COVID-19 TOWN HALL

April 15th, 2020
FAQ’S
Submit ?’s
COVID Task Force Update
  ▪ Next meeting Thursday, April 16th @10am
https://coronavirus.jhu.edu/map.html
COVID-19: U.S. at a Glance*

- Total cases: 579,005
- Total deaths: 22,252
- Jurisdictions reporting cases: 55 (50 states, District of Columbia, Guam, Puerto Rico, the Northern Mariana Islands, and the U.S. Virgin Islands)

States Reporting Cases of COVID-19 to CDC*

[Map showing states reporting COVID-19 cases]

Reported Cases
(last updated April 14, 2020)

- None
- 0 to 50
- 51 to 100
- 101 to 500
- 501 to 1000
- 1001 to 5000
- 5001 or more

COVID-19 Testing by Pharmacists

HHS Guidance for Pharmacists: The Office of the Assistant Secretary for Health issued new guidance authorizing licensed pharmacists to order and administer COVID-19 tests that the U.S. FDA has authorized. This guidance qualifies pharmacists as “covered persons” under the PREP Act, which provides protections for pharmacists who choose to administer FDA-authorized COVID-19 tests. This guidance does not specifically speak to reimbursement policy, state scope of practice (authority to order), and/or need for CLIA Waivers.

Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver: To offer testing for COVID-19, pharmacies may need to obtain a CLIA Certificate of Waiver.

AzPA is working with our national and state partners to get guidance out to you ASAP.
In support of the COVID-19 public health emergency, the Executive Order provides civil liability protections to the following:

- Licensed health care professionals licensed pursuant to ARS 32 Chapters (13, 15, 17, 18, 25 and 35);
- Volunteer health professionals who are registered and recruited through the Arizona Emergency System for the Advance Registration of Volunteer Health Professionals;
- Emergency Medical Care Technicians;
- Arizona health care institutions, treatment facilities and other sites designated by the Arizona Department of Health Services to aid in the state’s response to the COVID-19 public health emergency.

*Does not cover situations resulting from misconduct and willful negligence.*
Executive Order | Protection of Vulnerable Residents at Nursing Care Institutions, Residential Care Institutions, ICF-IIDs and DD Medical Group Homes from COVID-19

- Ensures compliance with all infection control guidance from CMS and CDC
- Requires facilities cohort COVID(+) COVID unknown residents from COVID(-) residents
  - Ensure separate, consistent staffing teams utilized for different cohorts
- Develop policies and procedures to facilitate the admission and readmission of residents who are ready for safe discharge from an acute care hospital without the requirements of a negative COVID-19 test result (COVID-19 + or unsure should be isolated for 14 days)
- Shall report through EMResource or alternative form to the Arizona Department of Health Services every week:
  - Number of COVID-19 positive residents
  - Number of transfers to and from an acute hospital
  - Number and type of PPE and the estimates use of PPE/week
- Must offer electronic visual form of communication, if visitation is restricted, in lieu of face to face visits for all residents

CLICK HERE
Enhanced Surveillance Advisory
Executive Order: 2020-30

April 14, 2020

This is in addition to the Executive Order 2020-13 Enhanced Surveillance issued on March 23rd.
Clarifies Guidance on Cohorting:

- Room sharing ("cohorting") might be necessary if there are multiple residents with known or suspected COVID-19 in the facility.
- As roommates of symptomatic residents might already be exposed, it is generally not recommended to separate them in this scenario.
- Residents who are symptomatic and being tested for COVID-19 should not be roomed with those who are confirmed to have COVID-19 unless they are already a roommate of a positive resident.

Patients should be discharged from higher acuity care based on their clinical needs, **NOT** based on the isolation period for COVID-19.
Transferring Patients to Lower Acuity Care

- **Do NOT** keep patients in the hospital for isolation purposes
  - Patients diagnosed with COVID-19 should remain in isolation for: 7 days after their COVID-19 test was collected AND until they have been free of fever and symptoms of acute infection* for 72 hours
  - Symptoms of acute infection is defined as a single temperature of 100.4 °F (38.0 °C) and/or cough. This excludes a residual non-productive cough from reactive airways disease or a baseline cough that has not changed.

