AHCCCS-Updates

- https://www.azahcccs.gov/AHCCCS/AboutUs/covid19FAQ.html
FAQ’S
Submit ?’s
COVID Task Force Update
Executive Order (See next slide)
Gov. Ducey EO: Expanding Access to Pharmacies

1. Allows emergency refills of maintenance medications up to 90 days
2. Waive electronic prescribing requirements for CII’s
3. Allow telephone CII medications and hardcopy can be sent within 15 days and via fax, scan, or photo
4. Waives hospital prescribing labeling restrictions for multidose medications
5. Listed requirements for prescribing hydroxychloroquine/chloroquine (*see next slide*)
6. Allows pharmacist to interchange therapeutically equivalent medications of the same FDA drug class unless noted “dispense as written”
7. Waives the requirement for companies producing hand sanitizer to have a permit
8. Allows an AZ licensed pharmacy to receive pharmaceuticals from unpermitted wholesaler or third-party logistics provider located in another state to alleviate shortages
9. Allows an AZ licensed pharmacy or wholesaler to receive pharmaceuticals from an unpermitted manufacturer located in another state or country to alleviate shortages
Executive Order | Hydroxychloroquine and Chloroquine Requirements

- The prescription must be presented with a diagnosis code for COVID-19 from the prescriber
  - For a phoned-in prescription, the pharmacist must document a diagnosis for COVID-19
  - The prescription is limited to no more than a 14-day supply
  - No refills may be permitted unless a new prescription is furnished

- Prophylactic prescriptions for the prevention of COVID-19 are STRICKLY prohibited unless peer-reviewed evidence citing prophylactic effectiveness becomes available

- This section does not apply to patients that are taking hydroxychloroquine and chloroquine for treatment other than COVID-19
From the Front Lines of Bench Research to the Front Lines of Patient Care: Attacking COVID-19 using Solid Science

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Burning Questions from Front Line Providers

1. What are the neurologic implications of COVID-19 infection?

2. Assuming CQ/HCQ has efficacy against COVID-19, would its greatest role be in prophylaxis, treatment of mild disease, treatment of moderate disease, or treatment of severe disease?

3. What is the theory behind why (or if) azithromycin (an antibacterial agent) could have a positive role in COVID-19 treatment/recovery?
Translational Model for Exploring COVID-19 Infection: Coronavirus in Felines

- Mark Olsen has been studying feline coronavirus

- Felines can be infected with coronaviruses:
  - Feline infectious peritonitis (FIP)
  - SARS-CoV-1

- In felines, coronaviruses entry target is also RAAS-mediated (ACE2, AMPN)

- Impact of infection can be widespread across multiple tissues resulting in different disease state manifestations (e.g., lethargy, fever, anorexia, jaundice, swollen lymph nodes, peritonitis, respiratory distress, ocular changes, seizures, behavior changes)

- **Nearly every known coronavirus in felines has demonstrated ability for CNS penetration**

- Treatment with drugs that fail to penetrate the BBB fail to stop neurologic progression

References:
Renin-Angiotensin-Aldosterone System (RAAS): Focus on ACE2 enzyme / co-receptor
COVID-19 causes viremia

COVID-19 disseminates via bloodstream

COVID-19 introduced to CNS via blood and/or upper nasal passage entry

COVID-19 docks on ACE2 via spike protein

Tissues that express ACE2 receptors are potential targets of COVID-19 giving rise to viral tropism
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Fact or Fiction?
CQ/HCQ + Azithromycin to treat COVID-19

• **KEY POINT**: HCQ + AZTH data presently available result of a trial that was likely conceived, executed, and published in < 30 days

• Upon critical review of the data, the combination of HCQ + AZTH appears serendipitous
  • Mild to moderate severity COVID-19
  • N=5/6 recovered
  • HCQ 50 mg BID
  • AZTH 500 mg x 1 day, then 250 mg daily x 4
  • Both agents suppress IL-6 release
  • Noted that patients with “abnormal ECG” were excluded (this would include QTc prolongation)

Azithromycin

Azithromycin

Ongoing infection/chronic inflammation

- Compromised autophagy and intracellular mycobacterial killing

- Inhibited bacterial growth, virulence factors, biofilm
- Inhibited mucin production, inflammatory cytokines, lysosomal enzymes
- Enhanced PMNL degranulation, ROS, some cytokines
- Enhanced PMNL apoptosis
- Enhanced generation of M2-like macrophages and regulatory DCs
- Modulated autophagy and acquired immunity
- Resolution of inflammation Enhanced macrophage phagocytosis and PMNL efferocytosis

IMMEDIATE FIRST 24H 2-3 DAYS WEEKS - MONTHS

Azithromycin

• Macrolide antibiotic that interferes with bacterial protein synthesis

• Depending on concentration and bacterial species, can be bactericidal or bacteriostatic

• Macrolides have immunomodulatory & anti-inflammatory effects
  • Have been used in treatment of cystic fibrosis
  • Activate NF-kB which suppresses release of inflammatory cytokines including IL-6

