



PALLIATIVE CARE CASE OF THE MONTH

How to Legally Prescribe Controlled Substances Julie Childers, MD

Volume 12, No. 17

September, 2012

Case: DK is a 30 year old woman with a history of sarcoma. She has had multiple resections for her disease, and chemotherapy. Currently there are enlarging tumors in her chest wall causing pain. She uses a fentanyl patch 100 mcg/hour, hydromorphone 4 mg tablets, and as-needed clonazepam to manage her pain and anxiety. She is planning to spend two weeks in California caring for a sick relative; preparing for this trip, she called a California pharmacy asking if they would fill these prescriptions from a doctor with a Pennsylvania license – the pharmacist there refused. She comes to the outpatient palliative care clinic asking how she will get her prescriptions refilled when they are due. How can the doctor legally prescribe DK's medications to her while she is out of state? What other regulations regarding prescriptions for controlled substances do practitioners need to know for the outpatient setting?

Discussion: With the passage of the Controlled Substances Act (CSA) in 1970, five schedules of pharmaceuticals were established in the U.S., based on their potential for abuse; substances with lower schedule numbers are considered to have higher abuse potential. Schedule I substances such as heroin, marijuana, and ecstasy, are considered to have no accepted medical use, and cannot be prescribed by physicians. Schedule II substances have a high potential for abuse and a recognized medical use. These include most opioids (morphine, oxycodone, fentanyl, etc) as well as psychostimulants such as methylphenidate and Dexedrine. Cocaine, with limited accepted use as an anesthetic and vasoconstrictor in otolaryngological procedures, is also Schedule II.

Commonly prescribed Schedule III opioids include hydrocodone (in quantities less than 15 mg/tablet), codeine in quantities less than 90 milligrams per dosage unit, and buprenorphine. Dronabinol and ketamine also are Schedule III. Propoxyphene (no longer available for prescription in the United States) and all benzodiazepines are Schedule IV substances, while Schedule V medications include cough suppressants containing small amounts of codeine, preparations containing small amounts of opium or diphenoxylate (used to treat diarrhea), and analgesics such as pregabalin.

By federal law, controlled substances must be signed and dated on the date when issued, though multiple prescriptions may be issued for future dates with a "do not fill until date", for up to a 90 day supply. No refills are permitted for Schedule II medications. There are no specific federal limits to quantities of drugs dispensed, though many states limit Schedule II drugs to a 30 day supply. There is no federal time limit within which a Schedule II prescription must be filled after being signed.

Original written prescriptions for Schedule II substances are required in most cases. Federal law does allow prescriptions to be faxed directly to the pharmacy for compounded parenteral medications (such as home PCAs), as well as for nursing home and for patients enrolled in hospice programs. In 2010, the Drug Enforcement Administration issued a rule allowing electronic prescribing of controlled substances for practitioners who meet federal guidelines for identity authentication.

For palliative care consultations please contact the Palliative Care Program at PUH/MUH, 647-7243, beeper 8511, Shadyside Dept. of Medical Ethics and Palliative Care, beeper 412-647-7243 pager # 8513, Perioperative/ Trauma Pain 647-7243, beeper 7246, UPCI Cancer Pain Service, beeper 644-1724, Interventional Pain 784-4000, Magee Women's Hospital, beeper 412-647-7243 pager #: 8510, VA Palliative Care Program, 688-6178, beeper 296. Hillman Outpatient: 412-692-4724. For ethics consultations at UPMC Presbyterian-Montefiore and Children's page 958-3844. With comments about "Case of the Month" call Dr. Robert Arnold at (412) 692-4834.



Discussion (continued): Federal law also allows practitioners to call in emergency three-day supply for Schedule II substances; however, there is no requirement for pharmacists to agree to fill an emergency prescription.

If a faxed prescription is accepted, the original written prescription must be received by the pharmacy within seven days.

Beyond the federal laws, each state establishes regulations regarding controlled substances which may be more restrictive than those described above. For example, tramadol is not a controlled substance under federal regulations, but as of 2011 Kentucky and Arkansas had designed it as a Schedule IV medication under their laws. Individual state policies are available online. A state's Board of Pharmacy web page usually is a good place to start when determining whether pharmacists in that state will accept out of state prescriptions. Some states (Indiana for example) only accept controlled substance prescriptions from licensed practitioners in their own state. In fact, California state law indicates that "A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005." Decisions about whether to accept out of state prescriptions are a matter of the pharmacist's professional judgment. Practitioners who plan to write a prescription for a controlled substance should first review the regulations in that state, and may need to call the out of state pharmacy directly to determine whether a prescription can be filled.

Resolution of the case: In the case of Ms. DK, the physician was able to contact her insurance company to obtain authorization for an early refill of her medication so she could fill them in her home state before her trip.

References:

1. <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html> (accessed September 6, 2012)
2. http://www.deadiversion.usdoj.gov/ecommm/e_rx/faq/practitioners.htm#intro (accessed September 6, 2012)
3. http://www.deadiversion.usdoj.gov/drugs_concern/ramadol.pdf (accessed September 17, 2012)
4. <http://www.medscape.com/resource/pain/opioid-policies> (accessed September 6, 2012)

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