- **Long-term care facilities should be accepting their COVID-19 positive residents back following discharge from acute care (as long as they have appropriate staffing and PPE)**

- ADHS is aware that some facilities are refusing transfer and they are working with their licensing office to address this.
Update: Arizona State Public Health Lab Testing Criteria

- Fever AND signs/symptoms of a lower respiratory illness has been changed to “fever OR signs/symptoms of a lower respiratory illness”
- Children in foster care have been added to this testing group

CLICK HERE
MCPH: Healthcare Facility Guidance for COVID-19

1. Fever and Symptom Monitoring for Healthcare Personnel
   - Develop a system to regularly monitor all healthcare personnel for fever and any respiratory symptoms. (For example, employees could be expected to monitor their temperature and any symptoms twice a day or before working a shift.)
   - Reinforce that employees should not report to work when ill.

   If healthcare personnel develop any symptoms consistent with COVID-19 (fever or respiratory symptoms) they must:
   - Cease contact with patients.
   - Put on a facemask immediately (if not already wearing).
   - Notify their supervisor or occupational health services prior to leaving work.

   What to do if healthcare personnel have had a known exposure to COVID-19:
   - Allow asymptomatic employees to continue to work after consultation with their occupational health program. Your monitoring system to ensure exposed healthcare personnel are monitored daily for the 14 days after the last exposure.
   - If the healthcare facility has a sufficient supply, healthcare personnel who were not wearing recommended PPE during the COVID-19 exposure could be asked to wear a facemask while at work for the 14 days after the exposure.

For Aerosol-generating Procedures
When in a room with a patient with, or suspected to have, COVID-19 and aerosol-generating procedures* (e.g., endotracheal intubation, non-invasive ventilation [BiPAP, CPAP] tracheostomy, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy) are being performed, all healthcare personnel should wear:
- N95 respirator (or equivalent)
- Gown
- Gloves
- Eye protection (e.g., goggles or face shield)

If available, use an AIIR for aerosol-generating procedures is recommended (otherwise use a private room with the door closed).

*According to the CDC it is uncertain whether aerosols generated from nebulizer administration and high flow O2 delivery are infectious. Aerosols generated by nebulizers are derived from the medication in the nebulizer. Collection of nasopharyngeal specimens is not aerosol-generating. Please see CDC Q&A for more information.

Also includes guidance on:
- Infection Control and Personal Protective Equipment Guidance
- Actions for healthcare facilities to take NOW to prepare for COVID-19 surge
- Isolation and discharge recommendations for patients with COVID-19
On April 4, 2020, the State Disaster Medical Advisory Committee approved the implementation of the **Treat and Keep Home** and **Treat and Refer** guidelines. These strategies will reduce the number of patients seeking medical care at hospitals when hospitalization is not clinically necessary.

**ADHS recommends that healthcare providers and healthcare facilities do the following:**
- Familiarize yourself with the guidelines available under **Treat & Refer Resources** on the [EMS and 9-1-1 Resources](#).
- Share this HAN with healthcare partners across the healthcare spectrum, including hospitals, urgent care facilities, doctors’ offices, and all levels of long term care facilities.
- Partner with your local EMS agencies in implementing these guidelines, as they will help decrease the burden on the acute care settings, conserve PPE, and limit further risk of spread of COVID-19.
PTCB Updates

Online Proctored Test Delivery Coming Soon
PTCB will soon launch online proctored exam delivery of the Pharmacy Technician Certification Exam (PTCE) for candidates earning their Certified Pharmacy Technician (CPhT) credential. This option allows technicians to take the exam online remotely from their own computer under the virtual supervision of a live proctor. Online proctoring for other credentials will follow. Read more.

