Review Article

Can Wisconsin Pharmacists Repeatedly Partially Fill Schedule II Controlled Substance Prescriptions at the Patient's Request?

by Michael E. DeBisschop, PharmD, Katherine E. Rotzenberg, PharmD, M.B.A., BCPS

Imagine a scenario like this (invented) example: Esmay Taylor, a regular patient, approaches your pharmacy counter. She appears much older than her 46 years would indicate. Before you can say a word, she looks you in the eye and says, "I'm worried about Isaiah," her teenage son. "I don't want these pills in the house with him there, but I can't imagine continuing on with this pain. You know all the things you read in the news these days." You look at the prescription, and see that it is for oxycodone, quantity 40, for acute pain associated with arthritis of her knee. Taylor's jaw is set, but her eyes glisten with the sheen of unshed tears. "Is there a way I could have less of these pills in the house, but still have the rest available—you know, just in case I need them? I don't want to have to bother the doctor again."

Background

Although the COVID pandemic has occupied much attention and energy over the past year, the opioid epidemic has continued unabated in the U.S. and Wisconsin. The most recently available national data indicate that 14,975 Americans died from a drug overdose involving prescription opioids in 2018.[1] For the same year in Wisconsin, there were 1,076 drug overdose deaths; specific data on deaths involving a prescription opioid are not available.[2] At the national and state levels, the 2018 statistics were an improvement over the previous year, but we are not out of the woods yet, as shown by more recent data.[3]

Provisional counts of Wisconsin drug overdose deaths from the Center for Disease Control's (CDC) National Center for Health Statistics (NCHS) are shown in Table 1.[3] In the most recent 12-month period for which data are available (July 2019-June 2020), Wisconsin experienced a 46.2% increase in drug overdose deaths due to opioids compared to the previous 12-month period, and a 112% increase since the July 2015-June 2016 reporting period (data not shown). The rate of deaths due to opioid overdose in Wisconsin continues to climb alarmingly.

The COVID pandemic has exacerbated the opioid epidemic, both in Wisconsin and nationally. More than 40 states have reported an increase in opioid-related deaths during the pandemic.[4] From March to July 2020, 325 suspected overdoses were recorded in Wisconsin, compared to 150 during the same period in 2019. This might be caused by increased isolation, stress, anxiety, and behavioral issues leading to more opioid use.[5]

One potential contributor to prescription opioid overdose deaths is the volume of unused prescription opioids in patients' homes. In a systematic review of prescription opioid use after inpatient or outpatient surgery, 67 to 92 percent of patients had unused prescription opioids, with average amounts ranging from 5 to 20 tablets remaining for the studies reporting this information. This might be acceptable if patients disposed of their prescription opioids appropriately; however, only a small number of patients (between 4 and 30 percent) planned to dispose, or actually disposed, of their leftover opioids.[6]

The U.S. Drug Enforcement Administration (DEA) sponsors an annual National Take Back Day during which the public is invited to safely dispose of their unwanted prescription drugs at collection sites in the community. Although the effort is aimed at eliminating excess controlled substance prescription medication, all medications are accepted. In October 2020, the DEA sponsored its 19th National Take Back Day and in Wisconsin collected almost 90,000 pounds of prescriptions from the public at 290 community collection sites. Both numbers lead the country, well ahead of more populous states like California and Texas.[7] Clearly, Wisconsinites have prescriptions to dispose of.

With the COVID pandemic continuing and the opioid epidemic intensifying, any potential solution for decreasing the quantity of unused prescription opioids in circulation should be considered. Could Wisconsin pharmacists help achieve this goal through repeated, patient-requested partial filling of Schedule II (C-II) controlled substance prescriptions? Both federal and state laws govern the use and handling of controlled substances;

TABLE 1. Drug Overdose Deaths in Wisconsin

Time Period	Drug Overdose Deaths	
	All Drugs	Opioids*
July 2018-June 2019	1113	715
July 2019-June 2020	1404	1045
Increase	**26.1%**	**46.2%**

