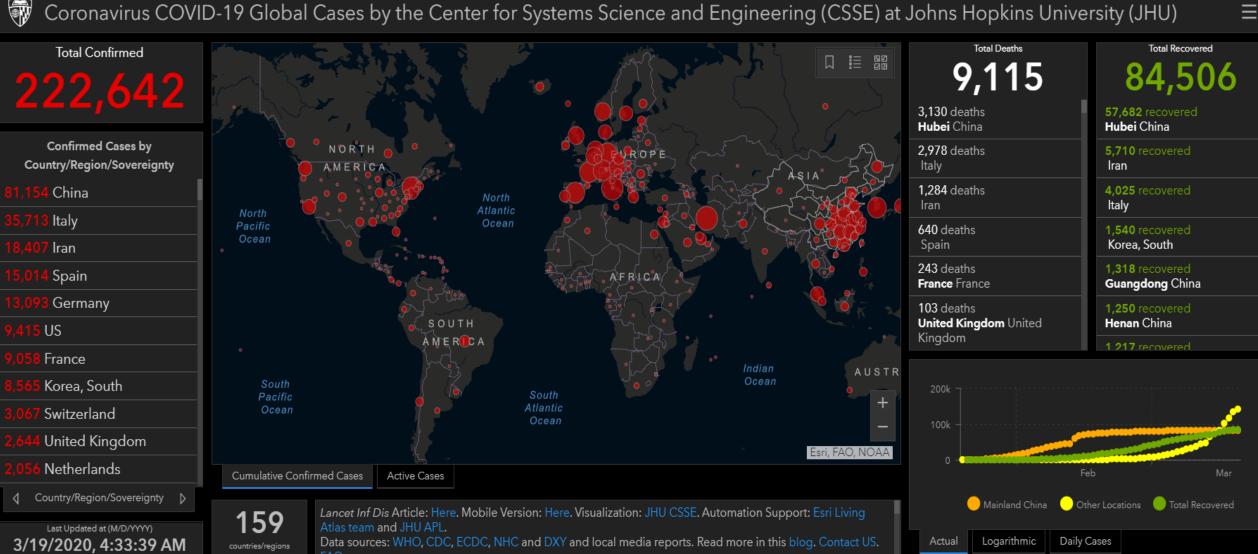


COVID-19 TOWN HALL

March 18, 2020



https://coronavirus.jhu.edu/map-faq.html

Ξ

USP

- <u>USP Response to Shortages of</u> <u>Garb and Personal Protective</u> <u>Equipment (PPE) for Sterile</u> <u>Compounding During COVID-19</u> <u>Pandemic</u>
- <u>Compounding Alcohol-Based</u>
 <u>Hand Sanitizer During COVID-19</u>
 <u>Pandemic</u>

Dear Valued Stakeholder,

In light of the rapidly evolving COVID-19 pandemic, the demand for garbing and personal protective equipment (PPE) and alcohol-based hand sanitizer is expected to outpace available supply. During this pandemic, USP supports State Boards and other regulators using **risk-based enforcement discretion** related to the implementation of USP compounding standards and the compounding of alcohol-based hand sanitizers for consumer use.

The USP Compounding Expert Committee developed the following informational resources that may be of assistance during this public health emergency:

- USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic
- <u>Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic</u>

Any additional questions should be directed to the USP Healthcare Quality and Safety staff at CompoundingSL@usp.org.

Sincerely,

Healthcare Quality & Safety Team

FDA-HAND SANITIZER

- Due to the Coronavirus Disease 2019 (COVID-19) pandemic, the FDA has received a number of queries concerning compounding of alcohol-based hand sanitizers. The agency issued guidance:
 - Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact FDA's human drug compounding team (CDER) at compounding@fda.hhs.gov.

