

COVID-19 TOWN HALL

June 3, 2020

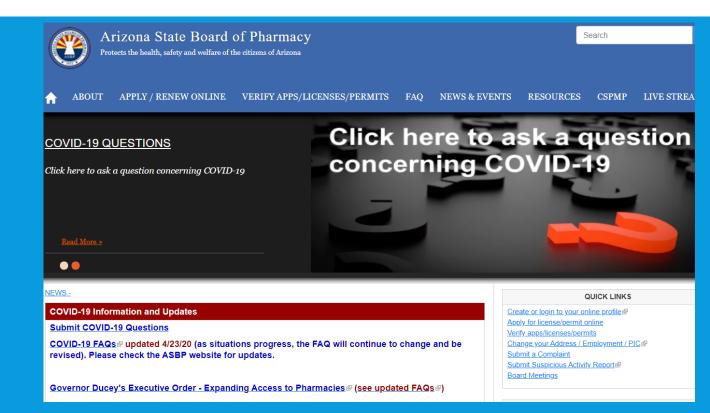


Board of Pharmacy Update

Kam Gandhi
Executive Director | AZ Board of Pharmacy

BOARD OF PHARMACY UPDATE

- FAQ'SSubmit ?'s



Legislative Session Recap

Jessie Armendt

Contract Lobbysit | Arizona Pharmacy Association

54th Legislature, 2nd Regular Session (2020)

ADJOURNED SINE DIE MAY 26TH, 2020

TOTAL DAYS OF SESSION: 135

GENERAL EFFECTIVE DATE: AUGUST 25TH, 2020

BILLS INTRODUCED: 1,607

BILLS PASSED: 89

BILLS VETOED:

BILLS SIGNED: 58

BALLOT MEASURES REFERRED: 0

AzPA Issues

HB 2117: pharmacy board; rulemaking authority - Lawrence

AzPA worked with the Board of Pharmacy on legislation to revise the definition of "pharmacy" – a technical fix to ensure licensed pharmacists can continue to practice outside of permitted pharmacies. Representative Jay Lawrence sponsored HB 2117 on AzPA's behalf and the bill sailed through the House without opposition, passing 59-0 on February 13th. It passed the Senate Health and Human Services Committee unanimously on March 4th and was approved by the Senate Rules Committee on March 9th, but then the legislative session came to a grinding halt. HB 2117 had not yet received a floor vote in the Senate when the legislature adjourned for its extended recess at the end of March and the Senate did not do any additional bill work when it returned to adjourn sine die in May.

AzPA Issues

5B 1334: pharmacists; vaccines - Pace

AzPA filed a sunrise application on November 1, 2019 seeking to expand pharmacists' scope to allow administration of vaccines without a prescription to individuals at least six years of age and the administration of vaccines with a prescription to individuals at least three years of age. Senator Tyler Pace agreed to sponsor this legislation on behalf of AzPA and AzPA spent the first several weeks of session negotiating language with the pediatricians' association. The pediatricians worried that increased ability to vaccinate at a pharmacy could reduce the frequency of well-child visits and sought statutory language ensuring that pharmacists would have to provide education to patients on the importance of well-child visits, to which AzPA agreed. However, even with the medical community's neutrality, AzPA still faced opposition from "anti-vax" groups, who have been fixtures at the Capitol over the last few years raising concerns about vaccine safety and seeking to expand exemptions. SB 1334 passed the Senate Health and Human Services Committee 5-1 and passed the Senate 26-4 but hit a roadblock in the House. House Health and Human Services Chair Nancy Barto has become increasingly skeptical of vaccines over the last several years and informed AzPA prior to session that she did not expect to give the scope expansion bill a hearing. It did not receive a committee hearing prior to the legislature's March adjournment and was not taken up by the House in its final week of session in May.