**This category includes "natural, semi-synthetic, and synthetic opioids, including methadone."[3]*

TABLE 2. Resources for Keeping Up-to-Date on State Pharmacy Advocacy Issues

Resources	*Website for Sign-up*	*Type of Notification*
Wisconsin State Legislature	https://notify.legis.wisconsin.gov	Legislative proposals (based on keywords); administrative rule proposals based on section (e.g. Phar)
Department of Safety and Professional Services, Pharmacy Examining Board Newsletter	https://public.govdelivery.com/accounts/WIDSPS/subscriber/new (sign in or create account, then select "Pharmacy Examining Board" under Newsletters)	Updates on actions of the Pharmacy Examining Board, including new and proposed rules as well as variances
Pharmacy Society of Wisconsin (PSW) Fast Facts weekly newsletter	https://www.pswi.org	Weekly newsletter on statewide and national pharmacy news, including legislative advocacy topics (included with PSW membership)

confusion can arise when these laws are not consistent with each other. This article will describe current federal and state laws and regulations governing partial filling of C-II prescriptions, how to reconcile differences between them, and offer recommendations for current practice.

The Comprehensive Addiction and Recovery Act of 2016

Many Wisconsin pharmacists might not know that there is a federal law in existence to help reduce the volume of unused prescription opioids in patients' homes. The Comprehensive Addiction and Recovery Act (CARA), signed into law in 2016, provides a coordinated federal response to the opioid epidemic.[8] CARA addresses prevention and education, law enforcement, treatment, recovery, and miscellaneous matters. Within those miscellaneous matters is section 702, of special interest to pharmacists because it amends the provisions regarding partial fills of C-IIs within the U.S. Controlled Substances Act. Specifically, this section allows partial fills of C-IIs to be requested by the patient or prescribing practitioner and allows the remaining portions of the prescription to be filled within 30 days of the date the prescription is written, up to the total quantity prescribed, if these practices are not prohibited by state law. In comparison, emergency oral C-II prescriptions may be partially filled with the remaining portion filled within 72 hours, which CARA did not affect.

For many years, pharmacists have recognized two instances when a partial fill of a C-II prescription is permissible, per DEA regulations and echoed in Wisconsin's regulations concerning controlled substances, Phar 8.[9,10] A pharmacy may be "unable to supply" the full quantity of a C-II prescription and a one-time partial fill may be dispensed, with the remainder required to be dispensed within 72 hours. In the past, DEA has permitted a broad interpretation of "unable to supply" including when the drug is not in stock (the traditional interpretation), when the drug is in stock but the pharmacy is waiting for verification or clarification, when the patient cannot afford to pay for the full amount, or when the patient did not want the full amount.[11] In addition, C-II prescriptions for patients in long-term care facilities or who are terminally ill may be repeatedly partially filled for up to 60 days.[9,10]

The CARA partial fill provisions were confusing to many. DEA regulations requiring C-II partial fills to be completed within 72 hours were still intact, and now CARA permitted 30-day partial fills. Were the laws compatible or contradictory? Lawmakers sent open letters to the DEA urging a revision of their regulations to be consistent with CARA.[12,13] However, the DEA did not revise their regulations, exacerbating the confusion.

In 2020, the DEA released a revision of their Pharmacist Manual, and finally provided some clarity around the situation. The DEA interprets CARA legislation and existing DEA regulation to be compatible and co-existing.[14] Per the updated Pharmacist Manual, the remaining portion of a C-II partial dispensing must be filled within 72 hours when the pharmacist is unable to supply (or for an emergency prescription). Partial quantities, up to the quantity specified on the prescription, may be filled within 30 days when requested by the patient or prescriber. The Pharmacist Manual goes on to indicate, however, that if state regulations have not changed, and they still only specify the 72-hour "unable to supply" provision for partial filling, then the stricter state law/regulation applies until the state makes a change. This is consistent with the general approach of adhering to the stricter law when federal and state law conflict. This principle ensures pharmacists are adhering to both sets of laws. As of the writing of this article, Wisconsin has not changed its statutes or regulations to parallel CARA.