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER)

> March 2020 Compounding

To ensure that pharmacists in their communities are empowered to effectively support the COVID-19 response, a number of pharmacy organizations are recommending federal and state policymakers take the following steps:

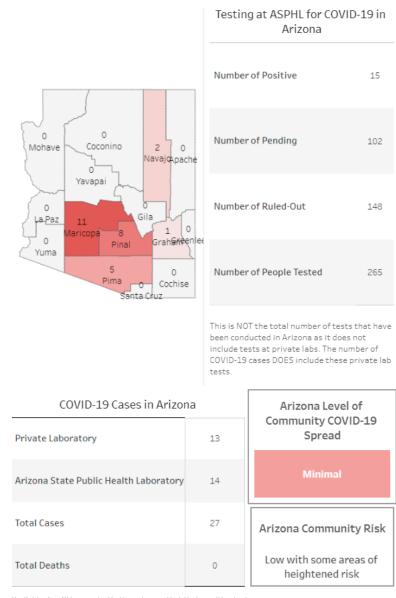
Authorize Test-Treat-Immunize: Authorize additional pharmacist-provided services. (Strep, Flu, COVID-19, Therapeutic substitution, RX adaptation, etc.)

MAXIMIZE SCOPE OF PRACTICE

Ease Operational Barriers: Address workforce and workflow issues that prevent full and effective pharmacist and technician engagement in COVID-19 response

Address Shortages and Continuity of Care: Remove barriers for pharmacists to provide continuity of care if a medical product shortage exists

Reimburse for Services: Remove reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response



	Updated Recommendations 3/17/2020
	-If someone in your family has tested positive for COVID-19, keep the entire household at home and contact your medical provider.
	- ADHS strongly recommends that dining establishments in areas of known community spread (including Maricopa, Pima, and Pinal) discourage dine- in traffic and instead provide curbside pick up or drive-through service.
	 Do not visit nursing homes or retirement or long-term care facilities unless to provide critical assistance.
1	- Recommendations to cancel or postpone mass gatherings of 10 or more people.
	- State-wide closures of Arizona schools from Monday, March 16, 2020 through Friday, March 27, 2020.
	- Recommend telework and other alternatives when available.
	 Increase hand hygiene (wash with soap and water for at least 20 seconds).
	- Stay home when you are sick.

ARIZONA

ADHS

• ADHS Healthcare Providers COVI19 Information:

<u>https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-healthcare-providers</u>

Standing Order

<u>https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-healthcare-providers</u>

This standing order is issued by Dr. Cara Christ, MD MS (NP #1639369036), Director of the Arizona Department of Health Services. This standing order authorizes any medical provider / trained personnel at a medically-supervised COVID-19 testing unit in Arizona to collect and send a SARS-CoV-2 RT-PCR test for any individual in accordance with the conditions of this order.

COVID-19 HOTLINE

The Arizona Poison and Drug Information Center is available to answer questions about COVID-19 from Arizona providers (for testing, patient guidance) and the general public (for testing, isolation, quarantine):

1-844-542-8201

STATE CAPITOL

- **SB 1639:** The school closure bill suspends the instructional hour requirements for the year, extends the statewide testing window, and holds school letter grades harmless if schools reopen by March 30th. If schools do not reopen by March 30th, it also directs public schools to offer general education instructional delivery in alternative formats, provides flexibility to public schools on special education programs, allows schools to generate transportation funding for use of transportation fleets to support students (e.g. delivering school lunches), allows schools to continue to pay employees, allows schools to use dollars for summer school, cancels statewide assessments, waives 3rd grade reading requirements, adjusts funding for students who take courses online, and requires the Department of Education to submit waivers to the appropriate federal agencies to address food and nutrition, assessment and accountability, and any other issues that impact educational attainment.
- <u>SB 1694</u>: The unemployment bill is an emergency measure to allow DES to implement alternative unemployment insurance benefit eligibility and employer contribution requirements for individuals and businesses affected by COVID-19.
- Governor Ducey held another press conference this afternoon at which he reiterated support for CDC recommendations against gatherings of 10 or more people and strongly recommended that restaurants not have dine-in options. He stated that he respects the choices of each city's leadership to do what is right for their city.
- Unknown whether they will recess or adjourn after the budget is finalized.

AHCCCS



https://azahcccs.gov/AHCCCS/AboutUs/covi d19FAQ.html



<u>Ouestion: Will AHCCCS relax refill</u> requirements for medications?

Answer: Yes, AHCCCS will relax refill requirements including allowing "refill too soon" and allowing 90-day refills for medications that are not Controlled Substances.

