment for 21 CFR 1306.13(b)(3). Many of the comments received regarding the request of partial fills from a practitioner stated that this proposed addition to DEA's regulations provides clear guidance to prescribers, and will encourage practitioners to prescribe schedule II controlled substances sparingly. There were also comments with a few suggested modifications and requests for clarifications on the proposed regulatory text for practitioner requested partial fills.

Commenters stated that practitioners rarely request a partial fill when the prescription is first issued, and they usually do not choose this option until it is presented by the pharmacist to them. A few associations and other commenters suggested that DEA explicitly recognize that the prescriber may authorize a partial fill at a later date, following a consultation with a pharmacist, constituting an amendment to the original prescription. In effect, many of the commenters requested the authorization for pharmacists to dispense a partial fill for the prescription without requiring the prescribing practitioner to issue a new prescription.

DEA Response: DEA appreciates all of the comments received in response to the proposed amendments for the partial fills requested by practitioners. DEA joins the commenters in hoping that this will help address the opioid

and overdose crisis and encourage practitioners to consider all options available when prescribing schedule II controlled substances.

Through this rulemaking, DEA has come to understand that many practitioners do not request partial fills on prescriptions for schedule II controlled substances initially. Instead, the request comes after the pharmacist receives the prescription and then contacts the prescribing practitioner to discuss that prescription. In response to the commenters' concerns, DEA wants to clarify in 21 CFR 1306.13(b)(3) that a partial fill may be authorized by the prescribing practitioner during subsequent communication between the pharmacist and practitioner following the date after the prescription was first issued. This authorization would still be considered a request by the practitioner and a new prescription will not be required.

Through this final rule, the pharmacist must add the partial fill request to the prescription for a schedule II controlled substance by notating on the prescription "Authorized by Practitioner to Partial Fill." The annotation must also include the name of the practitioner they spoke with, the date and time of the communication, and the pharmacist's initials.

DEA's regulations do not provide for pharmacists to modify prescriptions for schedule II controlled substances. As such, DEA does not consider the notations made by the pharmacist, as a result of the subsequent communication with a practitioner after the prescription was issued, to be an amendment or modification to the prescription. DEA declines the commenters' request to grant authorization for pharmacists to amend or modify prescriptions for schedule II controlled substances.

Request of a Partial Fill by a Patient

Issue: DEA received fifteen comments addressing the proposed provision for 21 CFR 1306.13(b)(4), most in support of partial fill by patient request. Many of the commenters also provided suggestions or sought clarification on issues presented in the questions in the "Economic Impact" section of the NPRM.⁴ Those issues are addressed later in "Discussion of Economic Comments" section.

Some commenters stated that this proposed amendment was too narrow of an interpretation of Congressional intent in the CARA. A commenter also said that it conflicts with the Federal Health Insurance Portability and

² 85 FR 78282, 78284, December 4, 2020.

³ See Guidance Documents (usdoj.gov) at <https://apps.deadiversion.usdoj.gov/guidance/#no-back-button>. Last accessed April 25, 2022. The guidance document portal is a website where individuals can access all of DEA's current guidance. The guidance documents are not binding and lack the force and effect of law, and therefore, not to be used as a substitute for regulation.

⁴ 85 FR 78282, 78290.

Accountability Act (HIPAA) privacy requirements found at 45 CFR 164.510(b)(3),⁵ which set the standard for limited uses and disclosures of protected health information (PHI) when the individual is not present. Specifically, a commenter noted that DEA, in the proposed rule, interpreted “patient,” as used in the CARA, to not include a member of the patient’s household. Commenters stated caregivers should be authorized to request a partial fill of prescriptions without the involvement of the patient, as many caregivers/representatives are dropping off and/or picking up prescriptions on behalf of the patient. Commenters also gave the example of a caregiver for a minor child or a caregiver for a dependent adult who has a medical power of attorney as someone who should be authorized to make the partial fill request. A commenter further stated that because patients are not usually initiating the partial fill request (without the suggestion/involvement of the pharmacist), they are unlikely to send a written request with the caregiver or call ahead to the pharmacy to make such a request.

Commenters also suggested that doctors should educate patients on the option to request partial fill of prescriptions, otherwise a patient may not make the request on their own. It was suggested this should include potential risk, and proper disposal, and address patients’ fears associated with both schedule II controlled substances and the partial fill process. This would promote patient-centered care and empower patients with the opportunity to contribute to their own treatment plan.

A commenter suggested that the partial fill request by the patient only be allowed with an accompanying recommendation by the pharmacist because the pharmacist would be more knowledgeable than the patient about patient tolerance and compliance history. Others maintained that the pharmacist should not have to concur with the patient on whether a partial fill is best for the patient, and that a pharmacist should be granted the authority to dispense the partial fill to the patient without the patient’s requesting or consenting to the partial fill. One commenter provided an

example to show that a pharmacist is more knowledgeable than the patient about how long a patient may need to take a prescription to address short-term pain management.

DEA Response: The comments pertaining to the questions in the economic impact section of the NPRM are addressed later in the “Discussion of Economic Comments” section.

With regard to allowing a partial fill at the request of a caregiver, DEA recognizes there is the possibility that there are situations where a caregiver is aware of the benefit for a partial fill request while the ultimate user (the patient) is unable to provide the request, however the possibility for abuse of this authority is greater than the possible benefit. Typically, the patient’s right to request, or not request, a partial fill of their prescription is their right to exercise; the caregiver’s authority is borne of the patient’s requests, and the division of authority should be maintained accordingly. Usually in those situations where a patient is unable to make the request themselves, a caregiver would also participate in the patient’s interaction with the prescribing practitioner. Their concerns would be addressed with the prescribing practitioner and the prescribing practitioner would be able to issue a prescription with a partial fill request.

While DEA understands the concerns regarding the HIPAA regulations, it should also be noted that the CARA only authorizes the “patient”—not a member of the patient’s household or the patient’s caregiver—to make such request. DEA’s interpretation of section 829(f) of the CSA is not too narrow, as that section only refers to “the patient or the practitioner that wrote the prescription” making the request for the partial fill. However, DEA acknowledges that in the case of a minor (under age 18), a parent or legal guardian is often the responsible party for the care of the child and therefore, is updating the regulatory text to allow the parent or legal guardian to make a partial fill request on behalf of the child. In addition, DEA also understands that there are instances where an adult patient may have a caregiver who is named as their agent in the adult patient’s medical power of attorney; therefore, DEA is updating the final regulatory text to allow a caregiver who is the agent named in the adult patient’s medical power of attorney to request a partial fill on behalf of that adult patient.

