PALLIATIVE CARE NETWORK OF WISCONSIN

FAST FACTS AND CONCEPTS #198
REGULATORY ISSUES FOR PRESCRIBING SCHEDULE II OPIOIDS AT THE END OF LIFE

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Background Schedule II opioids (e.g. morphine, oxycodone, methadone, hydromorphone) play a major role in the management of symptoms at the end of life. Because of possible abuse, trafficking, and diversion of opioids, federal statutes mandate that appropriate safeguards be adhered to by prescribing clinicians and dispensing pharmacists. There are regulations that are important to understand for patients in hospice and long-term care settings, or who may have rapidly changing symptoms at home. This *Fast Fact* will review US federal regulations regarding prescribing Schedule II drugs for adult and pediatric patients. **Note:** a) some states may impose additional restrictions – check with your state licensing boards for specifics, and b) individual pharmacists may enforce these regulations with variable stringency.

Prescription Information Prescriptions for Schedule II opioids must be written, dated, and signed on the day issued, and include the full name and address of the patient, the drug name, strength, quantity prescribed, and directions for use. The name, address, and Drug Enforcement Agency (DEA) registration number of the practitioner must also be included.

Refills and Prescription Series Refills are not allowed on Schedule II opioids; however there are no federal regulations limiting the number of days a prescription can cover (many state or local professional standards have limited this to a 30 or 90 day supply). It is permissible to write a prescription series for up to a 90 day supply of medication. For example, at a single office visit a patient can be given 3 prescriptions, each for 30 days worth of the same drug, with two of the prescriptions noting: "Do not fill until [1 or 2 months, respectively, from the issue date]."

Emergency prescriptions Emergency prescriptions can be phoned into a pharmacist. The pharmacist must make a reasonable effort to determine that the verbal authorization came from a registered practitioner and that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. This is often interpreted as a three day supply, but there is no regulation specifying how many days or doses constitute an emergency prescription. The prescribing clinician must quickly supply the pharmacy with a written prescription (postmarked within seven days if mailed). This prescription must have "Authorization for emergency dispensing" written on it as well as the date of the verbal order.

Facsimile prescriptions A facsimile prescription is sufficient for a Schedule II opioid used for direct parenteral administration (e.g. intravenous or spinal use), or for oral opioids for patients residing in a long-term care facility (LTCF) or who are receiving hospice care (even if at home). The script must note the patient's status (e.g. "Resides in LTCF," "Patient in hospice"). In other circumstances, written, not facsimile prescriptions, are required.

Partial dispensing Partial dispensing is allowed if the pharmacist is unable to supply the full quantity at one time. The remaining portion of the prescription must be filled within 72 hours. For patients in a LTCF or with a terminal illness, partial quantities up to 60 days from the issue date may be dispensed. The script must designate the patient is 'terminally ill' or in a LTCF.

Pharmacist changes to prescriptions Pharmacists may independently add or change the patient's address. After consultation with the prescriber, pharmacists may also add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. While the aforementioned changes are permissible, many pharmacists will request a rewritten prescription.

Patients with an addictive disease or in a drug treatment program Opioid addiction and pain can co-exist at the end of life. Clinicians approved for Schedule II prescribing by their DEA license can prescribe any Schedule II drug in the inpatient and outpatient settings (including buprenorphine and methadone) for pain and symptom relief, even if the patient is enrolled in an opioid maintenance program.

Clinicians are strongly advised to seek specialist help in these situations (from both pain and addiction specialists) as well as to work collaboratively with the patient's treatment program. To better identify cases of opioid misuse or diversion, it is recommended that at least one prescriber from every hospice have access to a prescription drug monitoring program. Standardized protocols on how to approach cases of suspected drug abuse and diversion in the home are also recommended for hospice organizations.

References

1. Chapter II--Drug Enforcement Administration, Department Of Justice, Part 1306: Prescriptions. U.S. Food and Drug Administration. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1306. Accessed July 30, 2015.
2. General Questions and Answers. Drug Enforcement Administration Office of Diversion Control. Available at: http://www.deadiversion.usdoj.gov/faq/general.htm. Accessed July 30, 2015.
3. Final Rule 2007 – Issuance of Multiple Prescriptions for Schedule II Controlled Substances. Drug Enforcement Administration Office of Diversion Control. Available at: http://www.deadiversion.usdoj.gov/fed_regs/rules/2007/fr1119.htm. Accessed November 29, 2007.
4. Gilson AM, Joranson DE. The Federal Drug Enforcement Administration "Prescription Series" Proposal: Continuing Concerns. *J Pain Palliat Care Pharmacotherapy*. 2007; 21:21-24.
5. Gilson AM, Joranson DE. Is the DEA's new "Prescription Series" Regulation Balanced? Pain and Policy Studies Group. Available at: http://www.painpolicy.wisc.edu/DEA/Rx_Series_Adoption.pdf. Accessed December 10, 2007.

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