AzPA Issues

SB 1493: pharmacists; dispensing authority; hormonal contraceptives - Ugenti-Rita

AzPA partnered with the Arizona Chapter of the American College of Obstetricians and Gynecologists to introduce legislation making birth control available at a pharmacy without a patient-specific prescription but instead pursuant to a standing order. Senator Michelle Ugenti-Rita agreed to sponsor the bill and proponents collected an additional 17 cosponsors on both sides of the aisle. However, House Health and Human Services Chair Nancy Barto expressed reservation about the bill early on and, after the Senate gave SB 1493 unanimous approval on February 20th, AzPA and others lobbied House leadership to assign it to a committee other than Barto's. As the committee hearing deadline approached, Senator Ugenti-Rita and AzPA decided to strike the bill onto a vehicle in House Commerce during the final week of committees. However, the COVID-19 pandemic halted session before the hearing and neither SB 1493 nor its vehicle bill received a committee hearing.

Major Legislation-Passed

CATEGORY	BILL INFO	ACTION
Taxation	HB 2771: tax credits; qualified facilities extension – Toma	Signed
K-12 and Higher Education	HB 2910: public school closures; coronavirus disease – Udall SB 1224: empowerment scholarships; qualifications; administration; appropriations – S. Allen SB 1492: Arizona teachers academy; program pathways – Boyer	Signed Signed Sent Gov
Legal and Regulatory Reform	SB 1274: professional regulatory boards; composition – Ugenti-Rita	Sent Gov
Health and Human Services	HB 2668: hospitals; unreimbursed costs; assessment; fund – Cobb SB 1051: DHS continuation; public health emergency – Brophy McGee SB 1397: insurance; preexisting condition exclusions; prohibition – Mesnard SB 1523: mental health omnibus – Brophy McGee	Signed Signed Sent Gov Signed

Major Legislation-Passed

CATEGORY	BILL INFO	ACTION
Public Safety and Transportation	SB 1305: personal delivery devices – Livingston	Sent Gov
Environment	SB 1145: temporary irrigation efficiency projects fund– Kerr	Signed
Elections	SB 1135: elections; counting center; electronic adjudication – E. Farnsworth	Signed

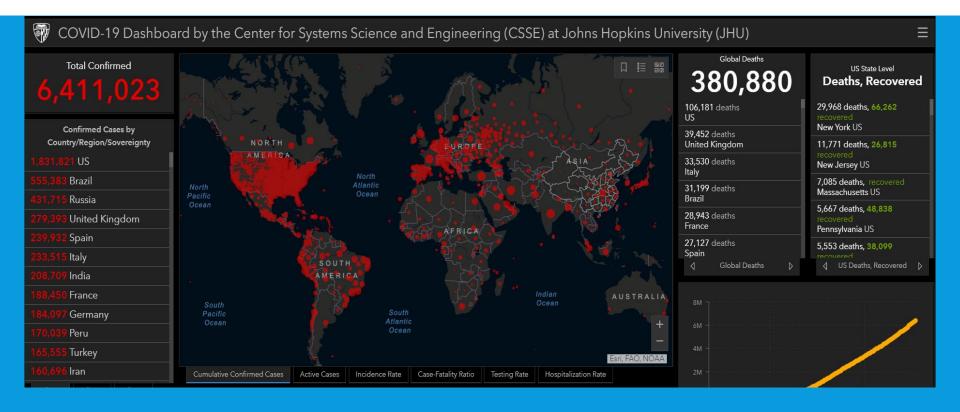
Look up bill language at www.azleg.gov

State and National Updates

Kelly Fine

Executive Director | Arizona Pharmacy Association

Worldwide Cases

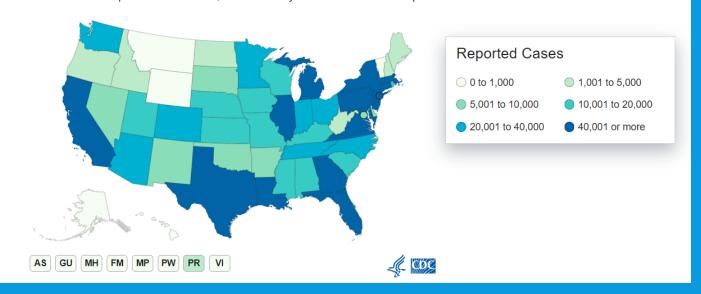


US Cases

Cases & Deaths by Jurisdiction

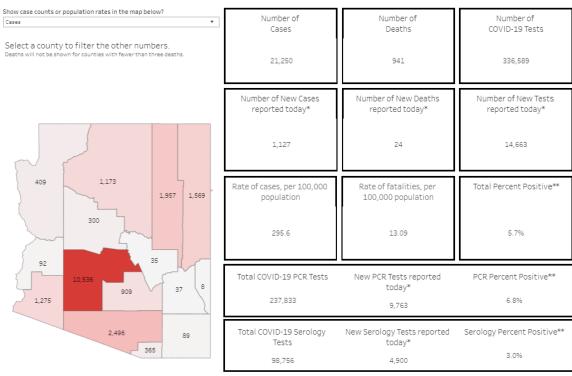
34 jurisdictions report more than 10,000 cases of COVID-19.