It is always good practice for a patient and their doctor to engage in open dialog about the potential risks, proper

disposal, and addressing the patient’s fears associated with both schedule II controlled substances and the partial fill process. It is not, however, within the purpose of this rule, or the mission of DEA to involve itself in the practice of medicine or to enforce the elements of good patient education beyond providing rules, policy, and enforcement.

Last, if a patient is requesting a partial fill then they are already taking good steps to mitigate any potential harm or damage that could come as a result of receiving the full prescription. A pharmacist would more than likely want to encourage the partial fill alternative rather than suggest against making the request. If a patient’s tolerance and compliance history is at issue, then a partial fill request would be best in mitigating any potential addiction behavior and diversion risks. In the event that a pharmacist does not want to have the consent of the patient for a partial fill, the pharmacist still has the option of suggesting a partial fill to the prescribing practitioner. Together, a pharmacist and the prescribing practitioner would be well-equipped with the knowledge to determine the dosage quantity necessary to manage a patient’s short-term pain.

Recording of Practitioner’s Partial Fill Request by a Pharmacy

Issue: There were six comments related to the proposed amendment in 21 CFR 1306.13(b)(5)(i), some of which discussed the recording requirement in relation to the economic impact. The commenters requested clarification of the pharmacist’s recordkeeping requirements for fulfilling partial fill requests by prescribing practitioners and patients, specifically regarding electronic recording of dispensing for written records when requested by a practitioner. Commenters stated that the recordation by the pharmacy is warranted and expressed appreciation towards DEA for not requiring a pharmacist to notate a partial fill request by a patient when the prescribing practitioner had already included the request on the prescription, unless the patient is asking for an even smaller amount. However, another commenter believes that the recordkeeping requirements are redundant and the regulatory text should be revised to just require pharmacists to make an annotation in the electronic dispensing record.

DEA Response: As proposed in the NPRM, and being finalized in this rule, 21 CFR 1306.13(b)(5)(i) will require the pharmacist to notate the quantity dispensed on the face of the written

⁵ This provision states that a “covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual’s best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions . . . or other similar forms of [PHI].” A covered entity under HIPAA is a health care provider, health plan, or health care clearinghouse involved in the transmission of PHI. See 5 U.S.C. 164.103 and 164.104(a).

prescription, in the written record of the emergency oral prescription, or in the record of the electronic prescription. When it is an electronic prescription, the quantity dispensed, date dispensed, and the dispenser must be linked to the record of the electronic prescription. However, due to commenters' concerns as well as common practices of DEA's Diversion Investigators, DEA is updating the regulatory text to allow the option for pharmacists to fulfill recordkeeping requirements for paper or emergency oral prescriptions using the pharmacy's electronic recordkeeping system.

The comments which also discussed the economic impact of recording the practitioner's partial fill request are addressed below in the "Discussion of Economic Comments" section.

Recording of Patient's Partial Fill Request by a Pharmacy

Issue: DEA received fifteen comments related to the proposed amendment in 21 CFR 1306.13(b)(5)(ii). Comments included appreciation for the clear communication of the requirements established by this rule, while others suggested modifications.

Of the commenters requesting modifications, several commenters suggested that DEA revise the proposed language to allow pharmacists to satisfy the recordkeeping requirement by making an annotation in the electronic dispensing record, regardless of the format of the original prescription. Commenters stated that DEA is creating a redundant requirement by requiring 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 record of the electronic prescription.

Lastly, commenters suggested that DEA eliminate the proposed dispensing recordkeeping requirement when a prescriber has already instructed a partial fill and the patient requests less than the instructions, as the total quantity dispensed compared to the total quantity prescribed will be obvious based on the dispensing record.

DEA Response: DEA recognizes that commenters found the NPRM to be clear in setting forth these recordkeeping requirements, as it was the intention to be clear in presenting and discussing the requirements that will be implemented with this final rule.

As stated in the previous response to issues identified for the practitioner's partial fill request, DEA is changing the regulatory text to allow pharmacists to satisfy the recordkeeping requirement by using the pharmacy's electronic system regularly used for recordkeeping. DEA notes that Diversion Investigators

regularly look at the pharmacy's electronic system for paper prescriptions also.

Regarding the notation of prescriptions based on the prescribing practitioners' method, written prescriptions, emergency oral prescriptions, or electronic prescriptions, this rule acknowledges that different types of prescriptions exist. Accordingly, the various types of prescriptions may require varying methods for annotation of the partial fill option to prevent over dispensing of controlled substances. This results in the illusion of redundancy because of the numerous means by which the partial fill can be requested.

Regarding the comment on the required documentation when a patient requests a lesser partial fill amount than that specified by the prescribing practitioner, DEA maintains that it is necessary for the dispensing pharmacist to annotate the patient's request.

Because of the justifications already established in 21 CFR 1306.13 for partial fill dispensing of a prescription for a schedule II controlled substance (e.g., 1306.13(a) partial filling due to inability of the pharmacy to supply the full quantity), and the legal mandate by the CARA for the patient's right to request a partial fill, it is necessary that annotation be made for any partial fill requests that may be different from the partial fill amount requested by the prescribing practitioner. The documentation of these modifications from the prescribing practitioner's original instruction of partial fill, at the request of the patient, helps to prevent any suspicion of diversion due to deviation from the original prescription. DEA does not interpret the CARA to allow any "assumption" for a justification of a more limited dispensing than originally requested.

Effective Date of Final Rule

Issue: An association requested that the effective date of the rule be set at six months after the publication of the final rule. The association stated that pharmacies will need adequate time to update their systems, policies, and procedures to be in compliance with the new requirements.

DEA Response: DEA acknowledges the association's concern regarding being in compliance with DEA's regulations. However, DEA notes that many, if not all, electronic pharmacy systems already have the ability to show partial fills. Also, many systems may have a free text field that would allow a pharmacist to use for additional notes. In addition, since many states have already implemented partial filling

regulations, DEA further believes that many pharmacies already have the needed systems to effectuate the allowance of partial fills. DEA notes that many of the policies and procedures that this association may view as a need to be updated are not so involved that pharmacies would need more than 30 days. As such, DEA is making this rule effective 30 days after the publication of the final rule.