How Wisconsin's Neighbors Have Incorporated CARA Provisions

Wisconsin's neighboring states—Minnesota, Michigan, Iowa, and Illinois—have implemented CARA's C-II partial fill language to varying degrees. CARA states that the 30-day partial fill may be implemented under the condition that it is not prohibited by state law. None of Wisconsin's neighbor states (nor Wisconsin itself) expressly prohibits this practice. Each of these states in some way incorporates DEA's long-standing 72-hour "unable to supply" partial fill regulation, as well as the 60-day partial fill allowance for terminally ill and long-term care facility patients. Michigan, through legislation passed in 2017, allows partial filling for C-IIs "consistent with federal law and regulations."[15] Specific situations

are not named. Iowa has promulgated regulations to expressly allow 30-day C-II partial fills "at the request of the patient or prescriber."[16] Minnesota and Illinois have not adopted any language in their statutes or regulations interpreting CARA, although neither state's laws expressly prohibit patient-requested partial dispensing of C-IIs. Minnesota's Board of Pharmacy issued a Frequently Asked Questions document in 2019 that confirmed that patient-requested partial fill of C-IIs for 30 days is allowable under federal law.[17] However, with the DEA's interpretation in the 2020 Pharmacist Manual that states should change laws or regulations to parallel CARA, additional action may be needed to implement these changes in Minnesota.

In summary, three of the four states that border Wisconsin have endorsed CARA in some way. Two states have passed regulations or statutes indicating that patient-requested repeated partial filling of C-IIs within 30 days is permitted in addition to existing DEA C-II partial fill regulations.

What Can Wisconsin Pharmacists Do?

In Wisconsin, there is currently no statute or regulation expressly permitting or prohibiting patient/prescriber-requested 30-day partial filling of C-II prescriptions per CARA. Wisconsin regulations reflect only the historical 72-hour "unable to supply" allowance for partially filling C-II prescriptions.[10] Given the DEA's interpretation in the new Pharmacist Manual that states should change their laws or regulations before implementing CARA, it must be interpreted that this practice is not yet legal in Wisconsin. As of the writing of this article, the Pharmacy Examining Board (PEB) is in the process of revising Phar 8. Revisions that include language specifically allowing the CARA provisions would help enable more flexible patient/prescriber-requested partial fills of C-II prescriptions. Pharmacists can advocate for this at the time when PEB invites comments on draft revisions of Phar 8, anticipated some time during the next 12 months (the current scope statement for this revision expires in February 2022).[18] Table 2 provides several resources that pharmacists can use to sign up for notifications of upcoming state legislation and rulemaking. The DEA has recently posted a notice of proposed rulemaking to clarify how partial fills may be requested and recorded under CARA, with public comments due February 2, 2021.[19] When the final DEA rules are published, they will further support state efforts to implement CARA partial fills.

In anticipation of this change, pharmacy computer systems may also need to be reviewed and potentially adjusted to permit and document partial fills for C-II prescriptions appropriately, ensuring they are recorded as partial fills and not documented as refills or assigned a new prescription number. Another challenge might be for prescription coverage providers to recognize this practice and cover partial fills and dispensing costs appropriately.

Until regulations implementing CARA are promulgated in Wisconsin, pharmacists will need to use other strategies to help patients limit unused opioids in circulation and combat the opioid epidemic. Pharmacists can work with prescribers to suggest appropriate prescription quantities for acute pain prescriptions. State regulations permit pharmacists to change the quantity prescribed for a C-II prescription; this must be done in consultation with the prescriber and should involve consultation with the patient.[20] Pharmacists can counsel patients on proper disposal options for unused prescriptions, including in-store medication disposal kiosks, prescription take-back days, or chemical and physical sequestrant options that render drugs irretrievable. Pharmacists can also educate patients about the ongoing opioid epidemic and the role that prescription opioids play in the epidemic. As a harm-reduction strategy, pharmacists can enroll with the Wisconsin Department of Health Services (DHS) to prescribe and dispense naloxone under the Statewide Standing Order,[21] or work with a local provider to dispense naloxone. The DHS website contains detailed information on naloxone dispensing by pharmacists, including patients who should be considered to receive it.

Conclusion

Given the severity and ongoing nature of both the opioid epidemic and the COVID pandemic, pharmacists should be considering every avenue to help decrease the risk of opioid overdose and unused prescription opioids in circulation. Pharmacists currently have several tools to help patients receive the appropriate quantity of opioids and dispose properly of unused prescriptions. Although not currently permitted in Wisconsin, in the future, pharmacists might be able to discuss with patients the possibility of repeatedly partially filling their opioid prescriptions at the patient's request. The opening case concerning Esmay Taylor highlights just one of many scenarios in which this approach could be a beneficial option. Pharmacists in Wisconsin should look for upcoming revisions to controlled substance regulations, and advocate for inclusion of language that parallels CARA.