This map shows COVID-19 cases and deaths reported by U.S. states, the District of Columbia, New York City, and other U.S.-affiliated jurisdictions. Hover over the map to see the number of cases and deaths reported in each jurisdiction. To go to a jurisdiction's health department website, click on the jurisdiction on the map.





Summary



^{*}Counts of new cases, deaths, and numbers tested reflect increases in the total numbers compared to the previous day.

^{**}Percent positive is the number of people with a positive test result, out of all people with COVID-19 testing completed in AZ.

ADHS Weekly Recap-5/30/20

According to ADHS, Arizona continues to be in <u>Phase 1</u> of the White House's Opening Up America Again.

- Continue to see a downward trend in influenza-like illness and COVID-like syndromic cases reported
- Percent positivity of diagnostic (PCR) tests appears to be increasing. This is most likely due
 to delays in laboratory reporting rather than a true increase in percent positivity.
- There is an upward trends in the number of COVID-19 inpatients reported by hospitals and the percent of inpatient beds in use.
 - It's important to remember that even with an uptick in COVID-19 admissions, COVID-19 cases make up a very small percent of the total hospital admissions. Over the month of May, we've remained pretty steady with about 9-12% of total inpatient beds reported to be in use by COVID-19 patients.

Traveling Soon?

Anyone who heads through Phoenix Sky Harbor International Airport will be required to wear a mask or other face covering <u>starting June 1</u>.

Exceptions to this requirement include:

- Children two years of age or younger
- Any child age 12 years or less unless parents and caregivers supervise the use of face coverings, or any individual who has a physical disability that prevents easily wearing or removing a mask
- Any individual who is hearing impaired and uses facial and mouth movements as part of communication,
- Individuals consuming food or beverages
- Individuals who are unable to wear a face covering due to a medical condition
- When necessary for identification verification purposes
- When necessary for taking photographs for Aviation Credentialing/Security Badging purposes

Schools Will Be Reopening in the Fall



- The Arizona Department of Education released a <u>roadmap</u> for reopening on June 1
- Reopening may look different between schools and systems
- The department covers four possible scenarios for reopening schools in the fall:
 - Option One: All students attend classes in person
 - Option Two: Some students in class at the start of the year, while others take part in distance learning.
 - Option Three: All students start with distance learning, with the goal of eventually returning to the classroom
 - Option Four: Intermittent distance learning throughout the year
 - Other Options: temperature checks, smaller class sizes, socially distanced desks, staggered start times, and maybe even kids in masks

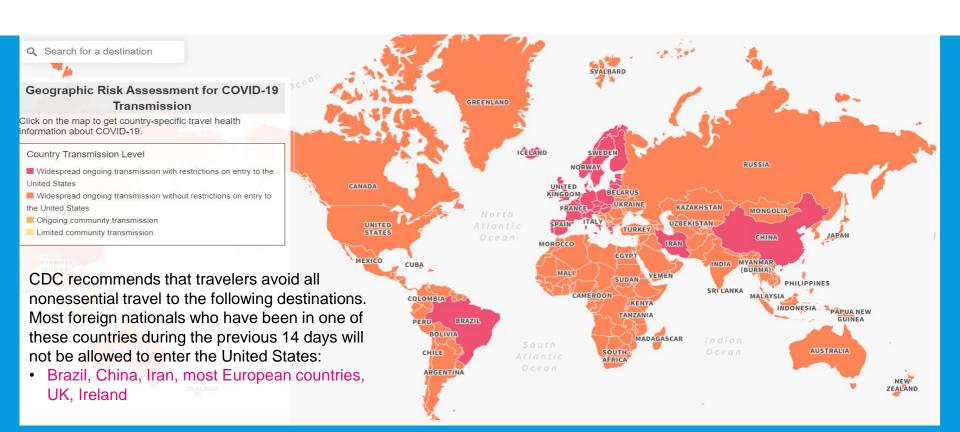
CDC-Recommendations for Antibody Testing Updated 5-25-20