Other Issues

Issue: DEA received a comment from an association which requested clarification and written guidance in addressing cases when a pharmacist is unable to supply the full quantity in a prescription for a schedule II controlled substance, as well as three additional situations. One of the additional situations, "Situation 2," pertains to when the prescription quantity exceeds the quantity limits set by state or local law. This situation has already been addressed above in the "General Requirements" Section. "Situation 1" asks for guidance to be provided when dealing with a partial fill resulting from a health plan insurer's benefit rules. For "Situation 3," the association wants guidance on how to proceed when the pharmacy has a policy which limits the quantity that can be dispensed at a time.

DEA Response: DEA has already implemented regulations addressing a partial fill as a result of a pharmacy being unable to supply the full quantity in a prescription for a schedule II controlled substance. Pursuant to 21 CFR 1306.13(a), the partial fill is permissible and the pharmacist has to make a notation of the quantity supplied on the face of the written prescription, the written record of the emergency oral prescription, or in the electronic prescription record. In addition, the remaining portion may be filled within 72 hours of the first partial filling. If the pharmacy cannot fill the remainder in that time, they are to notify the prescribing practitioner.

Situations (1) and (3) are not subject to section 702 of the CARA, as these would not be requests by the patient nor practitioner for a partial filling. For either of these situations to be covered by this rulemaking, they would need to be considered a request by the patient or the practitioner. In these situations, the pharmacist should discuss options for filling the prescription with the prescribing practitioner. Furthermore, in Situation (1), a patient's decision to receive the full prescribed amount despite health plan coverage limitation would also fall outside of section 702 of the CARA, as it would not be a partial fill request.

Out of Scope Comments

DEA appreciates all comments that were received during the comment period. DEA received some general comments which were outside of the scope of this rule. They did not touch on the actual changes to the proposed regulatory text, nor did they answer any of the economic questions that were put forth.

V. Discussion of Economic Analysis Comments

The NPRM contained a Regulatory Analysis section which assessed the economic implications of this rulemaking. DEA examined the costs and costs savings associated with this rulemaking, as well as considered three regulatory approaches regarding the need to require notification when a partial fill is requested by the patient. DEA stated that this was an evaluation of activities that were not previously permitted before the CARA amended the CSA to add 21 U.S.C. 829(f), and therefore, it was difficult to estimate the level of participation for partial filling of a prescription for a schedule II controlled substance. As such, DEA also asked eight questions of the public related to the economic impact of the NPRM.

Costs and Costs Savings

Issue: Many of the commenters questioned whether the patient will be charged two co-pays, stating that the filling of the remainder of the prescription should not create an additional financial burden for the patient. They further stated that this rule should have a positive economic impact because it should result in a lower co-pay, and if the remainder of the prescription needs to be filled, the additional co-pay should add up to be the same amount as a full co-pay. An association requested for DEA to state how a partial fill should be adjudicated by pharmacies to calculate out-of-pocket costs, so that access issues for patients are not created. Multiple commenters stated that this rule would have a positive impact because the unused prescriptions should decrease demand for opioids, making the drug prices lower. They also noted that implementing partial fills can reduce waste, cost, misuse, and abuse potential.

Commenters stated that the rule would increase the time, cost, and overall waste for practitioners by increasing the time spent writing and transmitting prescriptions. Commenters referenced an increased need to educate patients and practitioners, and that DEA should calculate this into the overall

increased-cost (Economic Impact) of this rule. One association in particular mentioned that while there is the potential to reduce the amount of unused drugs, they questioned whether there will be a significant cost savings. The association explained that most patients pay a co-pay which does not necessarily decrease based upon small changes in drug quantity. They also expressed the concern that if co-pays are not reduced for partial fills, then a patient may pay multiple co-pays, resulting in more money out of pocket.

Associations showed much support for Alternative 3, which was chosen by DEA, commenting that they support allowing pharmacists to dispense partial fills requested by the patients, without requiring notification to, or consent from, the prescribing practitioner. Commenters believe that this alternative places the least amount of burden on pharmacists, practitioners, and patients because it does not pose a threat to patient safety and allows a pharmacist to dispense the remainder of the full prescription. However, one association expressed concern that DEA's estimated time that it takes a pharmacist to record a partial fill (10 seconds) is too low, and recommended that DEA conduct a more in depth study to accurately determine the recording time. In addition, this association stated that it would be a larger time, cost, and administrative burden placed upon pharmacists in filling the remainder of the prescription, and advocated for pharmacists to be adequately reimbursed.

Commenters suggested that Alternative 3 will facilitate rule utilization by allowing a pharmacist to dispense per a patient's request independently of the prescriber. They opined that governmental regulation is not the most appropriate way to limit misuse and diversion. The commenters stated that partial fills requested by a patient should not require consent from a practitioner. They further commented that not requiring consent from a practitioner would reduce cost and burden to the practitioner, pharmacist, and patient. Commenters expressed that allowing a pharmacist to dispense the partial fill as requested by the patient without consent of the prescriber is the most cost-effective approach. One of these commenters stated that a provider would not refuse a partial fill request by the patient during this opioid epidemic.

DEA Response: DEA understands the concerns of co-pay affordability expressed by commenters and agrees that partial fills should not create an additional financial burden on patients. DEA joins the commenters in hoping the implementation of this rule will create

a positive economic incentive for all parties to request partial fills. DEA did not receive comments from industry regarding co-pays for partial fills. The intent of this rule is to implement section 702(a) of the CARA that amended the CSA to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. DEA does not have the authority to mandate how a pharmacy or an insurance company may charge for partial fills.

To estimate the prescriber's cost of specifying partial fill instructions on the prescription, DEA considered the entire duration of the interaction between the prescriber and the patient, as well as the prescription writing and transmittal process. While any additional time to specify the quantity to be dispensed in the partial filling is 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. DEA believes 10 seconds is a reasonable estimate and the corresponding cost is included in the economic analysis.

While DEA agrees that educating prescribers and patients regarding the option to partial fill may increase the likelihood of instructing or requesting a partial fill, DEA does not plan to require prescribers or pharmacies to inform patients due to the potential burdens. DEA informs prescribers and pharmacies of such issues through various routine conferences and outreach such as: Practitioner Diversion Awareness Conferences and Pharmacy Diversion Awareness Conferences.

Regarding the association's concern that the estimated burden to pharmacies is too low, DEA selected Alternative 3 to minimize burden to prescribers, patients, and pharmacies. While DEA always appreciates comments, the issue of the estimated burden being too low was not raised in any other comments, indicating it was not considered an issue of note. Additionally the absence of any suggested alternative for the process study or improved estimation leaves little room to directly address the comment. For these reasons DEA declines to revise the estimate. DEA believes the burden estimates contained in this rule are reasonable estimates.

