


UTAH SOCIETY OF
HEALTH-SYSTEM PHARMACISTS

Annual Meeting
September 18, 2021

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Speaker Introduction: Carrie Dunford, PharmD, BCPS, MBA


Carrie Dunford earned a baccalaureate of Pharmacy from the University of Utah School of Pharmacy and a Doctorate of Pharmacy from Idaho State University. She completed her Masters of Business Administration from Western Governors University. She worked in community pharmacy early in her career then hospital pharmacy for several years before accepting roles that focus on regulatory compliance and pharmacy leadership. She is currently the Pharmacy Services Internal Process Controls Director and Interim Chief Pharmacy Officer at Intermountain Healthcare. Carrie has served on the Utah Board of Pharmacy since 2017 and is currently the chairperson. She also serves on the Board of Trustees for Haiti Health Initiative, a group that provides medical and dental care along with educational opportunities to the people of rural Haiti. Carrie's hobbies include glamping at Bear Lake or Fairview Utah with her husband and two sons.



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Speaker Introduction: Karen M. Gunning, PharmD, BCPS, BCACP, FCCP

Dr Gunning received her Doctor of Pharmacy from the University of Utah and completed a postgraduate residency in Family Medicine at the University of Washington. She is a Professor (Clinical) of Pharmacotherapy, Associate Dean of Community Engagement, Adjunct Professor of Family & Preventive Medicine, and clinical pharmacist for the Family Medicine Residency Program at University of Utah Health. Dr Gunning has received the College of Pharmacy Teacher of the Year Award three times, and Specialty Teacher of the Year for the Family Medicine Residency Program twice; as well as receiving the Utah Society for Health System Pharmacist of the Year Award. In 2016, she received the University of Utah Distinguished Teaching award. She is a proud member of the Utah Board of Pharmacy.




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Updates from the Utah Board of Pharmacy: 2021

Carrie B. Dunford, PharmD, BCPS, MBA
Chairperson, Utah Board of Pharmacy

Karen M. Gunning, PharmD, BCPS, BCACP, FCCP
Pharmacist Member, Utah Board of Pharmacy



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Disclosures

- Carrie is employed by Intermountain Healthcare. Opinions and content in this presentation are not representative of Intermountain Healthcare.
- Karen is employed by the University of Utah College of Pharmacy, School of Medicine and University of Utah Health Pharmacy Services. Opinions and content in this presentation do not reflect the views and opinions of the University of Utah.
- Carrie and Karen are not lawyers, and are not employees of DOPL, or able to speak on behalf of DOPL. The information presented is not legal opinion, and is not all inclusive of Utah Pharmacy Law/Rules. Participants are urged to read the law themselves. Information presented is based on Pharmacy Practice Act Rules posted as of 3/11/2021
- There will be no discussion of off-label uses of drugs.



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Learning Objectives - Pharmacists

At the conclusion of this activity, *pharmacists* should be able to successfully:

1. Discuss the impact of changes to the Pharmacy Practice Act.
2. Explain the process for providing comments to Pharmacy Practice Act Rule changes.
3. Locate the public notification webpage for the Division of Occupational and Professional Licensing and identify opportunities for public comment.
4. Recognize several law updates from the 2020 Utah Legislative Session.



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Learning Objectives - Technicians

At the conclusion of this activity, *pharmacy technicians* should be able to successfully:

1. Discuss the impact of changes to the Pharmacy Practice Act.
2. Explain the process for providing comments to Pharmacy Practice Act Rule changes.
3. Locate the public notification webpage for the Division of Occupational and Professional Licensing and identify opportunities for public comment.
4. Recognize several law updates from the 2020 Utah Legislative Session.



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Federal vs State

- US Constitution 10th Amendment
 - The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people
- States protect the health, safety, and welfare of their citizens
- Division of Occupational and Professional Licensing Act
 - (58-1-101)



<https://www.constitution.com/constitution/amendment/10/> Accessed 8/12/2021
https://www.legis.utah.gov/UtahCode/Section_058-1-101 Accessed 8/20/2021



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Stipulation and Order

- Agreement with DOPL
- Signed by the Licensee
- Do you need an attorney?
- What if the professional doesn't agree to the stipulation and order
- Hearing

Agency & Disciplinary Action Search

Search by Name: Name (all or part) OR Search by License: License Number:

Pat Pharmacist

- License **XXXXXX-1701** — Pharmacist (DUPLICATE)
- Case 2021- **xxxx**
- **Stipulation and Order** - 07/12/2021

*NOTE: The disciplinary documents scanned and posted to this website include final orders issued by DOPL, with the exception of citations.
 **Pursuant to Utah Code §§ 4-106 and 107, all administrative disciplinary actions commenced over 10 years ago and certain actions over 5 years are not accessible online, but may be provided in response to a GDRM request.
 Click here for information on obtaining a copy of the disciplinary documents not posted on this site.

