Update on the Prescription Drug Abuse Epidemic for Pharmacists and Pharmacy Technicians

After completing this activity, the participant should be able to:
1. State the current prevalence of the diversion of prescribed controlled substances, as well as some concerns associated with this diversion;
2. Describe the differences among criteria for designating controlled drugs into different schedules;
3. Identify how federal and state laws regulating controlled substances may differ;
4. Outline the process for reclassification of controlled substances; and
5. Discuss how reclassification can affect pharmacists, pharmacy technicians, and patients.

Post-test/Rationale

1. During the period from 1991 to 2013, the number of prescriptions written for opiates:
   A. Doubled
   B. Increased 3-fold***
   C. Dropped by 10%
   D. Remained the same

Correct Answer: B
Opiate prescriptions increased from 76 million in 1991 to 207 million in 2013, a nearly 3-fold increase.

2. When the Drug Enforcement Administration is deciding if a drug should be placed into a schedule, 8 factors must be considered. Which of the following is NOT one of them:
   A. The risk of producing physiological dependence
   B. If the substance is a precursor of an already listed drug
   C. If the drug is sold over the Internet***
   D. The drug’s history and pattern of abuse

Correct Answer: C
The 8 required factors are shown in Table 2. Internet sales may be taken into consideration but are not a required factor; the other factors listed must be considered.

3. Who may request that a drug be placed on the list of controlled substances?
   A. Only the Drug Enforcement Administration (DEA) may initiate a request
   B. The DEA or the U.S. Food and Drug Administration (FDA) may initiate a request
   C. The DEA or a law enforcement official may initiate a request
   D. Any interested party may initiate a request***

Correct Answer: D
A proceeding to add, delete, or change the schedule of a drug may be initiated by the DEA, by the Department of Health and Human Services (HHS), or by petition from any interested party, including the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group, a state or local government agency, or an individual citizen.
4. The compounds listed in the Drug Enforcement Administration (DEA) published schedules:
A. Fall into 5 different schedules***
B. Are considered to be comprehensive and complete lists of controlled substances by the DEA
C. Include non-narcotic over-the-counter (OTC) products
D. All of the above

Correct Answer: A

There are 5 “C” schedules: C-I through C-V. The DEA states that these lists are intended as general references and are not comprehensive listings of all controlled substances. The law specifically excludes the regulation of distilled spirits, wine, malt beverages, and tobacco, as well as non-narcotic substances sold OTC (if approved by the U.S. Food and Drug Administration).

5. When considering if a drug should be scheduled, the Drug Enforcement Administration (DEA) seeks a recommendation from the U.S. Food and Drug Administration (FDA). The FDA recommendation:
   A. Is binding on the DEA, if the FDA recommends scheduling
   B. Is binding on the DEA, if the FDA concludes it should not be scheduled***
   C. Is merely advisory and is not binding on the DEA in any way
   D. None of the above, because the DEA is not obligated to seek a recommendation from anyone before making a decision

Correct Answer: B

While the Attorney General (AG) has the authority through administrative rulemaking to place a drug on the list of controlled substances, there is a shared responsibility with other agencies. The AG must first request from the U.S. Department of Health and Human Services (HHS) secretary "a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance." The findings of the HHS regarding scientific and medical issues are binding on the DEA and, if the HHS secretary "recommends that a drug or other substance not be controlled, the AG shall not control the drug or other substance." This means that if the HHS concludes that a drug does not pose a sufficient risk of abuse or danger to the public health, the drug cannot be scheduled.

6. Moving hydrocodone combination products from Schedule III to Schedule II:
   A. Became effective in 2014***
   B. Occurred rapidly as the result of timely action by the Drug Enforcement Administration and U.S. Food and Drug Administration
   C. Was strongly supported by users of the drug products
   D. Occurred shortly after pure hydrocodone was similarly treated

Correct Answer: A

The Drug Enforcement Administration (DEA) first requested guidance from the DEA in 2004 and the move was pushed by congressional action in 2012 before it became effective in 2014. More than 90% of users commenting at the public hearing opposed the change. Hydrocodone (without other ingredients), like other non-combination opiates, was made a C-II drug when the CSA was enacted.

7. In response to pharmacist concerns about added burdens related to upscheduling hydrocodone combination products, the DEA said:
   A. It was sympathetic and would reconsider their decision at a future date
   B. It did not feel there would be any added burdens
C. Procedures related to dispensing were not relevant factors in their decision making
D. There were no concerns raised by pharmacists about administrative burdens

Correct Answer: C
The DEA responded to comments received from pharmacists in the public hearing by stating the following: “processes and procedures associated with dispensing a controlled substance are not relevant factors to the determination of whether a substance should be controlled or under what schedule a substance should be placed if it is controlled.”

8. A previously unknown drug has surfaced in your community and its abuse has become a serious problem. The Drug Enforcement Administration:
   A. Must go through its usual rulemaking process, which can take up to 1 year before the drug can be considered illegal
   B. Must wait for Congress to declare its intent to control the drug
   C. May permanently place the drug into Schedule I if there is an immediate threat to public safety
   D. May temporarily place the drug in Schedule I if there is an immediate threat to the public safety while it conducts further studies

Correct Answer: D
Reactions to trends in the illicit use of previously uncommonly used drugs can also trigger changes in scheduling. The Drug Enforcement Administration may temporarily place a new drug into Schedule I, typically for 1 year, if it poses a threat to public safety, while it studies whether the drug should be permanently controlled.

9. The Drug Enforcement Administration (DEA) decided to place tramadol into Schedule IV because of all of the following reasons, EXCEPT:
   A. Tramadol is converted to an active metabolite with affinity for the mu-opioid receptor
   B. The DEA concluded that there would be a sufficiently high probability of diversion
   C. The DEA was concerned about the overprescribing of this drug in long-term care facilities
   D. Law enforcement officials reported a rate of confiscation of tramadol during their activities that was comparable to that of other C-IV drugs

Correct Answer: C
There were concerns that making tramadol a controlled substance would produce an adverse effect on patients and health care professionals in long-term care facilities by increasing the burden on prescribers, but there were no reports of overprescribing.

10. Some attribute the rise in heroin abuse to a reduced availability of prescription opiates. Other possible factors responsible for the increase in heroin use include all of the following, EXCEPT:
    A. Heroin has become cheaper in the last 2 decades
    B. Heroin has become available in purer forms
    C. Heroin has become easier to find, especially in suburban areas
    D. Heroin is easier to administer as an intravenous injection

Correct Answer: B
Heroin is available in forms that are less pure than in the past, and concern has increased over the contamination of heroin with higher potency opiates like fentanyl.