DEA appreciates the support for Alternative 3. DEA estimates this alternative minimizes the burden placed on patients, prescribers, and pharmacists.

Questions From the Regulatory Analysis Section on Benefits and Costs

Below are the eight questions asked in the NPRM to help determine the economic impact of this final rule. DEA has summarized the applicable comments received and addressed them, as applicable.

1. *Why do so many prescriptions for schedule II controlled substances result in unused dosages?*

Comments: No comments were received in response to this question.

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?*

Comments: Commenters pointed to the willingness of a practitioner to start giving instructions for partial filling, but stated their belief that many patients may be reluctant to change. A commenter stated that many of the patients are used to seeing their longstanding family providers who frequently prescribed the schedule II controlled substances without assessing other treatment options first. The commenters expressed that when practitioners attempt to discontinue prescribing these substances and have the patient use other treatment options, patients do not tolerate the change well, forcing practitioners to renew the prescriptions as they are, without partial fill instructions.

Commenters also provided feedback with discussions of how a practitioner giving partial filling instructions would increase the amount of time a provider spends writing and sending prescriptions, and increase the amount of education needed for a patient to understand the available options for filling a prescription. The commenters explained that a practitioner giving partial fill instructions will increase the visit time with each patient, and stated that DEA needs to calculate and include this extra time in the economic impact discussion of the final rule.

DEA Response: While DEA appreciates the opinions stated in the comments, DEA believes that they were speculative in nature. As there was no additional data provided that would warrant revision of DEA's estimated number of partial fills at the direction of the prescriber, no change to the estimate will be made.

Regarding the time that partial fill instructions would require, DEA took the physical requirements of writing the additional information into consideration in developing the

Economic Impact Analysis. The additional time to specify the quantity to be dispensed in the partial filling is minimal, especially when viewed in relation to the entire duration of the medical interaction between the prescriber and the patient. DEA estimates, for both the NPRM and this Final Rule, that each partial fill requested by the prescriber will require 10 additional seconds for the prescriber to specify the quantity to be dispensed. The resulting cost to prescribers is included in the regulatory analysis section below.

3. *How often would a prescriber instruct partial filling of a prescription for a schedule II controlled substance?*

Comments: Some commenters asserted that it is extremely rare for a prescriber to instruct that a prescription be partially filled. They added that it is only after a consultation with a pharmacist that the option is made available to the patient which indicates that prescribing practitioners are not utilizing and are not educating their patients on the option for partial fill.

DEA Response: As stated in an earlier response to comments, this final rule makes changes to proposed 21 CFR 1306.13(b)(3) so that a prescriber instructing a partial fill after a consultation with a pharmacist is considered as a partial fill at the request of the prescriber. DEA did not receive information that would allow DEA to refine the percent of the partial fill opportunity that will be realized as a result of this rule.

4. *Is it reasonable to anticipate a prescriber will exercise professional judgment and foresight in determining when partial fill would be most appropriate, resulting in a 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?*

Comments: Commenters stated that practitioners receive extensive training and are skilled in relaying facts and concerns to their patients. They further stated that most practitioners have the patient's best interests and health at heart and they will do what they can to facilitate best practices and patient safety.

Many commenters expressed concern regarding biases held by practitioners. Specifically, these commenters voiced concern that without criteria to go along with this rule, practitioners will use

their implicit biases to dictate when they choose to prescribe partial fills for a patient. Commenters stated that these biases are a result of racial and ethnic disparities in healthcare. One commenter gave an example that Black patients are less likely to be prescribed pain medications and they receive lower dosage amounts. A commenter also explained that there are some tribes with high rates of opioid addiction and therefore, some practitioners may prescribe less quantity or choose a partial fill for them based off assumptions rather than real risks for addiction.

DEA Response: While DEA did not get answers to the last part of this question, it is apparent that many commenters are concerned that instructions for partial fills will not be given equally across the board. DEA appreciates the commenters' concern and understands that this is a significant cause for concern. However, DEA does not regulate the practice of medicine and it is expected that practitioners would do so without bias. DEA's regulations are an extension of the CARA, and only serve to implement that legislation which was passed by Congress. While this issue may be of significant concern, it is therefore outside the authority granted to DEA by the CSA. DEA did not receive information that would allow DEA to refine the economic analysis.

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?*

Comments: The comments received by DEA stated that a patient would probably ask for the full prescription on the day that their pain is high, as they probably think the pain will remain at that level throughout their recovery. A commenter opined that when patients are suffering from an acute problem, it is unlikely that they would opt for partial fills because that would require two trips to the pharmacy in 72 hours versus one trip. Other commenters stated that patients are less likely to request a partial fill on their own when they do not know much about the prescribed drug and expected outcomes. They also said that patients need to have discussed with their practitioners the potential risks, proper disposal, and any of the patient's fears.

In addition, commenters expressed concern that socioeconomic factors could negatively impact the filling of the remainder of the prescriptions, as patients may not be able to afford the remainder of the prescription. These commenters stated that patients may not be able to afford the medicine, with possible additional co-pay fees, or may

lack the means for transportation to and from the pharmacy. Commenters further stated that patients may alternatively request the partial fill because they know that they will not need the entire amount prescribed and they want to limit the exposure for themselves or their households to the controlled substances.

DEA Response: DEA acknowledges that a current state of intense pain could influence one's ability to recognize that the level of pain will diminish over time. DEA encourages patients that are informed by their provider about the option of partial filling to discuss their options with the pharmacist and, with the pharmacist's help, make the best choice for their situations. DEA did not receive information that would allow DEA to refine the economic analysis.

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?*

Comments: DEA did not receive any comments specifically offering feedback on this question. However, DEA received comments offering insight for the other questions which helped DEA gain insight about the answer to this question. The commenters offered insight that a patient may face transportation issues or may be in so much pain at the time that the prescription would be written that they would not want a partial fill.

DEA Response: While DEA did not receive any feedback directed towards this question, DEA notes that responses to other questions helped DEA gain insight to this situation. DEA understands that some patients may experience hardships with getting to and from the pharmacy. DEA also acknowledges that there are times when a patient's pain may be so intense that they cannot recognize the likelihood that the pain will diminish with time. The comments received did not include information that would allow DEA to refine the economic impact analysis.

