



American Pharmacists Association

Improving medication use. Advancing patient care.

November 6, 2006

Michele M. Leonhart
Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537

Attention: DEA Federal Register Representative/ODL

Re: Docket No. DEA-287N

Dear Deputy Administrator Leonhart:

Thank you for the opportunity to comment on the September 6, 2006 *Federal Register* notice addressing the issuing of multiple prescriptions for Schedule II Controlled Substances. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA is the nation's first and largest association of pharmacists in the United States.

APhA agrees with the Drug Enforcement Administration (DEA) that the diversion and abuse of prescription medications is a significant public health problem. Pharmacists work collaboratively with prescribers and other health care providers to prevent the diversion of prescription medications and to identify incidents of abuse or addiction. However, any additional stigma attached to these drugs may significantly impact health care providers' willingness to prescribe and dispense appropriate pain medication and impede patients' access and willingness to use them.

While decreasing the number of controlled substance prescriptions written and dispensed may have been viewed as a way to decrease the opportunity for diversion and abuse, we are pleased that the DEA is proposing to support the issuance of multiple prescriptions for controlled substances. It is an important step towards ensuring that pain medications and other necessary controlled substances are available to the thousands of patients who still live every day in pain and could be helped by unimpeded and appropriate use of controlled substances.

As discussed in APhA's comment letter to the Agency dated March 18, 2005, the Association was troubled by the discussion in the interim policy statement related to the preparation of multiple prescription orders. Specifically, APhA was very concerned with the DEA's interpretation that a physician may not prepare multiple prescriptions on the same day with instructions to fill on different

days, arguing that this is tantamount to writing a prescription order authorizing refills of a Schedule II controlled substance, which is prohibited.

APhA never disputed the fact that prescription orders for Schedule II controlled substances may not be refilled. This is an established and settled matter of statutory, regulatory, and case law. However, APhA has long disagreed that the scenario in question – the preparation of multiple prescriptions on the same day with instructions to fill on different days – is equivalent to the authorization of refills. In this case, each prescription is prepared on a separate prescription order blank or form and each prescription order bears the date the prescription order was issued and signed, the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, and directions for use, and the name, address, and DEA registration number of the prescriber. Each prescription order meets the requirements for a controlled substance prescription under the CSA.¹ Each prescription order stands as a separate, new prescription order for the medication prescribed.

The preparation of multiple prescription orders on the same day with instructions to fill on different days is also a long-standing accepted medical practice – a practice the DEA itself has recognized and encouraged several times in the past. In a 1995 letter from the DEA to MEIJER, Inc., the Agency described a situation in which a prescriber “signs and dates as many as six prescriptions on the day of issuance...the prescriptions are noted that the pharmacist is not to dispense the prescription order for 30, 60, 90 or 120 days.” The letter continues to state that “there appears to be no violation of current federal laws or regulations in the prescribing manner you have described.”² The letter clearly illustrates that the Agency had no objection to this practice, and that the issuance of multiple prescription orders with instructions to fill on future dates is not in violation of the CSA or subsequent regulations. The DEA has reiterated this stance on several other occasions including official Agency correspondence dated January 31, 2003.

In that letter, the DEA clearly stated its approval of the practice: The DEA regulations do not prohibit a practitioner from issuing more than one prescription order at a time. If, in keeping with the practitioner’s professional medical judgment, multiple prescription orders are issued at one time, each must bear the actual date that the prescription order was issued and signed as well as the directions for dispensing. For example, if three prescription orders, each for a 30-day supply, are issued on January 9, 2003, each prescription must be dated January 9, 2003. In addition, the prescription orders to be filled at later dates must include directions for the dispensing pharmacist such as, “do not dispense before February 9, 2003.” Although Title 21 of the Code of Federal Regulations, Section 1306.12 (21 CFR 1306.12) prohibits the refilling of a prescription order for a Schedule II controlled substance, the DEA does not consider multiple prescription orders in the scenario outlined above as refills, and has authorized this practice provided that it is not in violation of the laws of the state in which the practitioner is licensed.³

Impact of restricting multiple prescription orders on Patient Care

Prohibiting prescribers from issuing multiple prescription orders at one time significantly impacts patient access to these necessary medications. Patients are required to visit their physician for each new prescription order – even if the patient has been successfully treated on the medication for some period of time. In most situations, patients must visit their physician or other prescriber on a monthly basis to obtain a new prescription order. Although prescribers could prescribe higher quantities of a medication

¹ 21 CFR Section 1306.05.

² Letter from G. Thomas Gitchel, DEA to Patrick Gavin, MEIGER, Inc. Dated June 8, 1995.

³ Letter from Patricia Good, DEA to Howard Heit, physician. Dated January 31, 2003.

to eliminate the need for frequent physician visits, the cost of a large supply may be cost prohibitive for cash paying patients and most insurance companies restrict patients to a 30-day medication supply. Even if patients have the financial means to secure larger supplies of medications, an approach that provides the patient with smaller, monthly supplies may still be desirable to avoid stockpiling medications that may not be necessary in the long term.

The need for frequent physician visits decreases access for some patients, and particularly disadvantages patients who are disabled, are of lower socioeconomic status, are faced with transportation challenges, or are unable to travel. Furthermore, while there is a lot of focus on controlled substance use in the treatment of pain, it is important to note that this policy affects all patients using controlled substances. For example, patients with attention deficit hyperactivity disorder (ADHD) may be treated with a Schedule II controlled substance such as Ritalin® (methylphenidate). Once these individuals are stabilized on a medication, there may not be a specific medical reason for the patient to see a prescriber every thirty days; however, under a multiple prescription restriction, ADHD patients must see their physician monthly to obtain new prescription orders. This greatly inconveniences parents and caregivers who must take time off from work and, often, remove their children from school for monthly physician visits.

