

COVID-19 TOWN HALL

October 28, 2020

Agenda

- COVID-19 State and National Updates
- · VEKLURY® (remdesivir) Update
- ROPA-Update & Clarification
- COVID-19 Vaccine Provider Onboarding Reminder
- . Q&A



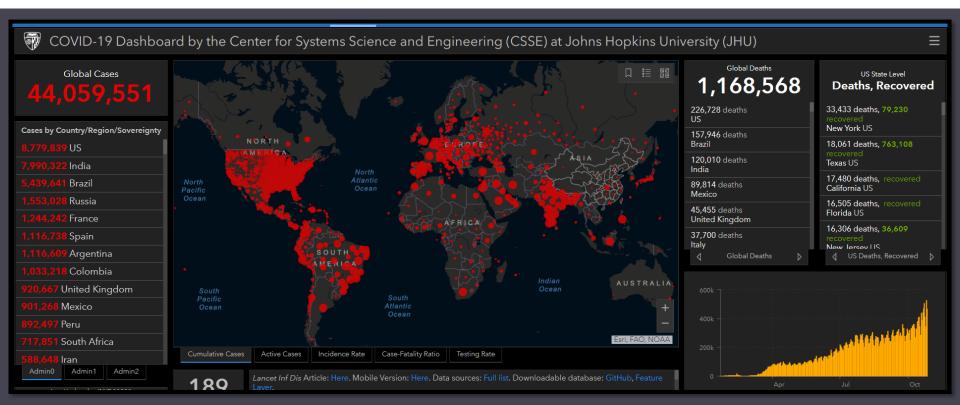
State and National Updates

Kelly Fine

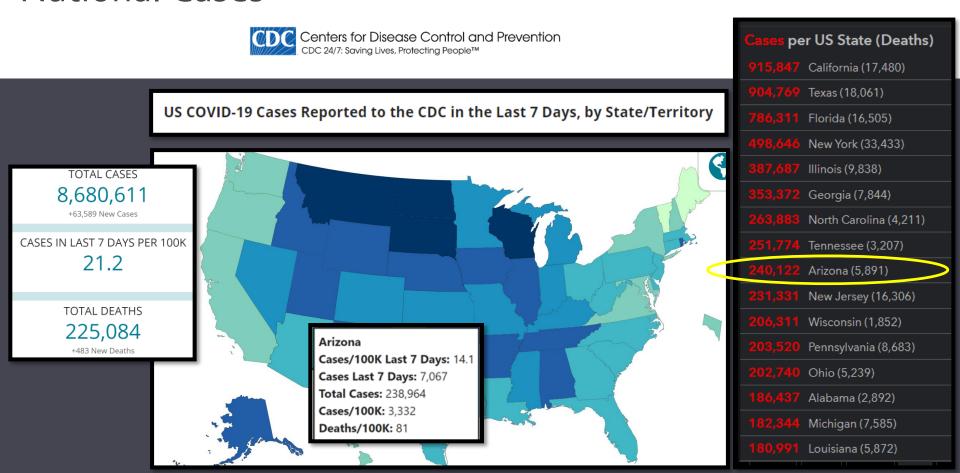
Executive Director | Arizona Pharmacy Association