7. *Is it reasonable to assume that when prescribers do not request a partial fill patients will generally not request a partial fill?*

Comments: While DEA did not receive comments that specifically addressed this question, it is reasonable to infer from the comments in general that patients may not request a partial fill when their practitioner did not prescribe it. As previously observed, commenters mentioned that many patients may choose to receive the entire quantity that was prescribed for various reasons. The commenters explained that a patient may know that

they will have a hard time returning to the pharmacy due to lack of transportation. Commenters also stated a patient may feel that they are in so much pain that they would need the entire amount. In addition, commenters mentioned that patients may not know that they can request a partial fill.

DEA Response: DEA appreciates the comments received that allowed for inference on answers to this question. While DEA wished to collect additional information to aid in the understanding of and possible refinements to the economic impact of this rule, no responses provided any such information that facilitated refining the existing economic analysis.

8. *Questions for industry including private and public plans and entitlements:*

a. *What are likely requirements for co-pay in a partial filling?*

b. *Would the co-pay be reduced?*

c. *Would there be a co-pay 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?*

Comments: No comments specifically answered these questions. Many commenters hoped that this provision would not result in a multiple co-pay charge. One association in particular voiced concern regarding partial fills resulting in double co-pays for patients. Commenters hoped that this would mean a lower co-pay for a partial fill, otherwise there would not be any savings.

DEA Response: DEA acknowledges and understands the commenters' concerns. With this rulemaking, DEA is not setting guidelines for insurance companies. DEA does not have the authority to mandate how insurance companies should charge their customers. DEA had hoped to receive feedback from insurance companies so that DEA could offer more guidance to the public, however no insurance companies provided comments on this question. DEA notes that its regulations already allow partial fills for prescriptions for schedules III–V controlled substances⁶ and in instances of limited supply, for schedule II

controlled substances.⁷ DEA anticipates that insurance companies would follow the same methods for assessing co-pays for prescriptions for schedule II controlled substances as it currently does for prescriptions for schedule III–V controlled substances. However, DEA cannot be sure of that theory; therefore, DEA defers to insurance companies on how they will handle co-pays for partial fills. DEA did not receive information that would necessitate refining the economic analysis.

VI. Provisions Being Implemented in the Final Rule

DEA is implementing and finalizing the proposed regulatory text with modifications, discussed below, to clarify concerns brought forth by commenters. As proposed, to implement the partial filling provisions of CARA for prescriptions for schedule II controlled substances, DEA is redesignating existing paragraphs (b) and (c) of 21 CFR 1306.13 as paragraphs (c) and (d), respectively. This final rule places the provisions for partial filling in new paragraph (b). Here, registrants will find the requirements for patients and practitioners to request partial fills under certain circumstances and the involved notation by the prescriber to specify the partial fill request, as well as the involved recording by the pharmacy of the partial filling itself.

General Requirements—21 CFR 1306.13(b)(1)

All of the “General requirements” provisions are being implemented as proposed, with the exception of 21 CFR 1301.13(b)(1)(ii). Generally, the prescribing practitioner or a patient must request a partial fill for a prescription for a schedule II controlled substance. Such a prescription may be partially filled if it is not prohibited by State law and it is written in accordance with the CSA, DEA regulations, and State law. Also, the total quantity dispensed in all of the partial fillings cannot exceed the total quantity prescribed by the practitioner.

In the NPRM, the preamble and the regulatory text in 21 CFR 1301.13(b)(1)(ii) stated that a prescription was invalid if it set forth a dispensing quantity of a controlled substance that exceeded the state limits, and therefore would be ineligible for a partial filling. In light of the public comments, as well as various

⁶ DEA regulations for partial filling of prescriptions for a controlled substance listed in schedules III, IV, and V are contained in 21 CFR 1306.23.

⁷ Partial fills of prescriptions for a controlled substance listed in schedules III–V are allowed through 21 CFR 1306.13. 21 CFR 1306.13(a) states when a partial fill of a prescription for a schedule II controlled substance is allowed due to limited supply at the pharmacy.

implemented state legislation and guidance providing exemptions or exceptions for prescriptions written in excess of the state limits, DEA will not implement that portion of the proposed amendment, and is deleting the final two sentences of the proposed regulatory text as a result.

Time Limitations—21 CFR 1301.13(b)(2)

DEA is adding 21 CFR 1301.13(b)(2) as proposed. After the first partial fill of the prescription for a schedule II controlled substance is filled, if a patient chooses to fill the remainder, the remaining portions must be filled no later than 30 days after the date of the prescription. However, when it is an emergency oral prescription, the remainder, if filled, must be filled no later than 72 hours after the date of the prescription.

Partial Fill Request by the Practitioner—21 CFR 1306.13(b)(3)

DEA is adding 21 CFR 1306.13(b)(3) which will require the practitioner to 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 record of the electronic prescription. This information must 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. In the case of an emergency oral prescription, this information must be given when the prescription is being communicated by the prescribing practitioner to the pharmacist. This approach ensures that the practitioner's intent regarding partial filling is made clear to the pharmacist, and is properly memorialized in the dispensing records.

The term “record of the electronic prescription” is being used in place of the term “electronic prescription record,” which was utilized in the NPRM. The previous term, “electronic prescription record,” was ambiguous and could imply a hard-copy/written prescription being tracked electronically by a pharmacist after receipt. The new term, “record of the electronic prescription,” clarifies a prescription that is generated and transmitted electronically, and is having a record attached by the prescription-tracking software utilized by the pharmacist.

This final rule amends the proposed provision to authorize a practitioner to stipulate a partial fill or refill at a later date than when issuing the original prescription, after an oral consultation between the practitioner and the pharmacist, and specifies that the

pharmacist must annotate the discussion on the prescription as stipulated in 21 CFR 1306.13(b)(5)(i).

Partial Fill Request by the Patient—21 CFR 1306.13(b)(4)

This provision is being finalized to allow a patient to request the partial filling of a prescription for a schedule II controlled substance at the pharmacy, even if the prescribing practitioner did not specify a request for a partial filling, as provided in 21 CFR 1306.13(b)(3). Section 702(a) of 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 the pharmacy in person. Therefore, this rule does not require an in-person request by the patient, but instead allows 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). As proposed and discussed earlier, the partial fill can only be requested by the patient, not a member of the patient's household or a caregiver. However, this final rule is revising the proposed provision to also allow others to request a partial filling where the patient is a minor child (under age 18) or an adult who has named their caregiver as their agent in the adult patient's medical power of attorney. In those situations, DEA authorizes the parent or legal guardian for the minor child and the caregiver named as the agent in the medical power of attorney for the adult patient to request the prescription for the schedule II controlled substance to be partially filled in the same manner that a patient may request the partial fill: in person, in writing if signed by the parent or legal guardian (for the minor child) or the caregiver named in the medical power of attorney (for the adult patient), or by a phone call from the parent or legal guardian (for the minor child) or the caregiver named in the medical power of attorney (for the adult patient) to the pharmacist. Finally, where a practitioner has requested the partial filling of a prescription, neither the patient, a parent or legal guardian (in the case of a minor), nor the caregiver named in the medical power of attorney (for the adult patient) may request a partial filling in an amount greater than that specified by the practitioner.