Many major pharmacy chains are offering free prescription delivery. Please inquire with your pharmacy for more details.



<u>Ouestion: Will AHCCCS allow a 30-day</u> prescription for a Controlled Substance to be filled early?

Answer: Yes, the pharmacy staff may contact the prescribing clinician to request approval for the early refill. If the prescribing clinician approves the early refill, the pharmacy staff will contact the health plan's Pharmacy Benefit Manager (PBM) Help Desk for an override.

BOARD OF PHARMACY

COVID-19 Task Force

- AzPA is a member
- Goal: discuss what actions the Board of Pharmacy can take to relax regulations to make it easier to take care of patients
- Submit your questions and suggestions: <u>https://pharmacy.az.gov/covid-19-questions#</u>

32-1910. Emergencies; continued provision of services

A. If a natural disaster or terrorist attack occurs and, as a consequence of the natural disaster or terrorist attack, a state of emergency is declared by the governor or by a county, city or town pursuant to its authority and the declared state of emergency results in individuals being unable to refill existing prescriptions, the board shall cooperate with this state and the county, city or town to ensure the provision of drugs, devices and professional services to the public.

B. If a natural disaster or terrorist attack occurs in another state and, as a consequence of the natural disaster or terrorist attack, a state of emergency is declared by the governor of that state and the declared state of emergency results in individuals being temporarily relocated to Arizona and unable to refill existing prescriptions, the board shall cooperate with this state to ensure the provision of drugs, devices and professional services to the relocated individuals.

C. When a state of emergency has been declared pursuant to this section, a pharmacist may work in the affected county, city or town and may dispense a one-time emergency refill prescription of up to a thirty-day supply of a prescribed medication if both of the following apply:

1. In the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy.

2. The pharmacist makes a good faith effort to reduce the information to a written prescription marked "emergency prescription" and then files and maintains the prescription as required by law.

D. If the state of emergency declared pursuant to this section continues for at least twenty-one days after the pharmacist dispenses an emergency prescription pursuant to subsection C, the pharmacist may dispense one additional emergency refill prescription of up to a thirty day supply of the prescribed medication.

E. A pharmacist who is not licensed in this state, but who is currently licensed in another state, may dispense prescription medications in those affected counties, cities or towns in this state during the time that a declared state of emergency exists pursuant to this section if both of the following apply:

1. The pharmacist has proof of licensure in another state.

2. The pharmacist is engaged in a legitimate relief effort during the period of time an emergency has been declared pursuant to this section.

F. The board may adopt rules for the provision of pharmaceutical care and drug and device delivery during a declared emergency that is the consequence of a natural disaster or terrorist attack, including the use of temporary or mobile pharmacy facilities and nonresident licensed pharmacy professionals.

G. A pharmacist's authority to dispense prescriptions pursuant to this section ends when the declared state of emergency is terminated.

A.R.S. 32-1910

A.R.S. 32-1974

- 32-1974. <u>Pharmacists; administration of immunizations, vaccines and emergency</u> medications; certification; reporting requirements; advisory committee; <u>definitions</u>
- E. A pharmacist who is certified to administer immunizations and vaccines pursuant to this section may administer without a prescription order:
- 1. Emergency medication to manage an acute allergic reaction to an immunization, vaccine or medication in accordance with the United States centers for disease control and prevention immunization guidelines.
- 2. Immunizations or vaccines to any person regardless of age during a public health emergency response of this state pursuant to section 36-787.

A.A.C R4 23-412

R4-23-412. Emergency Refill Prescription Dispensing

- A. When a state of emergency is declared under A.R.S. § 32- 1910(A) or (B) and the state of emergency results in individuals being unable to refill existing prescriptions, a pharmacist may work in the affected county, city, or town and may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication to an affected individual if both of the following apply:
 - In the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy, and
 - The pharmacist makes a good faith effort to reduce the information to a written prescription marked "emergency prescription" and files and maintains the prescription as required by law.
- B. If the state of emergency declared under A.R.S. § 32-1910(A) or (B) continues for at least 21days after the pharmacist dispenses an emergency prescription under subsection (A), the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication if the pharmacist complies with subsection (A)(2).
- C. A pharmacist's authority to dispense emergency prescriptions under this Section ends when the declared state of emergency is terminated