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Stipulation and Order

- Once signed then the probation or public reprimand goes to the board
- Any changes from the Board must be approved by the DOPL Director
- Conditions of the stipulation are carried out by the Board

Agency & Disciplinary Action Search

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Poll Ev

Question:

Pat Pharmacist is the PIC at the hospital. DOPL inspected the hospital and found violations of USP <797> laws. Pat's hospital agreed to pay the fine for the citation and the hospital was placed on probation for 5 years. Which of the following can be changed in a Board of Pharmacy meeting?

- a) Recommend reduction to the length of time the pharmacy is on probation
- b) Remove violations in the stipulation
- c) Remove the stipulation and order from the license
- d) Accept the corrective action plan or make additional recommendations

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A Little Board, yet?

<https://boards.governor.utah.gov/s/>

- Appointed by the Executive Director of DOPL
- Approved by the Governor
- 4-year term
- No compensation

<https://boards.governor.utah.gov/s/> accessed 8/12/2021

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DOPL

- Licensing
- Director approval
- Investigations
- Establish peer advisory committees*
- Licensure reinstatement*

BOARD OF PHARMACY

- Recommend Rules
- Recommend policy and budgetary matters
- Establish exam scores
- Licensing standards
- Supervision standards
- Hearings

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Utah Board of Pharmacy

- 7 Members
- 4 Pharmacists
- 1 Pharmacy Technician
- 1 Public Member

Name	Appointed	Expires
Christopher Sheard (Pharmacist)	07/01/2018	06/30/2022
Karen M. Gunning, Pharm.D. (Pharmacist)	07/01/2019	06/30/2023
Gary A. Hale, R.Ph. (Pharmacist)	07/01/2019	06/30/2023
Joseph B. Ligori (Public Member)	07/01/2019	06/30/2024
Sepideh Daery (Pharmacist)	07/01/2020	06/30/2024
Autumn Hawks (Pharmacy Technician)	07/01/2019	06/30/2025
Carrie B. Dunford, Pharmacist	09/07/2017	06/30/2025

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Advisory Pharmacy Compounding Education Committee

- 7 Members
- 5 pharmacists
- 1 pharmacist with a PhD
- 1 physician

Name	Appointed	Expires
Casey L. Sayre, Pharm.D, Ph.D.	02/04/2020	06/30/2021
Jeremy James Olsen, Pharm.D.	02/04/2020	06/30/2022
Adam R. Tarnoff, MD	02/04/2020	06/30/2022
Chris Cook, Pharm.D.	02/04/2020	06/30/2023
Hull O'Malley, Pharm.D.	02/04/2020	06/30/2023
Christopher M. Kane, Pharm.D.	02/04/2020	06/30/2024
Matthew Higley, Pharm.D.	02/04/2020	06/30/2024

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Controlled Substance Advisory Committee

Name	Appointed	Expires
James H. Rubie, Pharm. D, JD (Dept. of Health Designee)	1/1/2018	n/a
Erik D. Christensen MD (State Medical Examiner)	11/16/2016	n/a
Colonel Brian Redd (Dep. of Public Safety Designee)	02/23/2015	n/a
Jennifer M. McNAF (Bureau of Forensic Services Designee)	07/01/2020	n/a
Amberly R. Johnson (Utah Poison Control Center Designee)	07/01/2020	06/30/2024
Christopher Sheard, Pharm.D. (Utah State Board of Pharmacy)	10/25/2019	06/30/2022
Byron J. Talbot (Dentist and Dental Hygiene Licensing Board)	01/01/2018	06/30/2022
Byron Fred Burmester (Statewide Association of Prescribers)	07/01/2018	06/30/2022
Barbara Hurst MD (MD - Appointed by Governor)	07/01/2018	06/30/2022
Katherine Carlson MD (MD/Psychiatrist - Appointed by Governor)	07/01/2018	06/30/2022
Vacant (Substance Abuse Addiction - Appointed by Governor)	00/00/0000	00/00/0000
Kate Barton Miyagi ND (ND/Herpetologic Physician - Appointed by Governor)	07/01/2019	06/30/2023
Julie P. Balk APRN (APRN)	07/01/2019	06/30/2023
Trey E. Hansen (Public Member)	03/07/2019	06/30/2024
Craig William Davis MD (Physician Licensing Board)	03/07/2019	06/30/2021