Pharmacy's Recording of the Partial Fill of a Schedule II Controlled Substance

When Requested by the Prescribing Practitioner—21 CFR 1306.13(b)(5)(i)

This provision specifies how a pharmacist must record a partial fill of a prescription for a schedule II controlled substance when a practitioner makes such a request pursuant to 21 CFR 1306.13(b)(3), as discussed above. When presented with a prescription properly specifying a partial filling request, the pharmacist must record the partial filling in a manner similar to that required under the existing regulations for other circumstances.⁸ Specifically, upon each such partial filling request, the dispensing pharmacist must make a notation of the quantity dispensed on the face of the written prescription or in the pharmacy's electronic recordkeeping system, in the written record or in the pharmacy's electronic recordkeeping system of the emergency oral prescription, or in the record of the electronic 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 also required by 21 CFR 1311.205(b)(10)).

These above provisions were as proposed with slight changes for clarification. As previously stated, the term “record of the electronic prescription” has been used in place of the term “electronic prescription record” here also to ensure the understanding that DEA is referring to a prescription that is generated and transmitted electronically. Also, as said above DEA is also allowing the notation of the quantity dispensed to be notated in the pharmacy's electronic records due to the regular business practices of pharmacies, as well as common

⁸ Longstanding DEA regulations, which are not be changed by this 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 (21 CFR 1306.13(a)), the patient in a long-term care facility (21 CFR 1306.13(b)), or the patient has a terminal illness (21 CFR 1306.13(c)).

practices of DEA's Diversion Investigators.

This final rule is revising the proposed regulatory text to allow for where the prescribing practitioner conveys his or her request for a partial filling after issuing the prescription, and is based upon an oral consultation with the pharmacist. In those situations, the dispensing pharmacist must notate such discussion with the following: "Authorized by Practitioner to Partial Fill," the name of the practitioner, the date and time of the discussion, and the pharmacist's initials.

When Requested by the Patient—21 CFR 1306.13(b)(5)(ii)

With the addition of 21 CFR 1306.13(b)(5)(ii), when partially filling a prescription for a schedule II controlled substance at the request of the patient, the caregiver of an adult patient who is named in their medical power of attorney, or a parent or legal guardian of a minor patient (under age 18), the pharmacist must make the same notation on the prescription as when partially filling a prescription as requested by the prescribing practitioner on the initial prescription. Also, just as with the pharmacy's recording requirements when the prescribing practitioner is the requester, if the prescription is electronic, then the notation must be linked to the record of the electronic prescription. Since the prescription will not contain the partial fill instructions from the prescriber, this rule also requires the pharmacist to indicate on the prescription who specifically requested the partial fill (*i.e.*, whether it is the patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in the adult patient's medical power of attorney). On all of such partial fill requests and filling, the pharmacist must record: (1) "The [patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney, whichever is applicable] requested partial fill on [date such request was made]," and (2) the quantity dispensed. As referenced in the section *Partial Fill Request by Patient*, where a practitioner has requested the partial filling of a prescription, the patient, parent or legal guardian, or caregiver of an adult patient may not request a partial filling in an amount greater than that specified by the practitioner.

Here also, the regulatory text is being finalized with slight changes. As mentioned above, DEA is finalizing the regulatory text using the term "record of the electronic prescription" in place of the term "electronic prescription

record." Also with finalizing this provision, DEA is allowing the pharmacist to notate the quantity dispensed in the pharmacy's electronic records.

Additional Regulatory Text Change—Re-Designated 21 CFR 1306.13(d)(1)

As previously stated, DEA is finalizing this rule with changes for clarification in regards to the options which the pharmacy can notate the partial fill for recordkeeping requirements. This final rule adds the partial fill requirements of section 702(a) of the CARA into 21 CFR 1306.13(b) and redesignates existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively. In the redesignated 21 CFR 1306.13(d) in this final rule, there is a reference in existing paragraph (c)(1) to 21 CFR 1306.13(b), which DEA is updating with this rule. DEA is changing that reference in redesignated paragraph (d)(1) to 21 CFR 1306.13(c).

Regulatory Analysis

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This 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 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. In the NPRM, DEA welcomed all comments that would narrow the uncertainties in the presented analysis. Furthermore, DEA asked prescribers, patients, and health care industry, including insurance companies, eight specific questions. None of the comments contained enough information for DEA to update the economic analysis. Therefore, the analysis and conclusions below remain unchanged from the analysis contained in the NPRM.

The economic, interagency, budgetary, legal, and policy implications of this 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 provision 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, section 702(a) of 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 on the paper or electronic prescription, or after consultation with

a pharmacist, 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 for 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 the 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:⁹

- *Pharmacist requesting consent:* 29–1051 Pharmacists, \$60.64.

- *Prescriber's representative to give consent:* 43–6033 Medical Secretaries, \$17.19.¹⁰

- *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:¹¹

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

- *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 risks 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 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's representative	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

⁹ BLS, May 2018 National Occupational Employment and Wage Estimates, United States. https://www.bls.gov/oes/current/oes_nat.htm. (Accessed 2/6/2020.)

¹⁰ In this alternative, while the prescriber would be involved in providing consent, the time requirement on the prescriber is assumed to be

minimal, and thus excluded. The primary economic impact would be based on the time requirement for the prescriber's representative.

¹¹ 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.

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. 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. 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's representative	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, 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 Alternatives 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 this 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. While the initial proposed alternative did not include the possibility of a parent or legal guardian making the request on behalf of a minor and a caregiver named in a medical power of attorney making the request on behalf of an adult patient, the inclusion of these provisions in the final rule does not change the advantages of this alternative or the economic analysis discussed below. When the patient is a minor or an adult patient who has a caregiver, the parent, legal guardian, or caregiver is often the person filling the prescription and may request partial filling with minimal economic impact.

