



UTAH BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

When Will the Revised USP Chapters <795> and <797> Go Into Effect?

On June 1, 2019, United States Pharmacopeia (USP) published revisions to Chapters <795> and <797>. After receiving appeals from pharmacies and other stakeholders, the Appeals Panel recommended further engagement on the issues via the Compounding Expert Committee (CMP EC). The current versions of General Chapter <795> (revised in 2014) and General Chapter <797> (revised in 2008) remain official.

Standards-Setting Process

Once a standard revision is developed for USP–National Formulary, it is proposed for a 90-day public review and comment period in the *Pharmacopeial Forum*. After the public review and comment period, the CMP EC considers the comments received and determines whether further changes to the standard should be made. To finalize the standard, the CMP EC members vote. Once finalized, **USP and its supplements become official six months after being released to the public.**

During this time, the Utah Board of Pharmacy will also invite public comments as it meets to discuss whether to adopt the final revision in its entirety or a modified version.

How to Keep Up to Date

The Pharmacy Compounding Advisory Committee will ensure that any information that comes out regarding updates or meetings for USP Chapters <795> and <797> will be included on its agenda, which can be accessed on the Utah Public Notice Website. For additional information regarding the USP Appeals decision, please visit www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-decision-on-appeals-factsheet.pdf.

As of now, the Board does not have a time frame for implementation of the newest chapters, but the Board does not anticipate any changes within the next year.

Utah 2021 General Session Legislative Pharmacy Update

By David C. Young, PharmD, RPh

Health care was a focus throughout the 2021 legislative session with bills addressing pharmacy practice, managed care pharmacy, cannabis, and the coronavirus disease 2019 (COVID-19). The following is a brief summary of selected bills that directly impact the practice of pharmacy in the state of Utah.

Pharmacy Practice Bills

House Bill (HB) 178S01: Pharmacy Practice Modifications

Chief Sponsor: Representative Norman Thurston

Senate Sponsor: Senator Curtis Bramble

By January 1, 2022, this bill allows for the pharmacist to prescribe certain drugs or devices if:

- the drug or device is within the pharmacist's scope of training;
- has been designated by rule; and
- is not a Schedule I-IV controlled substance (CS).

The bill also addresses a public health issue (eg, pre- and post-exposure HIV prophylaxis, self-administered hormonal contraceptive, smoking cessation, naloxone).

The Utah Division of Occupational and Professional Licensing (DOPL) shall make rules regarding pharmacist prescribing in collaboration with pharmacists, physicians, advanced practice clinicians, and the Utah Department of Health. This multidisciplinary working group conducts monthly virtual meetings where **all** stakeholders are encouraged to be actively engaged in the development of the pharmacist prescribing rules. If you would like to be involved, please visit the following link for more information: www.utah.gov/pmn/sitemap/notice/686399.html.

HB 265: Pharmacy Software Amendments

Chief Sponsor: Representative Rosemary Lesser

Senate Sponsor: Senator Evan Vickers

By January 1, 2022, this bill requires that each CS prescription be transmitted electronically unless it is issued:

- for a patient residing in an assisted living, long-term care, or correctional facility;
- during a temporary technical or electronic failure; or
- during an emergency situation.

By July 1, 2024, this bill requires that pharmacy software capable of receiving CS prescription(s) be able to electronically transfer a prescription to a different pharmacy if:

- requested by the patient or provider;
- the prescription is unfilled; and
- it is approved by the pharmacist at the originating pharmacy.

Senate Bill (SB) 177S01: Pharmacy Practice Revisions

Chief Sponsor: Senator Vickers

House Sponsor: Representative Paul Ray

This bill amends the qualifications for licensure for a pharmacy technician trainee according to rules that will be established by the Board and DOPL.

This bill adds advanced practice registered nurses (APRNs), registered nurses, and physician assistants (PAs) as covered providers to dispense opiate medication-assisted treatment at an opioid treatment program.

This bill establishes a pharmacy benefits manager (PBM) audit time limit (seven to 60 days); the pharmacy has 30 days to respond to the audit. In addition, it clarifies what pharmacies can utilize to validate claims to PBM (eg, the pharmacy's own physical or electronic record, physical or electronic records, or valid copies of the physical or electronic records of a practitioner or health care facility).

This bill establishes that pharmacies have seven days to submit corrections to the Utah Controlled Substance Database (CSD).

This bill directs that DOPL, in collaboration with the Board of Pharmacy and Physicians Licensing Board, will establish training regarding pharmacist administration of naloxone and long-acting injectable(s). Pharmacists must complete training that is established in the rule and must include administration of naloxone or long-acting injectable(s) in a clinic or community pharmacy setting as directed by the physician.

Managed Care Bills

SB 140: Pharmacy Benefit Amendments

Chief Sponsor: Senator Vickers

House Sponsor: Representative Steve Eliason

By January 1, 2022, this bill requires that an insurer may not vary the amount reimbursed to a federally qualified health center (eg, 340B drug or 340B entity). The insurer or the insurer's pharmacy service may not:

- assess a fee, charge-back, or other adjustment;
- restrict access to the insurer's pharmacy network;
- require the federally qualified health center to enter into a specific pharmacy contract; or
- create a restriction or additional charge to patients who choose to receive drugs from a federally qualified health center on the basis that the federally qualified health center participates in the 340B discount program.