Michael DeBisschop is a Professor at the Medical College of Wisconsin School of Pharmacy in Milwaukee, WI. Katherine Rotzenberg is an Instructor in the Social & Administrative Sciences Division at the University of Wisconsin-Madison School of Pharmacy in Madison, WI.

PR *This article has been peer-reviewed. The contribution in reviewing is greatly appreciated!*

Disclosure: The authors declare no real or potential conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.

References

1. Overdose death rates. National Institute on Drug Abuse. Updated March 10, 2020. Accessed October 22, 2020. https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates
2. Substance use: drug overdose deaths dashboard. Wisconsin Department of Health Services. Updated March 23, 2020. Accessed October 29, 2020. https://www.dhs.wisconsin.gov/aoda/drug-overdose-deaths.htm
3. Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. Center for Disease Control and Prevention National Center for Health Statistics. Updated January 3, 2021. Accessed January 21, 2021. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
4. Issue brief: Reports of increase in opioid- and

other drug-related overdose and other concerns during COVID pandemic. American Medical Association. Updated October 31, 2020. Accessed November 12, 2020. https://www.ama-assn.org/system/files/2020-10/issue-brief-increases-in-opioid-related-overdose.pdf
5. Richmond T. Wisconsin opioid overdoses more than double during pandemic. AP News. Accessed November 12, 2020. https://apnews.com/article/c3e331526483cc34d54fa4e53d5d089d
6. Bicket MC, Long JJ, Provonost PJ, Alexander GC, Wu CL. Prescription opioid analgesics commonly unused after surgery: a systematic review. *JAMA Surg*. 2017;152(11):1066-1071. doi: 10.1001/jamasurg.2017.0831
7. 19th National Take Back Day. Drug Enforcement Administration Diversion Control Division. Accessed November 3, 2020. https://takebackday.dea.gov/sites/default/files/NTBI%2019%20Totals_0.pdf
8. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, §702, 130 Stat. 740 (2016). Accessed October 29, 2020. https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf
9. Prescriptions. 21 C.F.R §1306.13 (2020).
10. Wis. Admin. Code §Phar 8.07 (2020).
11. Abood RR, Burns KA. Pharmacy Practice and the Law. 9th Ed. Jones & Bartlett Learning. Burlington, MA. 2020.
12. Warren E, Capito SM, Grassley C, Feinstein D, Clark K, Stivers S. Letter to Acting Administrator Uttam Dhillon. Dated July 26, 2018. Accessed October 29, 20f20. https://www.warren.senate.gov/imo/media/doc/2018.7.26%20DEA%20Partial%20Fill%20Regs%20Update%20Letter.pdf
13. Grassley, colleagues urge DEA to swiftly issue regulations and guidance on partial fill law to better address nation's opioid crisis. Updated December 22, 2017. Accessed November 4, 2020. https://www.grassley.senate.gov/news/news-releases/grassley-colleagues-urge-dea-swiftly-issue-regulations-and-guidance-partial-fill
14. Drug Enforcement Administration Diversion Control Division. Pharmacist's Manual. Updated October 8, 2020. Accessed November 4, 2020. https://www.deadiversion.usdoj.gov/pubs/manuals/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf
15. Minnesota State Board of Pharmacy. Frequently Asked Questions – 2019 Legislation. Accessed November 11, 2020. https://mn.gov/boards/assets/FAQ2019Legislation04012020Update_tcm21-426252.pdf
16. Mich Comp Laws §333.7333(3) (2020).
17. Iowa Admin Code §657.10.27 (2020).
18. Wisconsin Legislature. Scope Statement SS 074-19. Updated August 12, 2019. Accessed November 11, 2020. https://docs.legis.wisconsin.gov/code/scope_statements/all/074_19
19. Partial filling of prescriptions for schedule II controlled substances. Fed Regist. 2020;85(234):78282-95. To be codified at 21 CFR §1306.13.
20. Wis. Admin. Code §Phar 8.05(7), (2020).
21. Opioids: standing order for naloxone. Wisconsin Department of Health Services. Accessed December 9, 2020. https://www.dhs.wisconsin.gov/opioids/standing-order.htm