2017 Legislation Affecting the Practice of Pharmacy

Several pieces of legislation were passed by the Minnesota Legislature during the 2017 Regular and First Special Sessions and signed into law by Governor Mark Dayton. A document that contains the changes in statutes can be found on the Board's Web site, but highlights are:

- Biosimilar substitution. A change to Minnesota Statutes §151.22 allows pharmacists to make substitutions, without the prescriber's approval, when biologic products are prescribed and a U.S. Food and Drug Administration (FDA) approved biosimilar product is available. Note that a pharmacist may **not** substitute a biological product, without the prescriber's approval, unless the FDA has determined the substituted biological product to be interchangeable with the prescribed biological product. In addition, within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must communicate to the prescriber the name and manufacturer of the biological product dispensed. However, this communication does not have to happen if there is no FDA-approved, interchangeable biologic product. There are several ways in which the information can be communicated to the prescriber. For example, simply billing a prescription to a pharmacy benefit manager (PBM) is considered communicating the dispensing to the prescriber, since prescribers have access to patient records maintained by PBMs. As with any other drug, a pharmacist cannot make a substitution if the prescriber has indicated that the prescription is to be dispensed as written (DAW). This change goes into effect on August 1, 2017.

- Labeling of opiate prescriptions. Minnesota Rules have long required that systemically administered controlled substances, and other drugs deemed appropriate in the professional judgment of the pharmacist, have special labeling – at least when dispensed to adults for

outpatient use) The labeling of all such drugs must include: "Caution: Taking this drug alone or with alcohol may impair your ability to drive." Controlled substances must also be labeled: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Legislation passed this year adds an additional labeling requirement for opiates. Whenever a prescription drug containing an opiate is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug must prominently display on the label or container a notice that states "Caution: Opioid. Risk of overdose and addiction." This can be done as part of the main prescription label, or auxiliary labels can be used. This change goes into effect on July 1, 2017. However, the Board understands that many pharmacies will need time to have software vendors make changes so that this notice can be printed on labels - or time to purchase appropriate auxiliary labels. Consequently, over the next several months, the Board will take no action as long as pharmacies can demonstrate they are making a reasonable effort to come into compliance with this new requirement.

- Quantity limits for opiates prescribed for acute dental or refractive surgery pain. When used for the treatment of acute dental pain or acute pain associated with refractive surgery (e.g. LASIK or PRK), prescriptions for opiate or narcotic pain relievers are limited to a four-day supply. The quantity prescribed needs to be consistent with the dosage listed in the professional labeling for the drug that has been approved by the United States Food and Drug Administration (FDA). (For example, if the FDA-approved labeling for a drug is such that the maximum recommended dose amounts to eight tablets per day, a prescriber can't prescribe 16 tablets per day). *However*, if in the professional clinical judgment of a practitioner more than a four-day supply is required to treat a patient's acute pain, the practitioner may issue a

prescription for the quantity needed to treat such acute pain. Pharmacists will need to do additional evaluation of prescriptions for opiate pain relievers, received from dentists and ophthalmologists, if the quantity exceeds a four-day supply. That might have to include a call to the prescriber to find out if the drug was prescribed for acute or chronic pain, if it was prescribed for refractive surgery or for some other ophthalmic condition, and if the prescriber has determined that a larger quantity is necessary when the pain is acute. This requirement goes into effect on July 1, 2017.

- Prescription eye drop coverage. Effective January 1, 2018, state-regulated health insurers will be required to cover refills of prescribed eye drops even when:
    - The refill is processed up to nine days early for a prescription that would normally last 30 days - or up to 15 days early, for a prescription that would normally last 90 days.
- Information about legislation that provides pharmacists with opportunities to volunteer. Legislation was passed that directs the Commissioner of Health to form a Palliative Care Advisory Council and to issue grants to establish Opioid Abuse Prevention Pilot Projects around the state. Pharmacists are among the health professionals who can serve on the Palliative Care Advisory Council. The opioid abuse pilot projects must "establish multidisciplinary controlled substance care teams that may consist of physicians, pharmacists, social workers, nurse care coordinators, and mental health professionals." Interested pharmacists should contact the Minnesota Department of Health for additional information.