Prohibiting the issuance of multiple prescription orders at one time also affects prescribers. While more frequent physician visits may produce higher incomes for prescribers (and higher health care costs for patients and insurance companies), it also increases the prescriber's workload. It may be difficult for prescribers to see every patient on a Schedule II medication every month. Physicians may be hesitant to prescribe a Schedule II drug – even when medically necessary – when doing so requires the patient to visit the prescriber every month for a new prescription order. This creates a chilling effect on health care providers' willingness to prescribe and dispense controlled substances. As we mentioned earlier, such a cost in dollars and in patient care – for minimal impact on the potential for diversion – is unacceptable.

Recommendations

APhA strongly supports the proposal to allow health care providers to provide individual patients multiple prescriptions, to be filled sequentially, for the same Schedule II Controlled Substances. Not allowing the practice is confusing, inappropriate, and jeopardizes patient care. Prescribers have been issuing multiple prescription orders in this manner for years with the Agency's approval. It is important that prescribers continue to be allowed to issue multiple prescriptions in this manner. Prescribers issue multiple prescription orders at one time to help improve patient compliance with drug therapy, decrease inconvenience for the patient and the provider, as well as decrease the quantity of controlled substances dispensed at one time.

However, we encourage the Agency to consider the recommendations as you finalize the rule:

1. §1306.12(b)(1) – we strongly recommend that the “90-day supply” be deleted from this clause. Retaining the language suggests that the Agency is seeking to change current law which does not limit the length of time for which an individual prescription order may be written or the total quantity, including number of dosages that may be written at one time. As has been stated previously in the Interim Policy Statement, this determination falls under the reasonable medical judgment of the prescriber. Instead, we recommend that the clause state, “An individual practitioner may issue multiple prescriptions authorizing the patient to sequentially fill prescription orders for the same Schedule II Controlled Substance, provided that the following conditions are met.”

2. §1306.12(b)(i) – we recommend deleting the term “properly” from the clause “The individual practitioner properly determines there is a legitimate medical purpose”. Properly is a subjective term. The goal of the Agency is presumably met with the later phrase, “and the individual practitioner is acting in the usual course of professional practice”.
3. §1306.12(b)(iii) – we recommend deleting the clause which states, “The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.” The term “undue risk” could be interpreted as imposing a new standard on practitioners. Furthermore, the proposed sequential prescription orders has the potential of decreasing the potential for abuse or diversion by limiting the number a doses a patient will have in their possession at any one time.
4. §1306.12(b)(iv) – recognizing that some state laws may be more restrictive in this area, we recommend that the Agency at a minimum provide further clarification about the ‘effective’ date of the multiple prescriptions. For example, a state law may not speak specifically to multiple prescriptions but may set an expiration date for any prescription. Therefore, without further clarification, a state may consider a prescription order written to be dispensed at a later date (after the initial prescription order) to be void/ expired before the prescription order is effective. In these cases, will the Agency consider the ‘effective’ date of the prescription the date that it was originally written or the date on which the pharmacist can dispense the prescription order?
5. §1306.12(2) – we strongly recommend that the Agency delete the reference to 90-days. As the second half of the clause states, it should be left up to individual practitioners to determine how often to see their patients and whether to prescribe multiple prescriptions. Furthermore, we recommend clarifying to what “medical standards” the Agency refers? We caution against referencing any medical standards that restrict the ability of a prescriber or dispensing pharmacist from using their professional judgment.

Striking an Appropriate Balance

APhA supports DEA efforts to curb the abuse and diversion of controlled substances; however, any efforts must be carefully balanced with the patient’s right to access necessary medications. APhA has a long standing concern that the fear of DEA investigation and/or prosecution among the medical and pharmacy communities will have a “chilling effect” on the prescribing and dispensing of medically necessary controlled substances, even though the vast majority of prescribers and pharmacists practice legitimate pain management and other uses of controlled substances.

Our strong support for the DEA proposal to allow multiple prescription orders of controlled substances to be filled sequentially is balanced by the series of recommendations listed above. This proposal is a necessary step towards breaking down the administrative barriers that decrease providers’ willingness to prescribe and dispense controlled substances and therefore patients’ access to these medications.

As the Agency continues its work to reduce the abuse and diversion of controlled substances, APhA encourages the Agency to work with physicians, pharmacists, state regulatory agencies, law enforcement agencies, and representatives of pain management and other consumer organizations. To that end, we reiterate our March 18, 2005 recommendations that the Agency convene a meeting of the principal working group to discuss the DEA’s concerns with the Prescription Pain Medications FAQ; consider using the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain as a litmus test when evaluating a prescriber’s actions; and encourage providers to institute pain management contracts for patients on long-term therapy and those with dependent behaviors in the past. APhA offers our assistance to the Agency in these efforts.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Kristina Lunner, Acting Vice President of Policy & Communications, at 202-429-7507 or KLunner@APhAnet.org with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gans". The signature is written in a cursive style with a large initial "J".

John A. Gans, PharmD
Executive Vice President

cc: Hrant Jamgochian, Esq, Director, State Relations & Political Action