Cannabis Bills

SB 81: Medical Cannabis Electronic Verification System Deadline Amendments

Chief Sponsor: Senator Vickers

House Sponsor: Representative Francis D. Gibson

This bill:

- delays the following existing operational deadlines for the medical cannabis program's electronic verification system until September 1, 2021;
- allows qualified medical provider employee access to the system on behalf of the provider;
- allows a prescribing provider access to dispensing and card status in the system regarding a patient the provider treats;
- connects state system to inventory control of medical cannabis pharmacy in real time;
- allows a parent or legal guardian who does not qualify for a medical cannabis guardian card to designate two caregivers in the system;
- allows for an individual from another state to register with the Utah Department of Health to purchase from a medical cannabis pharmacy on a limited basis;
- allows a patient to designate an assisted living facility, nursing care facility, or general acute hospital as a caregiver for medical cannabis purposes; and makes technical and conforming changes.

SB 170S02: Consumer Protection for Cannabis Patients

Chief Sponsor: Senator Luz Escamilla

House Sponsor: Representative Ray Ward

As of July 1, 2021, this bill:

- revises a standard label warning must include "recommending medical provider";

- adds limited medical provider (15 patients);
- allows pharmacy to record limited medical provider medical cannabis recommendation to state electronic verification system;
- requires pharmacy medical provider to verify limited medical provider recommendation;
- adds podiatrist, APRN, and PA as recommended medical provider;
- allows for conditional medical cannabis card (valid 60 days); changes medical cannabis card (valid six months);
- requires that pharmacy medical provider work on site; designate pharmacist-in-charge; and
- requires pharmacy medical provider four-hour continuing education per licensing cycle.

SB 192S03: Medical Cannabis Act Amendments

Chief Sponsor: Senator Vickers

House Sponsor: Representative Gibson

This bill:

- creates Cannabis Production Establishment Licensing Advisory Board (five voting members);
- imposes certain labeling requirements regarding derivative and synthetic cannabinoids;
- requires a medical cannabis pharmacy to provide an opaque, child-resistant bag;
- requires the processing and testing of derivative and synthetic cannabinoids to a certain product quality;
- requires the electronic verification system to communicate dispensing information to the CSD;
- allows the Compassionate Use Board to approve an individual for a medical cannabis card for periods shorter than a standard initial period of validity; and
- limits medical cannabis treatment recommendations to 275 of qualified medical providers patients – 600 if anesthesiology, gastroenterology, neurology, oncology, pain, hospice and palliative medicine, physical medicine and rehabilitation, rheumatology, endocrinology, or psychiatry; or qualified medical provider is contracted to provide hospice and palliative care.

Controlled Substance Bills

There were two significant bills passed regarding CS and the CSD:

HB 15: Controlled Substance Amendments

Chief Sponsor: Representative Ward

Senate Sponsor: Senator Michael Kennedy

This bill removes an exception to the seven-day limit on prescriptions for certain CS (Schedule II or III) after a surgery and requires a practitioner to check the CSD and consult with other practitioners when issuing a long-term prescription for an opiate or a benzodiazepine under certain circumstances.

HB 85: Controlled Substance Database Access Amendments

Chief Sponsor: Representative Craig Hall

Senate Sponsor: Senator Vickers

This bill authorizes DOPL to provide information to a licensed pharmacist authorized by a managed care organization to access information on behalf of the managed care organization for a specific fatality due to opioid use in collaboration with Utah's Opioid Fatality Review Committee to recommend policies to reduce opioid fatalities. This bill also creates an exception to certain restrictions on access to the CSD (ie, civil, judicial, or administrative action against managed care organization related to Medicaid coverage).

COVID-19 Bills

There were three significant bills passed regarding COVID-19:

HB 117S04: Vaccine Reporting Requirements

Chief Sponsor: Representative Ward

Senate Sponsor: Senator Michael McKell

This bill requires a vaccine provider (eg, medical facility, pharmacy, local health department, school, health professional office) to report vaccine information to the Utah Statewide Immunization Information System (USIIS) and allows for an individual to opt out of having vaccine information shared with the USIIS.

HB 294: Pandemic Emergency Powers Amendments

Chief Sponsor: Representative Ray

Senate Sponsor: Senator Derrin Owens

This bill terminated emergency powers and certain public health orders related to COVID-19 upon reaching certain thresholds of positivity and vaccination rates, and other criteria. It also:

- removed the statewide mask mandate required for large gatherings (>50) and K-12 school by April 10, 2021; and
- terminated K-12 mask mandate orders July 1, 2021.

HB 308: Covid-19 Vaccine Amendments

Chief Sponsor: Representative Robert Spendlove

Senate Sponsor: Senator Daniel McCay

This bill prohibits a government entity from requiring individuals to get a COVID vaccine, with a sunset date of July 1, 2024.

COVID-19 Agency Notices

DOPPL has a [web page](#) with COVID-19 agency notices, current office hours, and fingerprinting information. Please be sure to check the [web page](#) for notices regarding the practice of pharmacy.

National Pharmacy Compliance News Now Available!

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

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