

## LEGAL CAPSULES

By

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Hello and welcome back to the world of pharmacy law. Many times during the daily course of our practice, we are asked to give patients advice regarding their medications. Usually, the questions have nothing to do with pharmacy law or regulations, but for this month, consider this scenario. A single mother comes into your pharmacy and tells you her child routinely takes methylphenidate for his attention deficit disorder. She further states that he has been on this medication for quite a while and is very well controlled, but she still needs to see her son's provider every month to get a new prescription. Being an active duty Air Force member it can be difficult for her to see the provider and get a new prescription every month. She wants to know if the following options are viable:

- A. Can she just get one prescription written for 540 tablets that will last her for 90 days?
- B. Can her son's provider write three prescriptions for 180 tablets (30-day supply) at one visit, but date them for consecutive months? In other words, she sees the provider in January and he writes a prescription for 180 tablets with a January date, then gives her two other prescriptions, one dated February and one dated March for her to fill when due.
- C. Must she continue to make an appointment and see the provider each month to get a prescription?

Looking at this *strictly from a federal law* viewpoint, how do you answer?

Hopefully, you recognize that since methylphenidate is a schedule II controlled substance, the Controlled Substances Act (CSA) and U.S. Drug Enforcement Administration (DEA) regulations apply. In August 2005, the DEA published an Interim Policy Statement to clarify which of our three options listed above are legal. With that in mind, let's examine each one.

Option A. is legal according to federal law. Neither the CSA nor DEA regulations specify any limitations on the number of days supply of a schedule II medication a physician may prescribe per prescription. The essential requirement under federal law is that the prescription be issued for a legitimate medical purpose by a practitioner operating within the usual scope of his or her professional practice. Keep in mind however, that according to 21 U.S.C. 823(f), both the prescriber and the pharmacist have a corresponding responsibility to ensure the prescribing and dispensing of a controlled substance is done in a manner that will minimize possible diversion and/or misuse. Given the facts as presented in our scenario, there is absolutely nothing wrong with filling a 90-day supply of methylphenidate.

That brings us to Option B. According to the Interim Policy Statement, "For a physician to prepare multiple prescriptions [of a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance". This directly conflicts with the CSA which prohibits refills of a schedule II controlled substance prescription. In short, Option B is not a viable or legally acceptable practice.

So, let's look at Option C a bit closer. If the practitioner will not write a prescription for a 90-day supply of medication, must the patient return to the office every month to get a new prescription? In my best legalese, I would answer "maybe". While a provider may require the patient to make an office visit each month, nothing in the Interim Policy Statement requires a patient to visit his or her provider every month to get a new prescription, nor is this a requirement under the CSA or DEA regulations. What is required is that each time a provider prescribes a controlled substance the provider determines the patient has a legitimate medical need and the provider is acting within the usual scope of his or her practice. (21 C.F.R. 1306.04(a)). Note too that a provider must exercise the utmost care in determining if a patient needs to be seen each time a schedule II controlled substance is prescribed in order to safeguard against the possibility of diversion or misuse. Generally, if a provider determines a patient does not need to be seen each time a schedule II prescription is written, this must be done in accordance with sound medical practice. If the provider decides such, three options are available. First, the provider can mail a new prescription to the pharmacy. Second, the provider can mail a new prescription to the patient, and third, the provider can fax the schedule II prescription to the pharmacy. If the provider chooses to fax the prescription to the pharmacy, 21 C.F.R. 1306.11(a) states that the schedule II prescription cannot be dispensed until the original, signed prescription is presented to the pharmacy. In reality, the only thing faxing accomplishes is a reduction in the processing/waiting time for the patient.

Is there a "best" course of action to take if faced with this situation? Other than ruling out Option B, Options A and C are both viable, legally permissible choices. The wishes and needs of both the patient and the provider will need to be weighed to formulate the optimum solution. Until next time, practice safely!