Recommendations for Professionals:

- Antibody test results should not be used to diagnose someone with an active infection.
 - Antibody tests can support the clinical assessment of COVID-19 illness for people who are being tested 9 to 14 days after illness onset, in addition to recommended virus detection methods such as PCR.
 Antibody testing can help establish a clinical picture when patients have late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.
- Choose antibody tests that have <u>FUA</u> from the U.S. Food and Drug Administration.
- Do not use antibody tests to determine a person's immune status until evidence confirms
 that antibodies provide protection; how much antibody is protective; and how long protection
 lasts.
- Minimize false positive results by choosing an antibody test with high specificity and by testing populations and people who are likely to have had COVID-19.



CDC: <u>Travel Recommendations by Country</u>



FDA Will Make Some Changes Amid COVID-19 Permanent

- Some of the processes and policies FDA has implemented in response to the COVID-19 pandemic should be made permanent, according to FDA Commissioner Stephen M. Hahn.
- Hahn noted: "As this pandemic has evolved, it was clear to all of us that some FDA
 processes needed to be adjusted to accommodate the urgency of the pandemic and I
 think the entire FDA team has now seen first-hand that we need to take a critical look at
 some of our processes and policies."
- FDA staff has been asked "to identify the lessons learned from this pandemic and what adjustments may be needed, not just to manage this or future emergencies, but how to permanently make FDA more efficient in carrying out [its] regulatory responsibilities," Hahn said.. (Read More)

FDA Takes Action to Protect Public Health; Increase Supply of Alcohol-Based Hand Sanitizer

- The FDA has updated their guidance to provide additional clarification on the manufacturing and compounding of certain alcohol-based hand sanitizer products to help ensure that harmful levels of impurities are not present in ethanol used in hand sanitizer.
- Updates to the temporary guidance in April added data from fuel ethanol manufactures
 producing ethanol via fermentation and distillation noted that at least some of their fuel
 ethanol products have dangerous chemicals, including gasoline and benzene.
- Based on careful review and consideration of available data, we are specifying interim levels of certain impurities that we have determined can be tolerated for a relatively short period of time, given the emphasis on hand hygiene during the COVID-19 public health emergency and to avoid exacerbating access issues for alcohol-based hand sanitizer

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FDA Publishes Guidance on IRB Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products

- On June 2, 2020 the FDA issued guidance because of the substantial increase in the number of requests by physicians seeking to treat their patients with investigational drugs under the agency's individual patient expanded access (EA) pathway during the COVID-19 public health emergency.
- The recommendations in the guidance address establishing procedures for single IRB
 member review in response to physician waiver requests for exemption from full IRB
 review, as well as factors to consider when assessing benefits and risks for a particular
 patient being treated under expanded access.

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At-Home Coronavirus Test Kits