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Statutes and Rules

Have a great idea

Find a legislator to agree to sponsor the bill

Drafting

If the bill passes both the House and the Senate it becomes law

Rules can be written based on the delegated authority of the bill

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Rule Writing


Board Meetings

Utah's Open Meeting Laws

Review Proposed Rule Changes & Public Hearing Notices

Subscribe to updates

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Advocacy

- Be an active member of your professional organizations
- Contact your representatives
- Come to a board meeting
- Notify your employer

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Pharmacy Law Questions

- Refer to the law and rules
- Don't forget to check Department of Health Codes
- Check with your compliance or legal team at work
- Ask DOPL
- Board Meetings

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Getting into the details - Utah Law Updates in 2021

Karen Gunning, Pharm.D BCPS, BCACP, FCCP

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Key Concept for Pharmacists/Technicians: Supervision (not new but important)

R 156-1: General Rule of the Division of Occupational and Professional Licensing

- Frequently referred to in the Pharmacy Practice Act Rules
- Definitions that are key to pharmacy practice
- R156-1-102a - Global Definitions of Levels of Supervision
 - **“Direct” and “immediate”** = supervising licensee **is present and available for face-to face communication** with the person being supervised **when and where occupational or professional services are being provided**
 - **“Indirect”** = supervising licensee has given **either written or verbal instructions** to the supervisee, and **is present in the facility** or located on the same premises, and **is available to provide immediate face to face communication** as necessary
 - **“General”** = has **authorized the work** to be performed, **AND is available for consultation** by face to face contact, **OR by electronic or other means** without regard to whether the licensee supervising is present or located on the premises where the person is being supervised. **AND Can provide necessary consultation within a reasonable period of time AND personal contact is routine.**

<https://adminrules.utah.gov/public/search/R156-1-101/Current%20Rules>

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Test Your Knowledge - For Poll Everywhere

In the Utah law- What level of supervision is required for Pharmacy Technicians? Interns?

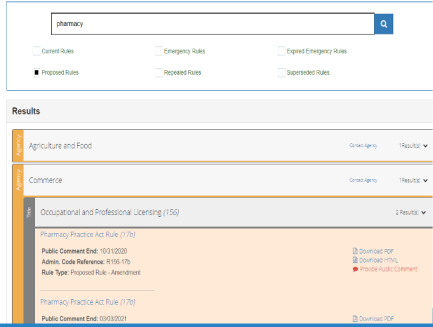
Bonus - where can you find this information?

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How to Keep up with Law Changes?

1. Sign up for legislative bill updates with a focus on pharmacy
 - a. <https://le.utah.gov/tracking/trackingLogin>
2. Subscribe to alerts from the DOPL website about board meetings, rule hearings
 - a. <https://www.utah.gov/pmn/sitemap/notice/696747.html#>
3. Catch up with this website
 - a. <https://adminrules.utah.gov/public/search//Current%20Rules> ----->



The screenshot shows a search interface for 'pharmacy' on the Utah Administrative Rules website. It includes filters for 'Current Rules', 'Emergency Rules', 'Expired Emergency Rules', 'Proposed Rules', 'Repealed Rules', and 'Superseded Rules'. The results section shows categories like 'Agriculture and Food', 'Commerce', and 'Occupational and Professional Licensing (159)'. Under 'Occupational and Professional Licensing (159)', there are two results for 'Pharmacy Practice Act Rule (170)', with details for public comment end dates and rule types.

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Rule Changes from 10/2020

- **R156-17b-102 Definitions:**
 - "Compounding," as defined in Section 58-17b-102(18), in accordance with 21 U.S.C. 353a(e) does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.
 - Deleted "mail service retail pharmacy" and "retail pharmacy" from definitions
- **R156-17b-203 Advisory Pharmacy Compounding Education Committee**
 - Added in physician membership, and requirement for members to be licensed in good standing in Utah
 - Added requirement that at least one member attend at least one board meeting of each - BOP, Physicians Board, and Osteopathic Physicians board.
- **R156-17b-614a. Operating Standards - Class A or Class B Pharmacy - General Operating Standards**
 - changed requirements for labeling of compounded sterile and non sterile agents that are dispensed to a patient/patient agent
 - Removed a bunch of wording here and moved to R156-17b-614e (new section)