A.A.C. R4 23-413

R4-23-413. Temporary Recognition of Nonresident Licensure

- A. When a state of emergency is declared under A.R.S. § 32-1910(A) or (B):
 - A pharmacist who is not licensed in this state, but who is currently licensed in another state, may dispense prescription medications in those affected counties, cities, or towns in this state during the time that a declared state of emergency exists under A.R.S. § 32-1910(A) or (B) if both of the following apply:

a. The pharmacist provides proof of current licensure in another state, and b. The pharmacist is engaged in a relief effort during a state of emergency.

- Acting under the direct supervision of a pharmacist, a pharmacy technician or pharmacy intern not licensed in this state, but currently licensed or registered in another state, may assist a pharmacist in dispensing prescription medications in affected counties, cities, or towns in this state during the time that a declared state of emergency exists under A.R.S. § 32- 1910(A) or (B) if both of the following apply:
 - a. The pharmacy technician or pharmacy intern provides proof of current licensure or registration in another state, and
 - b.The pharmacy technician or pharmacy intern is engaged in a relief effort during a state of emergency.
- B. The recognition of nonresident licensure or registration shall end with the termination of the declared state of emergency

A.A.C. R4 23-617

R4-23-617. Temporary Pharmacy Facilities or Mobile Pharmacies

- A. Pharmacies located in declared disaster areas, nonresident pharmacies, and pharmacies licensed or permitted in another state but not licensed or permitted in this state, if necessary to provide pharmacy services during a declared state of emergency, may arrange to temporarily locate to a temporary pharmacy facility or mobile pharmacy or relocate to a temporary pharmacy facility or mobile pharmacy if the pharmacist-in-charge of the temporary pharmacy facility or mobile pharmacy ensures that:
 - The pharmacy is under the control and management of the pharmacist-in-charge or a supervising pharmacist designated by the pharmacist-in-charge;
 - 2. The pharmacy is located within or adjacent to the declared disaster area;
 - 3. The Board is notified of the pharmacy's location;
 - 4. The pharmacy is properly secured to prevent theft and diversion of drugs;
 - The pharmacy's records are maintained in accordance with Arizona statutes and rules; and 6. The pharmacy stops providing pharmacy services when the declared state of emergency ends, unless it possesses a current resident pharmacy permit issued by the Board under A.R.S. §§ 32- 1929, 32-1930, and 32-1931.
- B. The Board shall have the authority to approve or deny temporary pharmacy facilities, mobile pharmacies, and shall make arrangements for appropriate monitoring and inspection of the temporary pharmacy facilities and mobile pharmacies on a case by-case basis.
- C. A temporary pharmacy facility wishing to permanently operate at its temporary site shall apply for and have received a permit issued under A.R.S. §§ 32-1929, 32-1930, and 32-1931 by following the application process under R4-23-606.
- D. A mobile pharmacy, placed in operation during a declared state of emergency, shall not operate permanently

ADDITIONAL RESOURCES

Arizona Department of Health Services

<u>Common FAQs for Healthcare Professionals from the CDC</u> – Answers to common questions such as: who's at risk, can you be re-infected, and how we protect ourselves as providers.

National Pharmacy Association COVID-19 Webpages: <u>APhA</u>, <u>ASHP</u>, <u>NCPA</u>, <u>NACDS</u>, <u>PTCB</u>, and <u>ASCP</u>

Decision Tree & Flyers for Your Pharmacy: FIP's <u>Decision Tree for</u> <u>Pharmacists to Guide Patients, CDC's Practicing Good Hygiene</u>, and CDC's <u>Symptoms to Watch</u>

The President's Coronavirus Guidelines for America -- 15 Days to Slow the Spread of Coronavirus (COVID-19) More at <u>Whitehouse.gov</u>

DISCLOSURES





Information is changing by the moment stay informed. We will keep you updated through email and social media as best we can as things change. Check with your employer! They may be implementing different procedures than what was discussed.

THANKYOU!

We want to thank all of you for being on the front lines of this pandemic.