In-Person Testing Now Available at Some Test Centers for Essential Services
Select Pearson VUE test centers will reopen on April 16 to deliver in-person testing for pharmacy technicians taking PTCB exams and other essential service providers across the US. The designated 150 testing locations administering exams are cleaned and disinfected frequently and limit the number of individuals in the test center at one time. Read more.

Free Job Postings in the PTCB Career Center
PTCB is committed to supporting pharmacy employers who are hiring technicians in response to COVID-19. Employers can now post open positions for free on PTCB’s Career Center, as well as review applications and search technician resumes. If you or your employer are hiring, post job openings now at no cost. Visit careers.ptcb.org.

FDA approved respirators from other countries for use in the US during the COVID-19 pandemic

- On March 24, 2020, the FDA issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators (KN95)
- Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea, and Mexico who have similar standards to NIOSH.
- On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator meets certain standards.
DEA Announces Flexibilities for Satellite Hospitals or Clinics as a Result Of COVID-19

- Allowing a DEA-registered hospital or clinic to handle controlled substances at a satellite hospital or clinic location under their existing registration.

- Providing flexibility to allow distributors to ship controlled substances directly to these satellite hospitals or clinics.

- If in a case where hospital patients are cared for in a satellite hospital or clinic that is not a corporate affiliate of, or owned by, the entity that holds the DEA registration of the hospital or clinic, the DEA recommends entering into a written agreement to create an agency relationship with the hospital of clinic.
USP Operational Considerations for Sterile Compounding During COVID-19 Pandemic

- Statement from USP supporting risk-based enforcement discretion related to compounding standards.
- Addresses the assignment of beyond-use-dates, considerations for certification and recertification of engineering controls, and recommendations for cleaning and disinfecting a facility when someone is sick.
- CLICK HERE (see April 11, 2020 update)

Assignment of Beyond-Use Dates

The global drug supply chain is impacted by the COVID-19 pandemic, leading to supply disruptions and shortages of drug products. In consideration of the current resource constraints and increased waste of drugs, compounders should apply Beyond-Use Dates (BUDs) conservatively based on both chemical and physical stability and microbiological considerations. The currently effective General Chapter <797> does not prohibit longer BUDs after sterility testing and when justified according to the section titled Storage and Beyond-Use Dating. To help manage drug supply and patient access to essential medications, the CMP EC is providing as guidelines the following BUDs, which are based on stakeholder input received by the CMP EC during the COVID-19 pandemic, as well as stakeholder comments that were received during two previous public comment periods on proposed revisions to General Chapter <797>, all of which were thoroughly evaluated by the CMP EC during the revision process. The BUDs below may be assigned if compounding does not otherwise deviate from General Chapter <797> standards:

- For low- and medium-risk level compounded sterile preparations (CSPs) prepared in a segregated compounding area, apply BUDs conservatively, not to exceed:
  - 12 hours at controlled room temperature
  - 24 hours in a refrigerator

- For low- and medium-risk level CSPs prepared in a cleanroom suite, apply BUDs conservatively, not to exceed:
  - 4 days at controlled room temperature
  - 10 days in a refrigerator for medium-risk level CSPs
  - 14 days in refrigerator for low-risk level CSPs
  - 45 days in a solid frozen state at -25° to -10° or colder

- If a single-dose container is entered or punctured only in ISO Class 5 or cleaner air, it may be used up to:
  - 12 hours after initial entry or puncture, as long as the storage requirements during that 12-hour period are maintained.
  - Opened single-dose vials must not be stored for any time period.