Worldwide Cases



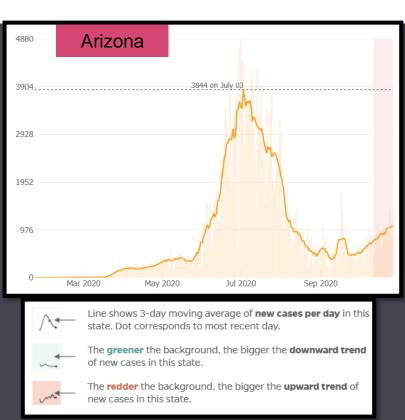


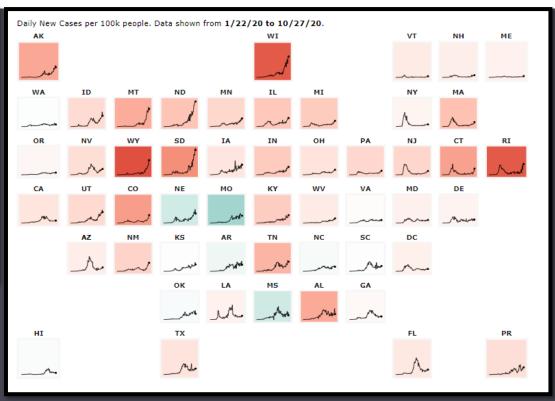
National Cases

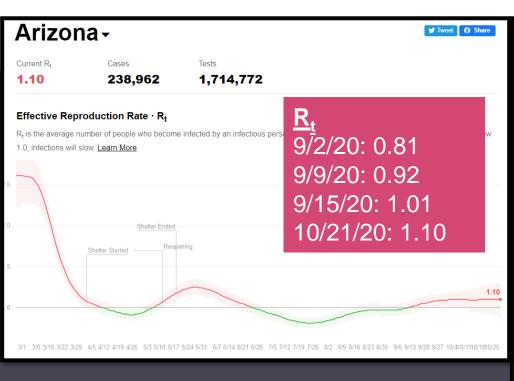


Daily confirmed new cases (3-day moving average)



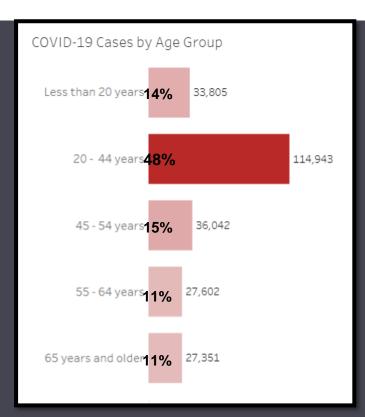


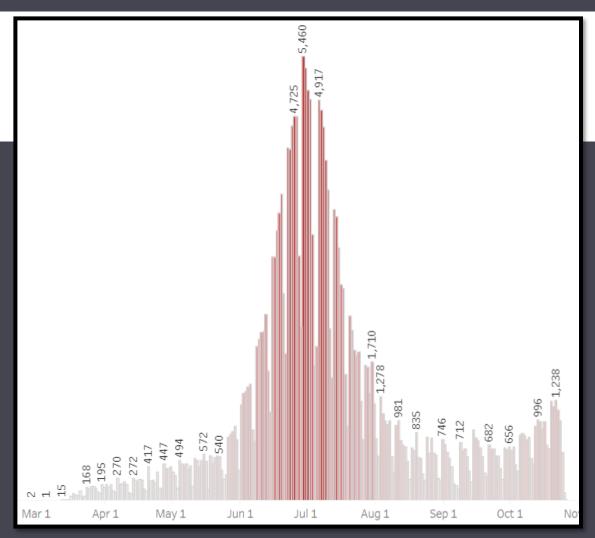






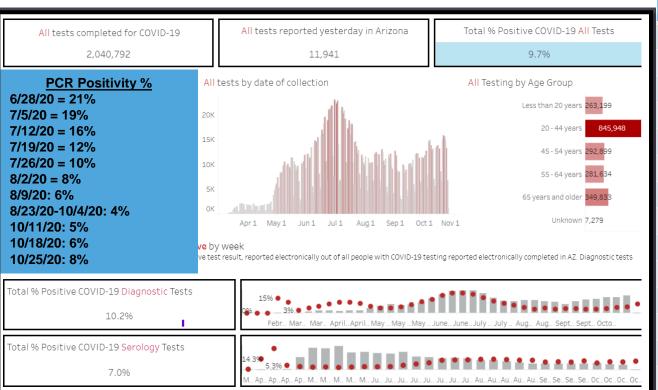
Cases by Day & Age Group





Laboratory Testing





| Date | Total % Positive | PCR % Positive | Sero % Positive |
|----------|---------------------|-------------------|--------------------|
| 6/17/20 | 7.1% | 8.7% | 3.1% |
| 6/24/20 | 8.6% | 10.5% | 3.0% |
| 7/1/20 | 9.9% | 12% | 3.2% |
| 7/8/20 | 11.3% | 13.6 | 3.4% |
| 7/15/20 | 11.9% | 14.2% | 3.7% |
| 7/22/20 | 12.4% | 14.6% | 4.4% |
| 7/29/20 | 12.7% | 14.6% | 4.9% |
| 8/5/20 | 12.6% | 14.4% | 5.3% |
| 8/11/20 | 12.4% | 13.9% | 5.7% |
| 9/1/20 | 11.5% | 12.6% | 6.4% |
| 9/8/20 | 11.2% | 12.2% | 6.5% |
| 9/15/20 | 11% | 11.9% | 6.6% |
| 10/20/20 | 9.9% | 10.4% | 6.9% |
| 10/27/20 | 9.7% | 10.2% | 7% |