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Rule Changes from 10/2020

- **NEW: R156-17b-614e. Operating Standards - Compounding.**
 - (1) A person engaging in sterile or nonsterile compounding shall practice in accordance with all applicable federal and state laws and rules, and in accordance with the USP-NF, including:
 - (a) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations;
 - (b) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations; and
 - (c) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.
 - (2) These operating standards shall apply:
 - (a) to any person licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding; and
 - (b) to the compounding of all sterile or nonsterile compounded pharmaceuticals, antineoplastic drugs, or non-antineoplastic drugs, no matter where the patient is located.
- **R156-17b-614g: Operating Standards - Class A or B Pharmacy - Remote Dispensing Pharmacy**
 - Removed requirement for board review of each application
 - Removed requirement about board review of applications when there is more than one application in a specific area.
 - Reworded some of the other points in this section.

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Rule changes from 3/2021

- R156-17b-303b Qualifications for Licensure - Pharmacist - Pharmacy Internship Standards
 - Wording clean up
 - Removed the requirement for practice supervision to have to be by a pharmacist to allow for non pharmacist preceptors as allowed by ACPE accreditation Standards.
 - Re-affirmed that if a pharmacy intern is suspended or dismissed by the college - the pharmacy intern shall notify DOPL within 15 days of the suspension or dismissal.
 - Reaffirmed that if an intern ceases to meet **each** requirement for intern licensure the intern shall surrender their intern license to DOPL within 60 days, unless an extension is granted by the division in collaboration with the board.
- R156-17b-305 Qualifications for Licensure Pharmacist by Endorsement
 - Removed.
- R156-17b-602 Operating Standards - Pharmacy Intern
 - Removed reference to "approved preceptor"

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Rule Changes 3/2021

- R156-17b-606 Operating Standards Pharmacist Preceptor
 - removed word "approved"
 - added terminology that a preceptor must have a license active and in good standing permitting practice ***in the jurisdiction where the pharmacist is acting as a preceptor.***
 - CHANGED: supervision from **direct to indirect**
 - **Maintained** precepting ratios for both working shifts and volunteer activities
 - Removed that the preceptor has to have written approval from the college/school
 - Removed references to the PCCU Internship competencies.
 - Reworded - the preceptor shall document the number of hours, and evaluate the quality of the interns performance.
 - Removed the reference to the Utah Pharmacy Intern Experience Affidavit.
 - REAFFIRMED: ***"preceptor is responsible for the pharmacy intern's actions related to the practice of pharmacy while the pharmacy intern is practicing under the preceptor's supervision."***

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Rule Changes 3/2021

- **NEW:** R156-17b-612a Operating Standards Prescription Devices
 - Applies to: nebulizers; spacers for use with nebulizers or inhalers; and diabetic testing supplies
 - READ: Pharmacy Practice Act 58-17b-610.8
 - By prescription or by a written record of a patient's current diagnosis; or treatment protocol
 - May dispense the above products without a traditional prescription if there is a written record of the diagnosis or treatment protocol.
 - Must notify provider of device dispense within 5 business days
- **NEW:** R156-17b-612b Operating Standards - Exhausted Prescription for Insulin
 - READ: Pharmacy Practice Act 58-17b-608.2 Insulin prescriptions and diabetes supplies
 - May dispense a refill for insulin for up to 60 days after attempts to contact the provider have been unsuccessful.(RULE) Must notify prescriber within 30 days (ACT)
 - Read - several points key for documentation including you have to put "exhausted prescription" on label, and this can occur only 1 time per exhausted prescription.
 - Note - act also allowed for therapeutic interchange of testing supplies and syringes
 - Note - act also allowed for interchange of "interchangeable biological product" if available for insulin

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Rule Changes 3/2021

- R 156-17b -626 Operating Standards - Appropriate Substitutes for Albuterol
 - Allows therapeutic interchange for albuterol products.
- R 156-17b-901 Operating Standards - Charitable Prescription Drug Recycling Program
 - Must register with DOPL
 - Formulary can't include controlled substances, compounded drugs, or REMS drugs
 - Pharmacy has to create a training program.
 - If you are going to do this - read rules and act very carefully and develop a plan.
 - *SB 097 passed 2021 also makes changes to process*

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What rule changes are coming for 2021/2022?

- Based on legislative changes in 2021 Session
- Once act is changed - board is charged with working with DOPL to come up with rules for new laws.