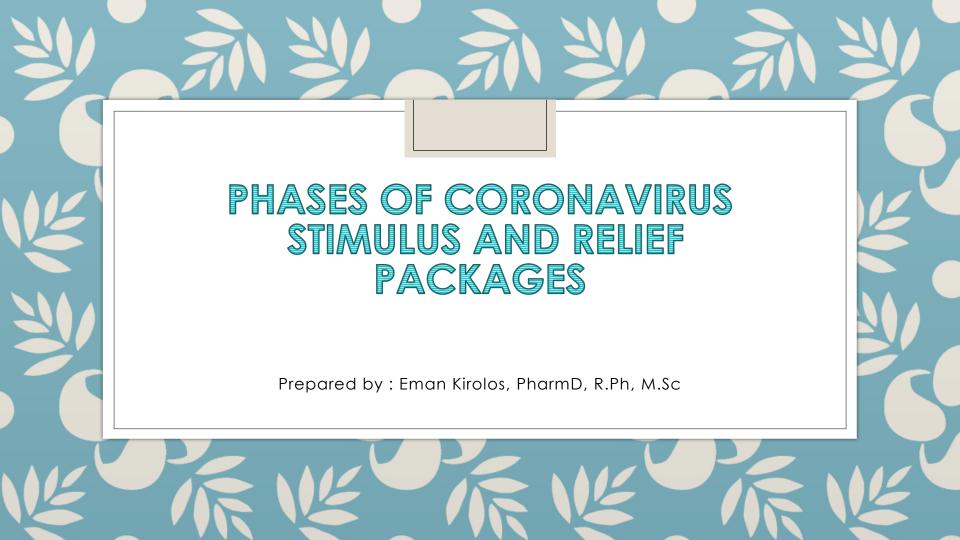
- The FDA has approved the emergency use of six at-home kits, all of which must be sent to a lab.
- Experts are still concerned about the at-home test accuracy and the cost that sometimes isn't covered by insurers.
- On May 29th the FDA took steps to further support the development of COVID-19 tests for at-home self-collection by including a voluntary <u>EUA template</u> for at-home sample collection kits to its website.
- For COVID-19 diagnostic tests that use at-home specimen collection kits and are intended for use in clinical decision making, developers are generally required to submit a request for an EUA prior to distribution and use of such test. In cases where the developer has not obtained an EUA, these tests may be used as part of a research study that complies with FDA's regulatory requirements for device investigations.

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Scientists Question Data Cited In Two Coronavirus Studies Published In Prominent Journals

- The New England Journal of Medicine issued an "<u>expression of concern</u>" about the study it published that "suggested widely used blood pressure medicines were not raising the risk of death for people with COVID-19." In its communication, the journal expressed concerns about the reliability of the database.
- Similarly, The Lancet issued an <u>expression of concern</u> about the study it published that "tied the malaria drugs hydroxychloroquine and chloroquine to a higher risk of death in hospitalized patients with the virus." The Lancet said questions have been raised about the data used in the study.
- A group of scientists have questioned the data used in studies who both share some of the same authors and both relied on the same database, which the group of scientists say may not be reliable.





- * Families First Coronavirus Response Act (FFCRA) or Families First Act- Phase one
 - ➤ Signed into law on March 18th
 - > Provides paid leave, free testing, protection for public health workers, and important benefits to families and children.
 - > Provides tax credits for small and midsize businesses.

- * Coronavirus Aid, Relief, and Economic Security Act or CARES Act- Phase Two
 - ➤ Signed into law on March 27, 2020
 - > Provides over \$ 2 trillion economic relief package for public health and economic impacts of COVID-19.
 - > Provides assistance to American workers, families, and small businesses and preserve jobs for American industries

- * Coronavirus Aid, Relief, and Economic Security Act or CARES Act- Phase Two
 - ➤ Unemployment Information links:

https://www.usa.gov/unemployment#item-35882

https://www.dol.gov/general/topic/termination

 $\frac{https://www.careeronestop.org/LocalHelp/UnemploymentBenefits/Find-Unemployment-Benefits.aspx?newsearch=true\&location=AZ\&persist=$

https://des.az.gov/services/employment/unemployment-individual/apply-ui-benefits

https://des.az.gov/services/employment/unemployment-individual/covid-19-ui-qa

https://uiclaims.azdes.gov

- Paycheck Protection Program and Healthcare Enhancement Act or Enhancement Act Phase Three
 - > Signed into law on April 24, 2020.
 - ➤ Provides assistance to more than 1 million small businesses with less than 10 workers, helping more than 30 million Americans
 - Authorizes up to \$349 billions of forgivable loans all loan terms will be the same for everyone

- On May 15, the U.S. House of Representatives narrowly passed (209 against 199), H.R. 6800, the Health and Economic Recovery Omnibus Emergency Solutions Act (HEROES Act) as phase four.
- Provides \$3 trillion in tax cuts and spending.
- * Financial relief to state, local, and tribal governments, extensions to enhanced unemployment benefits, debt collection relief, and direct cash payment to households.
- * Republican-controlled senate prefers to "wait and see" how the U.S. economy reacts to previous stimulus packages. (Unlikely to pass)
- The White House has indicated its opposition to the legislation and stated that President Trump would veto the legislation.