Hospitalizations & Ventilator Use



| INPATIENT BEDS IN USE ICU BED | | ICU BEDS IN USE | | V | 'ENTILATORS IN U | SE | | |
|-------------------------------|------------------|--------------------|----------|-----------------|------------------|----------|-----------------|---------|
| Date | Total (in use %) | # COVID | Date | Total (in use%) | # COVID | Date | Total (in use%) | # COVID |
| 6/15/20 | 6,231 (81%) | 1,506 | 6/15/20 | 1,307 (80%) | 502 | 6/15/20 | 707 (38%) | 340 |
| 6/22/20 | 6,469 (83%) | 2,136 | 6/22/20 | 1,412 (84%) | 614 | 6/22/20 | 716 (41%) | 386 |
| 6/29/20 | 6,488 (85%) | 2,793 | 6/29/20 | 1,435 (86%) | 683 | 6/29/20 | 773 (45%) | 455 |
| 7/6/20 | 6,472 (82%) | 3,356 | 7/6/20 | 1,481 (90%) | 869 | 7/6/20 | 895 (51%) | 544 |
| 7/13/20 | 6,721 (85%) | 3,5 1 7 | 7/13/20 | 1,498 (88%) | 970 | 7/15/200 | 996 (52%) | 674 |
| 7/20/20 | 6,636 (83% | 3041 | 7/20/20 | 1,448 (85%) | 865 | 7/20/20 | 952 (49%) | 608 |
| 7/27/20 | 6,386 (81%) | 2564 | 7/27/20 | 1,433 (84%) | 814 | 7/27/20 | 920 (47%) | 574 |
| 8/3/20 | 6,487 (81%) | 2024 | 8/3/20 | 1443 (83%) | 638 | 8/3/20 | 795 (41%) | 474 |
| 8/11/20 | 6,476 (81%) | 1469 | 8/11/20 | 1378 (80%) | 510 | 8/11/20 | 679 (36%) | 346 |
| 8/31/20 | 6435 (81%) | 729 | 8/31/20 | 1289 (77%) | 253 | 8/31/20 | 556 (30%) | 150 |
| 9/7/20 | 6300 (79%) | 657 | 9/7/20 | 1265 (76%) | 212 | 9/7/20 | 541 (29%) | 112 |
| 9/14/20 | 6352 (80%) | 550 | 9/14/20 | 1294 (78%) | 138 | 9/14/20 | 460 (25%) | 76 |
| 10/19/20 | 7175 (83%) | 777 | 10/19/20 | 1355 (81%) | 170 | 10/19/20 | 463 (25%) | 91 |
| 10/26/20 | 7278 (85%) | 861 | 10/26/20 | 1377 (83%) | 187 | 10/26/20 | 524 (29%) | 100 |

FDA Waives Some Track and Trace Requirements

- The FDA <u>announced</u> it will delay enforcement of certain provisions of the Drug Supply Chain Security Act (DSCSA) until November 2023 due to the pandemic.
- The FDA will not enforce that dispensers (i.e., pharmacies) must investigate product identifiers on suspect and illegitimate product.
- The FDA is also delaying enforcement of the distributor verification requirement for saleable returned product. Both were scheduled to take effect next month.

HHS Partners with CVS and Walgreens to Provide COVID-19 Vaccine to Long-Term Care Facilities

- HHS and DOD announced a CDC partnership with CVS and Walgreens to provide vaccine services in nursing homes and assisted living once a COVID-19 vaccine has been approved and authorized.
- Facilities can partner with CVS, Walgreens, or existing LTC pharmacy and indicate what that is. The program is not limited to CVS and Walgreens.
- Facilities need to sign up between October 19th-November 6th and indicate their pharmacy preference through the <u>NHSN portal</u>. Assisted living facilities will indicate their pharmacy preference through an <u>online sign-up form</u>.
- FAQ

CDC Expands Definition of Close Contacts

- CDC revised how it defines "close contact" in relation to how people can contract the novel coronavirus.
- CDC previously defined close contact as someone who spends 15 minutes or more time within 6 feet of an infectious person.
- The agency now says it is someone who spends a cumulative 15 minutes or more within 6 feet of someone who was infectious over 24 hours. This indicates that the time spent does not have to be consecutive.

