Issue Brief: Partial Fills of Schedule II Controlled Substances, updated March 2017

Partial fills for opioid analgesics, as a means to help curb prescription drug abuse and misuse, is an important policy priority for SPPAN, and is widely supported. We were pleased to see partial fill of Schedule II controlled substances included as Section 702 of the landmark Comprehensive Addiction and Recovery Act (CARA) signed by the President in July 2016, and we are actively monitoring related legislation in the states and encouraging the federal Drug Enforcement Administration to issue regulations as soon as possible.

Trends Related to Proposed Partial-Fill Policies in Early 2017:

With the flurry of state legislation related to pain care already proposed in early 2017, we are seeing a trend in partial fill language that appears based in a bit of confusion. The intent of CARA's language is to allow partial fills of Schedule II controlled substance prescriptions at the request of the prescriber or the patient (subject to limitations). This is intended to allow the rest of the refill to be dispensed to the patient if needed, without an additional prescription. However, language introduced in some states (e.g., IN, IL, IA) would mandate that the remainder of the prescription must be voided when a partial fill is elected. Upon further education, policymakers generally agree to amend the language to match the intent of the language in CARA. Read below for further information on this issue.

- **IL SB 2011**—This would require that the remainder of a partially filled prescription of "an opioid substance listed in Schedule II" be voided, instead of incorporating by reference the partial fill rules found in 21 C.F.R. §1306.13. See AIPM's letter.
- **IN SB 226**—As introduced, this would require that the remainder of a partially filled prescription of "an opioid medication" be voided, instead of incorporating by reference the partial fill rules found in 21 C.F.R. §1306.13. See AIPM's letter. As currently amended, it also mandates that initial prescriptions to adults for opioids, and all prescriptions to minors for opioids, may only be issued in up to a seven-day supply except in cases related to palliative care, cancer-related pain, medication-assisted treatment for a substance use disorder, or other conditions adopted by rule. After AIPM submitted comments, the partial fill provisions were corrected as we had urged; however, the "chronic pain" exception from the seven-day limit that was in the original bill has been removed, to which we object.
- **IA HSB 99 / SSB 1134**—These companion study bills include language similar to IL SB 2011, above, and would void the remainder of a partially filled prescription of "an opioid medication" and require a new prescription be written if a patient requests the remainder of the initial prescription to be filled after the initial partial fill. See AIPM's letters submitted to the House and Senate.

Note: In the above examples, Illinois includes language that denotes Schedule II opioids, while both Iowa's and Indiana's language refer to "opioid medications". Schedule II medications include more than just opioids, and all medications in this class have significant abuse potential. The same benefits achieved by allowing partial fills of

opioids should, therefore, apply equally to other Schedule II medications. **We encourage states to include all Schedule II medications in bills such as these** in order to most accurately implement the intent of the Comprehensive Addiction and Recovery Act (2016).

Why does SPPAN support the idea of partial fill?

Anecdotally, we hear many stories about people who only use a few, if any, of their prescribed opioids during an acute pain episode. One recent study of patients undergoing five common outpatient surgical procedures revealed that, on average, only 28% of prescribed opioid medication doses were taken (Hill et al., *Annals of Surgery*, 2017;265:709-714). We believe that dispensing fewer pills initially, with an option to later obtain the rest only if needed, would allow people with pain to have access to needed medications, while also preventing an overabundant supply of unneeded medications that can be potentially diverted or unnecessarily consumed. In theory, an additional benefit is that partial fills would save insurers a great deal of money by enabling them to only pay for the number of pills that are really needed to address serious acute pain.

Partial fills are already permitted for Schedule III, IV, and V medications.

21 C.F.R. §1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:
(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

Partial filling of Schedule II prescriptions is controlled by 21 C.F.R. §1306.13.