- * Certain provisions from the HEROES Act, , as Democrats' priority negotiations, will likely reappear in future legislation, potentially as part of a bipartisan stimulus and relief bill later this summer.
- 1. Waive Cost-sharing of COVID Treatment and vaccines -previous phases addressed only testing (not treatment or prevention).
- 2. Revise and fund additional HC provider relief grants relief fund payments as full reimbursement for uninsured patients, grants will be limited to covid providers whether diagnostic or treatment (as opposed to ALL Medicare providers per current relief fund).
- 3. Provide Significant Aid to Certain Healthcare Providers: CDC, CMS, IHS, Substance Abuse and Mental Health Services Adm., Health Resources & Services Adm.
- 4. Medicaid and Medicare Reimbursement Changes for Hospitals COVID outlier payment in addition to the CARES 20% add-on for Medicare COVID patients.
- 5. Increase Public and Nonprofit Hospitals' Access to High-Speed Internet rural hospitals

- 6. Provide Temporary Medicaid Support to States, Tribes and Providers from July 1, 2020 to June 30, 2021 the Federal Medical Assistance Percentage (FMAP) would increase by a total of 14% to state Medicaid programs and to 100% for "Urban Indian Organizations", would prevent HHS from finalizing Medicaid Fiscal Accountability Regulaion (MFAR) or any similar regulation (that establish more state and provider reporting requirements) until the end of the current public health emergency.
- 7. Revise the Medicare Accelerated and Advanced Payment Program give providers a full year before offsetting claims and two years to repay the balance with a reduced interest rate (1%)
- 8. Expand Access to Health Insurance would allow COBRA- eligible individuals to maintain their employer-sponsored coverage after a layoff, reduction in hours or LOA without having to pay premiums through January 2021.
- 9. Expand Federal, State and Local COVID-19 Testing and Tracing Efforts increase financial support and mandates to expand testing availability and address public health demands.

- 10. Provide \$500 Tax Deduction for First Responders and Front-Line Employees for COVID-19-Related Expenses COVID-19 front-line employees who performed at least 1,000 hours of essential work during the applicable taxable year.
- 11. Increase Workplace Safety for Healthcare and Other Workers Through Emergency OSHA Standards.
- 12. Provide Funds for Government Oversight Efforts and to Combat Fraud and Abuse \$ 75 million to HHS-OIG for targeted audits by GAO (Government Accountability Office) and DOJ.

https://docs.house.gov/billsthisweek/20200511/BILLS-116hr6800ih.pdf

https://www.jdsupra.com/legalnews/u-s-house-passes-heroes-act-12-18945/

SAFE Banking Act – Secure And Fair Enforcement Act

- ❖ Part of Pelosi's massive, 1,815-page HEROES bill, an initiative led by Colorado Democratic Rep. Ed Perlmutter
- . Under review, since last year by the Senate committee on Banking, Housing, and Urban Affairs.
- Proponents of the initiative claim that it promotes public safety by offering marijuana industry an alternative to dealing in cash- a factor experts say is motivating burglaries at dispensaries.
- * Per Morgan Fox, media relations director at Cannabis Industry Association, the Federal regulations are outdated and allow insensible cannabis banking policy because a loan candidate can be disqualified solely based on criminal record.
- Perlmutter co-filed a separate bill, the Emergency Cannabis Small Business Health and Safety Act, in late April that would entitle marijuana companies for COVID-19 relief programs.

SAFE Banking Act – Secure And Fair Enforcement Act

- * Kevin Sabet, president of Smart Approaches to Marijuana is opponent to allowing people with criminal records access to US financial system especially that cannabis remains illegal under the Federal Law.
- * Records show that amid the mandatory social distancing, the sales of cannabis products broke records with the help of curbside pick up especially in states where cannabis use is legalized such as Colorado, California, Nevada, Oregon, and Washington

https://www-denverpost-com.cdn.ampproject.org/c/s/www.denverpost.com/2020/05/12/marijuana-banking-heroes-act-coronavirus/amp/

https://www.jdsupra.com/legalnews/covid-19-and-cannabis-the-pandemic-62123/

https://www.congress.gov/bill/116th-congress/house-bill/1595/text

Questions?