CLICK HERE

Pharmacists MUST have an NPI Number



Q SEARCH NPI REGISTRY 1 H



Create a New Account

You need an Identity & Access Management System (I&A) User ID and Password to create and manage NPIs.

Individual Providers, Organization Providers, Users working on behalf of a provider



If you don't have an I&A account, need to update your existing I&A account, or don't remember your User ID or Password, select the CREATE or MANAGE AN ACCOUNT button below to go to I&A.



Once you have successfully created your I&A account, your existing Type 1 NPI will be associated with your I&A

After successfully creating your I&A account, return to NPPES and use your I&A User ID and Password to log into NPPES where you can create and maintain the NPI data associated with your provider(s).

CREATE OF MANAGE AN ACCOUNT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services



Medicari

NPI: What You Need to Know



VaccineFinder

COVID-19 VACCINE ADMINISTRATION DATA REPORTING

- Jurisdictions will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's <u>VaccineFinder</u>.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway* to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and other external systems, as well as to report vaccine administration data to CDC.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

To be determined:

- Jurisdiction responsibility/involvement concerning reporting of data from multijurisdictional providers
- Method and frequency for vaccination providers to report information to VaccineFinder



FOR IMMEDIATE RELEASE August 19, 2020

Contact: HHS Press Office 202-690-6343

media@hhs.gov

HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic

The U.S. Department of Health and Human Services (HHS) issued a third amendment - PDF* to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

"Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic." said HHS Secretary Alex Azar. "The Trump Administration has worked to allow pharmacists—alongside all of America's heroic healthcare workers—to practice at the top of their license, empowering the public with more options to protect their health and well-being."

The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA).
- . The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- · The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunizationrelated continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.



HHS.gov HHS Order #2

FOR IMMEDIATE RELEASE September 9, 2020 Contact: OASH Press Office 202-205-0143

ashmedia@hhs.gov

Trump Administration Takes Action to Expand Access to COVID-19 Vaccines

Today, under the leadership of President Trump, the U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to safe and effective COVID-19 vaccines when they are made available. This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

"This action builds upon our Administration's progress toward delivering a safe, effective, and widely available vaccine by 2021," said Assistant Secretary for Health ADM Brett P. Giroir, M.D. "Allowing pharmacists to order and administer COVID-19 vaccines will greatly expand convenient access for the American people."

To qualify as "covered persons" under 42 U.S.C. § 247d-6d((i)(8)(B) when administering COVID-19 vaccines authorized or licensed by the U.S. Food and Drug Administration (FDA) to persons ages 3 or older, state-licensed pharmacists and pharmacy interns licensed or registered by their state board of pharmacy must satisfy the following requirements:

. The vaccine must be FDA-authorized or FDA-licensed.

- The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is
 approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must
 include hands-on injection technique, clinical evaluation of indications and contraindications of
 vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic CPR
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunizationrelated continuing pharmacy education during each state licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the
 jurisdiction in which he or she administers vaccines, including reviewing the vaccine registry or other
 vaccination records prior to administering a vaccine.
- The licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and
 the adult caregiver accompanying the patient of the importance of a well-child visit with a
 pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any
 applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and
 Prevention COVID-19 vaccination provider agreement and any other federal requirements that
 apply to the administration of COVID-19 vaccine(s).

The authorization preempts any state and local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above. The authorization does not preempt state and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.



FOR IMMEDIATE RELEASE October 21, 2020

Contact: ASH Press Office 202-205-0143

ashmedia@hhs.gov

Trump Administration Takes Action to Further Expand Access to Vaccines, COVID-19 Tests

Today, under the leadership of President Trump, the U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health (ASH), issued guidance - PDE* under the Public Readiness and Emergency Preparedness Act (PREP Act) authorizing qualified pharmacy technicians and State-authorized pharmacy interns to administer childhood vaccines. COVID-19 vaccines when made available, and COVID-19 tests, all subject to several requirements. This guidance clarifies that the pharmacy intern must be authorized by the State or board of pharmacy in the State in which the practical pharmacy internship occurs, but this authorization need not take the form of a license from, or registration with, the State board of pharmacy.

"Pharmacists and their staff are critical to the COVID-19 response," said Assistant Secretary for Health ADM Brett P. Giroir, M.D. "Together with pediatricians and family physicians, they are ensuring that Americans receive the vaccines they need where they need it."