Prior to the passage of CARA:

Although partial filling of prescriptions is permitted under 21 C.F.R. §1306.23 for Schedule III, IV, and V controlled substances, 21 C.F.R. §1306.13 only allows for the partial filling of a prescription for a Schedule II medication if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

In consideration of CARA, moving forward:

21 C.F.R. §1306.13 is the rule that will soon be updated in accordance with CARA's new partial fill allowance.

Under that new provision, a pharmacist may partially fill a prescription for a Schedule II medication at the request of the prescriber or the patient. The remaining portion may be filled, but not later than 30 days after the date on which the prescription was written. However, this allowance will still be contingent upon state law—partial fills

will still be prohibited if they are prohibited by state law. This will be a barrier that will need to be addressed in some states that expressly prohibit partial fills—we will need to lobby to change those laws/rules to match the updated §1306.13. However, in other states, such as Florida, it won't be a problem because the state, in addressing partial fills, references §1306.13 of the Code of Federal Regulations.

Copayment, Coverage, and Incentivization

Implementing a partial fill rule should greatly benefit the public, as it should result in far fewer unused opioid pills available to divert, misuse, and lead to overdose. Patients experiencing acute pain would still get what they need to heal effectively, and insurers would only have to pay for pills that are actually needed.

However, to be effectively implemented, the complexity of copayment, coverage, and incentivization decisions must be addressed. From the pharmacists' side, providers who are dispensing these partially filled (and sometimes, later fully dispensed) medications should be reimbursed for their time each time they fill a portion of the prescription (i.e., a dispensing fee). Additionally, insurers should cover partial fills when they are dispensed rather than waiting to reimburse when the entire prescription is dispensed, particularly since it is anticipated that second fills will be rare. The recent study mentioned above, examining patients undergoing five common outpatient surgical procedures, revealed that, on average, only 28% of prescribed opioid medication doses were taken. What's more, a follow-up study revealed that when surgeons were educated about the study's findings, and given guidance about how many doses of opioids to prescribe for these surgeries, only one of the study's 246 subjects needed an additional prescription.

On the other hand, there is a natural disincentive for patients to request a partial fill if they would be required to pay more out-of-pocket by going back for the rest of the prescription. And pharmacists need payment incentives to account for their time spent dispensing and to encourage communication with both patients and prescribers during and after partial fills. Clinicians who prescribe opioids for acute pain episodes will need to support the concept of partial fills and communicate proactively with their patients about the opportunity. Insurers will need to be on board, and in theory, the fact they would pay for many fewer pills should be a good incentive. And, of the utmost importance, patients will need to understand what partial fills mean to them and how and when they are able to access the remainder of their prescription if it is actually needed. If patients are charged an additional dispensing fee, it will be important to study whether the fee causes patients to forego filling their medications despite their need for the medication. Patient access to their medications should not be limited by their or their prescriber's decision, to obtain a partial fill.

Awareness about Partial Fills

As touched on immediately above, in order to be a successful tool, partial fills must be understood by health care providers, including pharmacists, and by the general public (as potential patients experiencing an acute pain episode). SPPAN is convening a group of leaders, including prescribers, pharmacists, and consumer organizations, to create tools for building understanding and awareness (e.g., webinar, fact sheet). It is essential that healthcare providers and patients communicate about the use of partial fills so that the tool is understood and used appropriately whenever possible.

SPPAN's plans for implementation in 2017:

- Monitor proposed state legislation pertaining to partial fills, urging the states to refer to the partial fill language (soon-to-be-updated) in CFR §1306.13.
- Analyze states' current statutes and regulations to determine which states will need to change state policy to match the new federal rule.
- Monitor DEA action with respect to issuing a new rule, and comment on that new rule as necessary.
- Draft model language to change problematic state policies so that it is ready for introduction when the federal rule changes.
- Engage in discussions with stakeholders about copayment and reimbursement issues to help develop consensus language that supports optimal implementation in new policies.
- Educate both providers and the general public about the utility of partial fills.

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