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Legislative Session 2021: SB 0177 - Pharmacy Practice Act Revisions

- Changes to Pharmacy Practice Act: **58 17b 309.7 - Opioid treatment programs**
 - Defines covered providers for medication assisted treatment programs
 - Covered provider can dispense if they are operating under the direction of a pharmacist
 - This will cause changes to **R156-17b-309.7** in the Rules to incorporate the "covered provider" designation
 - Pharmacist to provide general supervision of the covered provider - delegation to the covered provider who can't then delegate the task to anyone else.
- Changes to **58-17b-622 Pharmacy benefit management services -- Auditing of pharmacy records --Appeals.**
 - defines and adds "audit completion date" and adds wording on how a pharmacy may respond to an audit
- Changes to **58-17b-625 Administration of long acting injectable and naloxone**
 - removes specific drugs, adds board/division shall make rules to establish training for administration of naloxone and long acting injectables.

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Legislative Session 2021: SB 0177 - Pharmacy Practice Act Revisions

- Changes to **58-37f-203** - this is the controlled substances database act
 - "a pharmacist may submit corrections to data that the pharmacist has submitted to the controlled substance database within seven business days after the day on which the division notifies the pharmacist that data is incomplete or corrections to the data are otherwise necessary"
- Changes to **58-17b-305.1 - Qualifications for licensure of pharmacy technician trainee**
 - Allows the division/board to make additional criteria for pharmacy technician trainee licensure
 - Board is working on changes to 156-17b-303a to ensure protection and quality of technician trainee experience and education

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Legislative Session 2021: HB 265 - Electronic Prescribing and Transfer of Controlled Substances

- HB 265 - Pharmacy Software Amendments
 - As of 1/1/2022 each controlled substance must be transmitted electronically unless: Assisted living, LTC, Correctional facility, Veterinarian, Technical/electronic failure, emergency situation
 - On 7/1/2024 pharmacy software capable of receiving controlled substances prescription shall be able to electronically transfer to different pharmacy:
 - Upon patient or provider request
 - Rx unfilled
 - Approval of pharmacist at originating pharmacy
- Board and Division currently creating rules around this.

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Legislative Session 2021: HB 178 - Pharmacist Prescribing

- NEW LAW: 58-17b-627 Prescription of Drugs or Devices by a Pharmacist
 - Beginning 1/1/2022 if:
 - Within the scope of the pharmacists training and experience
 - Designated by DOPL by rule
 - not controlled substances
 - Division to make rules to designate what prescription drugs/devices may be prescribed under this section - beginning with drugs that address a public health concern designated by the department of health - including
 - PReP, PEP, Self Administered Hormonal Contraceptives, Smoking cessation, Naloxone
 - Create guidelines that a pharmacist must follow when prescribing - including notifying pcp or health care provider, address when the pharmacist should refer the patient
 - Rules should be made in collaboration with individuals representing physicians and advanced practice clinicians, and the Utah Department of Health.
- Rule making is underway - JOIN US!

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Test your Knowledge! Poll Everywhere

If a prescription for albuterol says in the sig: use 1 puff twice daily with a spacer - do you need to call the provider for a prescription for a spacer?

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Rule Changes Being Discussed by the Board & DOPL

- Changes to requirements for operating standards for manufacturers, virtual manufacturers and wholesaler/distributors
- Additions to the operating standards for PICs - Including requirements for pharmacy self audit maintained on site for 2 years - prompted by change in PIC, DMPIC, or RDPIC, opening new facility, and prior to end of licensing renewal cycle.
- Changes to the controlled substance act rules regarding electronic transmission of prescriptions - Rules needed for SB 0177
- Changes to administration of long acting drugs - rules needed for SB 0177
- Changes to R156-17b- 601, 612, 613 regarding the role of the pharmacy technician
- Changes to R156-17b-303a - pharmacy technician trainee education requirements
- Additions → school and other organization based use of albuterol inhalers and epi-pens

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Who is responsible for knowing all this?

YOU ARE

- As licensed professionals - technicians and pharmacists - **you** are responsible for knowing about law changes
- What type of system will you use to ensure you are practicing legally and utilizing the most up to date state laws?

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References

1. <https://nabp.pharmacy/wp-content/uploads/2020/10/September-2020-Idaho-Newsletter.pdf>
2. https://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf
3. <https://rules.utah.gov/> and <https://rules.utah.gov/publications/utah-state-bull/>



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Updates from the Utah Board of Pharmacy: 2021

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