This guidance authorizes both qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer to FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard immunization schedule, if the requirements listed below are satisfied:

 The vaccination must be ordered by the supervising qualified pharmacist. The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians. • The vaccine must be FDA-authorized or FDA-licensed. • In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s). • In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule. • The qualified pharmacy technician or State-authorized pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include a hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. • The qualified pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the relevant State licensing period(s).

The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or State-authorized pharmacy intern.
The qualified pharmacy technician and State-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer

The supervising qualified pharmacist must comply with any applicable requirements (or conditions
of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal

requirements that apply to the administration of COVID-19 vaccine(s).

The supervising pharmacist is responsible for complying with requirements related to reporting

 The supervising qualified pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary care provider when available and submitting the required immunization information to the State or

local immunization information system (vaccine registry).

COVID-19 Testing

adverse events.

patients as appropriate.

This guidance also authorizes qualified pharmacy technicians and State-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared, or authorized.

Resources

Well-Child Visit Templates: A Task Force on Pharmacist Engagement in State-Based COVID Vaccination comprising APhA, NASPA, and NCPA and state pharmacy association executives developed three tools for use by pharmacists to satisfy the requirement under the HHS Amendments authorizing pharmacists to administer childhood and COVID-19 vaccines.

- Well-Child Visit Brochure (PDF)
- Template Referral Form Well-Child Visit (Word)
- Well-Child Checkup Letter (Word)

Pediatric
Vaccine
Refresher for
Pharmacists



AzPA Vaccine Administration
Training Program for
Technicians.

Live and On-demand program!



CPR Training That Fits Your Schedule



What is HeartCode® BLS?

HeartCode® BLS is the online portion of BLS blended learning, It uses a variety of eLearning assets such as dramatizations, eSimulations, animations, self-directed learning, and interactive activities to teach students BLS knowledge and skills. After completing the online portion, students must attend a structured Instructor-led hands-on session that focuses on meaningful skills practice, debriefing, team scenarios, discussions of local protocols, and skills testing.



Advisory Committee on Immunization Practices (ACIP)

| | Final - October 27, | 2020 |
|------------|---|-------------------------------------|
| Friday, Oc | tober 30, 2020 | |
| 10:00 | Coronavirus Disease 2019 (COVID-19) Vaccines | |
| | Introduction | Dr. Beth Bell (ACIP, WG Chair) |
| | Update from Vaccines and Related Biological Products Advisory | Dr. Doran Fink (FDA) |
| | Committee (VRBPAC) meeting | |
| | NVX-CoV2373 Vaccine Candidate | Dr. Filip Dubovsky (Novavax) |
| | Janssen's SARS-CoV-2 Vaccine Program | Dr. Jerry Sadoff (Janssen) |
| 11:45 | Break | |
| 12:00 | Update on vaccine implementation planning | Dr. Janell Routh (CDC/NCIRD) |
| | Vaccinate with Confidence | Dr. Amanda Cohn (CDC/NCIRD) |
| 12:30 | Lunch | |
| 1:15 | FDA safety surveillance systems | Dr. Steven Anderson (FDA) |
| | Post-authorization safety monitoring plans | Dr. Tom Shimabukuro (CDC/NCEZID) |
| | Modeling strategies for the initial allocation of COVID-19 vaccines | Dr. Matthew Biggerstaff (CDC/NCIRD) |
| | Discussion | |
| 2:30 | Break | |
| 2:45 | Updates to immunity and epidemiology to inform COVID-19 | Dr. Megan Wallace (CDC/NCIRD) |
| | Ethical principles for early vaccine allocation | Dr. Mary Chamberland (CDC/NCIRD) |
| | Work Group interpretation of data | Dr. Sara Oliver (CDC/NCIRD) |
| | Policy questions, Evidence to Recommendation Framework, and | Dr. Kathleen Dooling (CDC/NCIRD) |
| | Discussion | 7.1 |
| 4:45 | Adjourn | |

FDA approves first treatment for COVID-19

VEKLURY® (remdesivir)

Dawn Dynak

Associate Director, National Accounts - Strategic Accounts West (AZ, CA, NV) Gilead Sciences, Inc.

Package Insert

Betty Chan PharmD, AAHIVE, BCGP

Principal Medical Scientist Gilead Sciences, Inc.