III. Analysis of Benefits and Costs

This rule allows partial fills of prescriptions for schedule II controlled substances at the request of the patient (including the parent or legal guardian of a minor or the caregiver of an adult

named in a medical power of attorney) or the prescribing practitioner, if not prohibited by State law. The 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 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 end up being for improper use, diversion, 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 risk that patients or others may develop physical dependence or an addiction to prescribed scheduled II controlled substances.

The supply of unused drugs in U.S. households contributes to concerns related to opioids and illicit drug use. Keeping and storing unused medications in households poses several risks related to misuse, diversion, accidental overdose, and consumption of spoiled substances.¹² 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,¹³ between 9.1 and 12.2 percent prescribed opioids for chronic pain develop an opioid use disorder,¹⁴ an estimated 4 to 6 percent who misuse prescription opioids transition to heroin,^{15 16 17} and about 80 percent of people who use heroin first misused prescription opioids.¹⁸ 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."¹⁹ According to the Substance Abuse and Mental Health Administration (SAMHSA), 47.2 percent of people who

misused pain relievers in the past year obtained the last pain reliever they misused "from a friend or relative in some way (*i.e.*, being given them, buying them, or taking them without asking)." ²⁰ Also, although opioid medications are effective in managing acute pain after surgery, even short-term use of opioids can lead to long-term dependence.²¹

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.²² This economic burden equates to approximately \$41,600 per person with opioid use disorder.²³ DEA estimates approximately \$41,600 in societal benefit accrues each time we prevent an individual from developing opioid use disorder. This 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 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 cost savings, DEA estimated the cost of excess medicine and calculated the approximate percent cost savings

opportunity that may be realized by this rule.

In 2017, 163,683,029 prescriptions for schedule II controlled substances 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.²⁴ 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.²⁵ 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.²⁶ As of September 2019, 36 States have placed limits on the amount of opioids that can be prescribed by doctors.²⁷ 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.²⁸ Based on review of state limits for prescribing of opioids, DEA estimates there are 34 states with pill or day limits in place, representing 68.7 percent of the U.S. population.²⁹ DEA believes

¹² "Safe Disposal of Unused Controlled Substances: Current Challenges and Opportunities for Reform," Avalere, <http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf>.

¹³ Vowles KE, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. *Pain* 156(4):569–576. (2015).

¹⁴ Katherine M Keyes, and Caroline Rutherford. Prevalence of addiction in chronic pain: reanalysis of Vowles et al., 2015. *Pain* 163(5):e693–e695. (2022).

¹⁵ Muhuri PK, Gfroerer JC, Davies MC. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. *CBHSQ Data Rev.* August 2013.

¹⁶ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. *JAMA Psychiatry* 71(7):821–826. (2014).

¹⁷ Carlson RG, Nahhas RW, Martins SS, Daniulaityte R. Predictors of transition to heroin use among initially non-opioid dependent illicit pharmaceutical opioid users: A natural history study. *Drug Alcohol Depend* 160:127–134. doi:10.1016 (2016).

¹⁸ See note 15.

¹⁹ "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-naïve-patients>.

²⁰ SAMHSA, The National Survey on Drug Use and Health: 2020 <https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health>.

²¹ 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.

²² 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 misuse.

²³ \$78.5 billion/1.935 million patients = \$40,568 per patient.

²⁴ 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.

²⁵ "Opioid Prescribing Limits Across the States," Marilyn Bullock, PharmD, BCPS, FCCM, 2/5/2019, pharmacytimes.com.

²⁶ *Ibid.*

²⁷ "Opioid prescription limits and policies by state." https://ballotpedia.org/Opioid_prescription_limits_and_policies_by_state. (Accessed 2/3/2020.)

²⁸ *Ibid.*

²⁹ 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,

partial fill provisions under this rule are likely to have an 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.³⁰ The study found that patients prescribed opioids after surgery consumed, on average, only 33 percent of the prescribed medication.³¹ 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 does not have a basis to estimate the actual number or percentage of prescriptions for schedule II 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 rule on payments to pharmacies, in terms of price per dosage units, co-pays, 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.³² 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.³³ 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% × 67 pills) per full prescription filled.³⁴ To calculate the total cost savings for patients not needing to dispose of their unused schedule II controlled substances, 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 × 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,³⁵ and the estimate of pound/pill of .0069,³⁶ the total cost savings for unused pills not needing to be disposed of is \$3,106,245 (80,389,369 × \$5.60 × .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).³⁷ Therefore, the total annual cost savings of this 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 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 or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription record, along with other information required in 21 CFR 1306.05. A practitioner may authorize a partial fill at a date after which the prescription was issued, after consultation with a pharmacist. 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 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

Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia.

³⁰ 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.

³¹ Ibid.

³² "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.

³³ Ibid.

³⁴ IMS Health IQVIA Data 2017. The 67 average number of pills dispensed was determined by dividing the total number of extended units in 2017 by the total number of prescriptions (10,921,740,149/163,683,029). From IQVIA's data dictionary, the term "extended units"—"represents the total number (new plus refill) of dispensed tablets, capsules, milliliters, and so forth. For solids, this is the number of tablets; for creams, grams; and liquids, mls."

³⁵ Siler, S., Duda, S., Brown, R., Gbemudu, J., Weiner, S., & Glaudemans, J. (n.d.). *Safe Disposal of Unused Controlled Substances*. Retrieved September 21, 2018, from <http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf>.

³⁶ <http://michigan-open.org/statewide-drug-takeback-event-nets-900-pounds-of-opioids-more/>.

³⁷ "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 allowed to select more than one method.

estimated loaded hourly wage for a prescriber is \$144.74.³⁸ Therefore, the 10 additional seconds to specify the quantity to be dispensed equates to \$0.40.³⁹ 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 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, this rule will require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.⁴⁰ Specifically, the dispensing pharmacist must make a notation of the quantity dispensed on the face of the written prescription or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription (similar to current requirements under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in a prescription for a schedule II controlled substance). When the pharmacist partially fills a prescription, after the prescriber has conveyed this request in a consultation with a pharmacist in accordance with paragraph (b)(3), the pharmacist must note the following: "Authorized by Practitioner to Partial Fill," the name of the practitioner, the date and time of the discussion, and the pharmacist's initials. Also, for each such partial filling (whether requested by the

prescriber on the prescription or after consultation with the pharmacist), 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 prescription refills of schedule III and IV controlled substances. DEA believes the most common scenario will be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information will 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 must 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 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 \$0.24.⁴¹ As discussed above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year that will 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 rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist will 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 will equate to a cost of \$14.42. Additionally, there will be a similar cost to the 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 will 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 medication. Furthermore, while this rule will permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient will 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 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 will 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 assumes the mid-point (50 percent), or \$656,028,165

³⁸ 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.