- When assigning these BUDs, considerations should be given to:
  - Ensuring personnel monitoring (e.g., gloved fingertip and thumb sampling) is successfully completed every 6 months.
  - Increasing frequency of surface sampling in the primary engineering control to determine effectiveness of cleaning procedures and work practices.
Vitamin D: Importance of the Sunshine Hormone in Whole Body Health

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Vitamin D and Whole Body Health

- Rickets
- Osteoporosis/osteomalacia
- Periodontal disease
- Cardiovascular disease: hypertension, diseased heart muscle, congestive heart failure, ischemic heart disease
- Malabsorption: cystic fibrosis, Crohn’s disease, inflammatory bowel
- Cancer: colon, breast, lymphoma, ovarian, prostate, pancreatic, colorectal, melanoma, multiple myeloma
- Metabolic syndrome: diabetes
- Autoimmune disorders: allergies, asthma, rheumatoid arthritis, type-1 diabetes, systemic lupus erythematosus, autoimmune thyroiditis, multiple sclerosis, myasthenia gravis
- Infectious diseases: influenza, HIV-1, tuberculosis, septicemia
- Dermatologic: eczema, psoriasis, acne, urticaria

- Mood disorders
  - Seasonal affective disorder
  - Manic depression
  - Unipolar depression
  - Postpartum depression
  - Premenstrual syndrome
- Brain development
  - Autism Spectrum Disorder
  - Schizophrenia
- Cognitive disorders
  - Dementia
  - Strokes
- Parkinson’s disease
- Muscle weakness and pain
  - Fibromyalgia
  - Chronic fatigue syndrome
  - Neuropathy
- Headaches/migraines
- Seizures
- Hearing loss
- Infertility
- Macular degeneration
Risk of Vitamin D Deficiency

- Darker skin: African-American, Hispanic, Middle East, Asian
- Winter months/lack of sunlight (UVB radiation)
- Use of sunscreens/protective clothing
- Lack of fortified foods or supplements / not eating oily fish with vitamin D
- Vegetarians (restriction of dairy with fortified vitamin D), vegans
- Elderly/nontraumatic fractures/osteoporosis
- Infants and children / lack of vitamin D due to sun restriction or supplements
- Pregnant or lactating women
- Hospitalized/institutionalized patients
- Chronic renal and/or liver disease
- Gastrointestinal diseases, malabsorption, gastric bypass, IBS
- Obesity (BMI > 30 kg/m²)
- Low cholesterol levels for synthesis
- Drugs that affect vitamin D metabolism or absorption (e.g., anticonvulsants: carbamazepine, phenobarbital or phenytoin, glucocorticoids, antifungal drugs, HIV medications, cholestyramine)

Vitamin D3 Supplements

• Daily dosing
  • Once vs. twice daily dosing
  • Adults: D3 5000 IU/day for optimal health
  • Higher doses: overweight and/or obese
  • Toxicity: hypercalcemia and hyperphosphatemia with high calcium intake

• Levels should be done after taking vitamin D3 after 2-3 months of constant daily dosing

• Target levels: 40-80 ng/ml 25(OH) D3

• Fall (or spring) levels recommended after stable 25(OH)D3 dosing

• Sun avoidance, seasonal changes, sun screen (SPF ≥30), skin color, and obesity affect 25(OH)D levels
Evidence that Vitamin D Supplementation Could Reduce Risk of Influenza and COVID-19 Infections and Deaths

Nutrients 2020 doi:10.3390/nu12040988

• “To reduce the risk of infection, it is recommended that people at risk of influenza and/or COVID-19 consider taking 10,000 IU/d of vitamin D3 for a few weeks to rapidly raise 25(OH)D concentrations, followed by 5000 IU/d.”

• Goal: raise 25(OH) above 40-60 ng/ml

• Randomized controlled trials and large population studies should be conducted to evaluate these recommendations.
COVID-19: Potential Implications for Individuals with Substance Use Disorders

• Smoking or vaping tobacco or marijuana
  • Aerosols from e-cigarettes may harm lung function
• Opioid use disorder (OUD)
  • Poorer respiratory/pulmonary health
  • Slower breathing and decreased oxygen in the blood (hypoxia)
• Methamphetamine use disorder
  • Constricts blood vessels and may cause pulmonary damage and hypertension
• Higher rates of homelessness or incarceration
• Polysubstance use: tobacco, alcohol, opioids, cannabis, stimulants
• Co-occurring conditions: COPD, CVD, respiratory diseases, sleep apnea

THANK YOU!

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