Product Information

ROPA- (Referring, Ordering, Prescribing and Attending)

UPDATE

ROPA- (Referring, Ordering, Prescribing and Attending)

The <u>Patient Protection and Affordable Care Act (ACA)</u> and the <u>21st Century</u> <u>Cures Act (Cures)</u> require that all health care providers who provide services to, order (refer), prescribe, or certify health care services for AHCCCS members must be enrolled as an AHCCCS provider.

- Until these Acts passed, referring, ordering, prescribing and attending providers were required to obtain a National Provider Identifiers (NPI's) but were not required to be enrolled as an AHCCCS provider.
- After Jan. 1, 2021 claims which include referring, ordering, prescribing or attending providers who are not enrolled with AHCCCS will not be reimbursed.

CLICK HERE

ROPA-Continued

- AHCCCS informed us that pharmacists do <u>NOT</u> have to register with AHCCCS as providers as we discussed on the call. They have created an exception process and are in the process of gathering immunization trained pharmacist's NPI's, State Board of Pharmacy license numbers, and necessary demographic information.
- If you work for Fry's, Safeway/Albertsons, Walgreens, CVS, Walmart, Bashas, or Costco: your company will be working directly with AHCCCS to provide this information on your behalf therefore you do not need to do anything.
- If you are an immunization trained pharmacist (or will be before January 1, 2021)
 that works for another pharmacy who plans to offer vaccines to AHCCCS members
 please fill out this survey and I will submit the information to AHCCCS to follow-up
 on.

CLICK HERE TO COMPLETE SURVEY

COVID-19 Provider Onboarding



Pandemic Vaccine Provider Onboard Form 1

The Arizona Immunization Program Office (AIPO) does not know if/when COVID-19 vaccines will become available. However we want to be prepared and engage our partners now, so we are ready when vaccines are available for distribution in Arizona.

Both VFC and non-VFC providers who would like to administer future COVID-19 vaccines must complete the Pandemic Provider Onboarding survey forms.

After submitting this form, you will be sent to a page with a series of subsequent survey forms. The forms serve two purposes: 1) to ensure the signatory provider knows the requirements, and 2) to ensure the facility is able to meet each requirement. The signatory provider is required to complete all of the surveys and be approved by the AIPO before this facility will be able to order future potential pandemic vaccines.

As we learn more about future vaccines we may add additional survey forms to the onboarding tool to pass the information along.

Onboarding is not an instantaneous process. It will take AIPO time to add providers to ASIIS and review requirements. Onboard now. Plan for it to take time.

The onboarding tool has the high level requirements for the signatory provider. Provider staff can go to AIPO Train to learn how to order, receive, store, administer, document, and account for pandemic vaccines in ASIIS.

We appreciate your continued efforts to help Arizonans be healthy and vaccinated.

CLICK HERE

Every pharmacy that wants vaccine from the state allocation needs to complete the Pandemic Provider Onboarding Form.

You do not have to be a VFC provider to order COVID vaccine but will require many of the same requirements.

Pandemic Provider Onboarding Cont...

The signatory physician responsible for overseeing the vaccines (Kelly Fine) is required to complete a series of forms (surveys) before Arizona Pharmacy Association can order vaccines. The forms serve two purposes: Ensure the signatory provider (Kelly Fine) knows the requirements. Ensure the facility is able to meet each requirement. Please click on the "Begin Survey" button below to complete the next form. The CDC Agreement survey forms will appear after the first few forms are completed. All survey forms must be submitted before they will be reviewed by the AIPO As new information about pandemic vaccines becomes available, we may add more surveys to the survey queue. Status Survey Title Completed Storage and Handling Completed Arizona State Immunization Information System (ASIIS) Begin survey Vaccine Planning Begin survey CDC Agreement Section A Begin survey CDC Agreement Section B Begin survey Prescribing Providers (part of CDC Agreement) - #1

MY COURSES

https://aipo.myabsorb.com/#/signup-form



Dose Accountability Webinar September 22nd

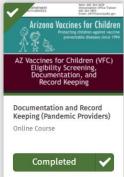


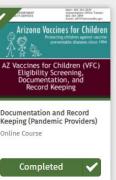


ASIIS Inventory Reconciliation

Online Course











Start







Vaccine Inventory (Pandemic Providers)

Online Course

Completed





Start 0



All COVID-19 vaccine providers need to complete this training

Questions?