³⁹ 10 seconds \times (1 hour/3,600 seconds) \times \$144.74/hour = \$0.40.

⁴⁰ See note 2.

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

(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 will 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 this rule will permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient will follow the prescriber's instruction, based on consultation between the prescriber and the patient.

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

Summary

In summary, DEA estimates that the total cost savings of this 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) over the next five years. 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 analysis is reasonable. 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.

Executive Order 12988, Civil Justice Reform

This 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132. This 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 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 Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

This rule includes provisions regarding partial fill of prescriptions for

schedule II controlled substances. This rule will allow partial fills of such prescriptions at the request of the patient or the prescribing practitioner, if not prohibited by State law. A request for partial fill can be made by the patient, a caregiver named in an adult patient's medical power of attorney, or parent or legal guardian of a minor patient. This 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) will still be subject to the partial fill provisions contained in this rule.

This 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 will be affected by this 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,⁴² to the U.S. Small Business

⁴² "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.)

Administration (SBA) size standards.⁴³ DEA estimates a total 326,033 entities,

⁴³ 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.)

of which 318,362 are small entities, will be affected by this rule. Table 4 details

the number of entities, SBA size standard, and estimated number of

small entities for each affected industry.⁴⁴

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 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. A practitioner may authorize a partial fill at a date after which the prescription was issued, after consultation with a pharmacist. 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 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 \$0.40.⁴⁵ 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 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.⁴⁶

When a prescribing practitioner has properly specified his or her intent to partially fill a prescription for a schedule II controlled substance, this rule will require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.⁴⁷ Specifically, the dispensing pharmacist must make a notation of the quantity dispensed on the face of the written prescription or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription (similar to current requirements 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 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. DEA believes the most common scenario will be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information will 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 must 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 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 \$0.24.⁴⁸ 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 will 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.⁴⁹

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 average cost ranges from 0.009 percent of revenue for the smallest of small hospitals, and 0.487 percent for the smallest of small

⁴⁴ For the purposes of this analysis, "firms" and "entities" are used synonymously.

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

⁴⁶ 326,033 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).

⁴⁷ See note 2.

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

⁴⁹ \$4,365,034/18,852 = \$232 (rounded to nearest whole dollar).

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 6—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	7,275,056	0.0005
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 rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist will 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 will 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 will 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 rule would permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient will 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 rule 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 will 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 rule is a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This rule will result in an annual effect on the economy of \$100,000,000 or more; DEA estimates this rule will result in an annual cost savings of \$659 million and a net cost savings of \$647 million 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. DEA has submitted a copy of this final rule to both Houses of

Congress and to the Comptroller General.

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 rule. This rule will 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 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 requiring 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 pharmacist will be required to record the partial filling in a manner similar to that required under the existing regulations (for other circumstances).⁵⁰ Specifically, upon each such partial filling requested by the 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). Where there is an oral consultation between the pharmacist and the prescribing practitioner after the prescription is issued, in which the prescribing practitioner conveys his or her request for a partial filling after issuing the prescription, the dispensing pharmacist must notate such discussion with the following: “Authorized by Practitioner to Partial Fill,” the name of the practitioner, the date and time of the

discussion, and the pharmacist’s initials. For electronic prescriptions, there needs to be an electronic prescription record and the record needs to be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy will 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 will 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)).

Upon partially filling a prescription for a schedule II controlled substance at the request of a patient, a caregiver named in an adult patient’s medical power of attorney, or parent or legal guardian of a minor patient, dispensing pharmacists will need to make a notation of the following on the face of the written prescription, in the written record of the emergency oral prescription, or in the record of the electronic prescription: (1) “The [patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney, whichever is applicable] requested partial fill on [date such request was made]” and (2) the quantity dispensed. In addition, for each such partial filling, the pharmacy will 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 will 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.

If you need additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

Any additional comments on this collection of information may be sent in writing 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.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 18, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, DEA amends 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:
 - a. Redesignate paragraphs (b) and (c) as paragraphs (c) and (d);
 - b. Add a new paragraph (b); and
 - c. Amend newly redesignated paragraph (d)(1) by removing the cross-reference “§ 1306.13(b)” and adding in its place the cross-reference “§ 1306.13(c)”.

The addition and reads 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 schedule II controlled

⁵⁰ Longstanding DEA regulations, which are not be changed by this 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)).

substance 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.
- (iii) The partial fill is requested by the patient, by one acting on behalf of the patient (parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney), 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 schedule II controlled substance, 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 schedule II controlled substance, 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 record for an electronic prescription. After consultation with a pharmacist, a practitioner may authorize a partial fill for the prescription at a date after which the prescription was initially issued; however, the prescription 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 schedule II controlled substance, if filled, must be filled not later than 72 hours after the prescription is issued. The pharmacist must notate this subsequent request in accordance with paragraph (b)(5) of this section. All required information in this paragraph, except that of an authorization for

partial filling at a later date, 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 at the time that the oral communication is taking place.

(4) *How a patient or one acting on a patient's behalf 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. A caregiver named in an adult patient's medical power of attorney may request the adult patient's prescription be partially filled. When a patient is a minor (under age 18), a parent or legal guardian of the minor may request the prescription be partially filled. Where a practitioner has requested the partial filling of a prescription in accordance with paragraph (b)(3) of this section, neither the patient, the parent or legal guardian (in the case of a minor), nor the caregiver of an adult patient named in a medical power of attorney may request a partial filling in an amount greater than that specified by the practitioner. A request by the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient may be made: in person; in writing if signed by the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient; or by a phone call to the pharmacist from the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient.

(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, as requested when the prescriber issued the prescription, 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 or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription. When the pharmacist partially fills a prescription, after the prescriber has conveyed this request in a consultation with a pharmacist in accordance with paragraph (b)(3), the pharmacist must note the following: "Authorized by Practitioner to Partial Fill," the name of

the practitioner, the date and time of the discussion, and the pharmacist's initials. In addition, for each such partial filling (whether requested by the prescriber on the prescription or after consultation with the pharmacist), 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, the caregiver of an adult patient who is named in their medical power of attorney, or a parent or legal guardian of a minor patient, in accordance with paragraph (b)(4) of this section, the pharmacist must make a notation of the following on the face of the written prescription or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription: (I) "The [patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney] 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.

* * * * *

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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