• **Efficacy in viral infections?**
  • Mechanistic studies and clinical trials undertaken for > 10 years
  • *In vitro* data showing viral suppression against Zika + rhinoviruses
  • *In vivo* human clinical trials for treatment of influenza and RSV have largely failed

Respiratory medicine. 2018;138:129-36.
The European respiratory journal. 2010;36(3):646-54.
Chloroquine/Hydroxychloroquine Immunomodulatory Mechanism

Chloroquine/Hydroxychloroquine

- CQ indicated for malaria treatment
- HCQ indicated for prophylaxis/treatment of malaria, SLE, RA
- CQ has definite CNS penetration (used successfully to treat cerebral malaria)
- CQ + HCQ have large volume of distribution resulting in deep tissue penetration
- Long half life of 20-60 days

- CQ + HCQ have broadspectrum, host-based, antiviral activity secondary to multiple plausible mechanisms:
  - Acidification of lysosomal and endosomal vesicles
  - Impacting viral replication
  - Altered glycosylation of ACE2 (link to COVID-19)

- CQ + HCQ have immunomodulatory & anti-inflammatory effects
  - Suppress IL-1, IL-6, TNFα
  - Perhaps more effective when used in combo with IL-6R antagonist mAB tocilizumab (Actemra®)

Inflammopharmacology. 2015.23(5):231-69.
Antiviral research. 2019;169:104547.
Tying it all together

1. What are the neurologic implications of COVID-19 infection?
   - Possible that COVID-19 is infecting CNS in some patients which could be contributing to Type II respiratory failure secondary to brain dysfunction
   - If present, need drugs that penetrate BBB to halt neurologic progression

2. Assuming CQ/HCQ has efficacy against COVID-19, would its greatest role be in prophylaxis, treatment of mild disease, treatment of moderate disease, or treatment of severe disease?
   - Not enough data (yet) to support or refute efficacy in COVID-19
   - Plausible MOA of hindering transmission (or CNS progression) through impact on ACE2
   - CQ + HCQ penetrate BBB → this is a positive
   - Large volume of distribution → will be present in multiple tissues → positive for mitigating viral tropism
   - Theorized MOA against COVID-19 is host-mechanism
   - May be most beneficial when used in combination with other immunomodulators (e.g., IL-6 antagonists) or antivirals (that TARGET virus)

3. What is the theory behind why (or if) azithromycin (an antibacterial agent) could have a positive role in COVID-19 treatment/recovery?
   - Not enough data to support or refute efficacy in COVID-19
   - Plausible MOA include antiviral +/- immunomodulatory +/- anti-inflammatory properties
   - Theorized MOA against COVID-19 is host-mechanism
   - Noted concern about CQ/HCQ + AZTH and QTc prolongation
(Other) Burning Questions from Front Line Providers

Any interest in learning more about these topics?

1. What is the role of immune modulators in treating COVID-19 (e.g., IL-6 blockers, steroids)?

2. Why do some people develop ARDS with COVID-19 while others are asymptomatic? Can we predict who will develop ARDS based on risk factors, comorbidities, genetics, other factors?

3. What is the likelihood of an effective vaccine development in the foreseeable future?

4. What is the anticipated longevity of immunity after recovering from active infection?
KELLY FINE

Executive Director-
Arizona Pharmacy Association
We have received many emails from stakeholders about a few of our policies and we wanted to clarify a few things:

- Our guidance for hospital and health systems, which includes the “one mile radius” provision, is still in draft and we are planning to issue a revision. This draft guidance document was issued for public comment and has not been implemented.

- Although federal law specifies a 5 percent limit on interstate distribution of compounded drug products for pharmacy compounders, we do not intend to enforce the 5 percent limit until after we have finalized a Memorandum of Understanding (MOU) and given states an opportunity to sign it. The MOU is currently in draft form.

- We do not consider drugs that are on FDA’s shortage list or that have been discontinued and are no longer marketed as “commercially available” under the “essentially a copy” provision for pharmacy compounders.

- We also do not consider a compounded drug produced by an outsourcing facility as “essentially a copy” if it is identical or nearly identical to an FDA-approved drug that is on FDA’s drug shortage list. The agency also does not intend to take action under this provision if the facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

See human drug compounding and drug shortages for more information. Please email compounding@fda.hhs.gov with questions.
Guidance to Pharmacies and Pharmacy Staff - to minimize their risk of exposure to the virus and reduce the risk for customers during the COVID-19 pandemic.


**Filling prescriptions**

Although the actual process of preparing medications for dispensing is not a direct patient care activity, the other components of medication dispensing such as prescription intake, patient counseling, or patient education may expose pharmacy staff to individuals who may have respiratory illness. In addition to following workplace guidance, pharmacy staff should:

- Provide hand sanitizer on counters for use by customers and have sufficient and easy access to soap and water or hand sanitizer for staff.
- Encourage all prescribers to submit prescription orders via telephone or electronically. The pharmacy should develop procedures to avoid handling paper prescriptions, in accordance with appropriate state laws, regulations, or executive orders.
- Filling and dispensing prescriptions does not require use of PPE. After a prescription has been prepared, the packaged medication can be placed on a counter for the customer to retrieve, instead of being directly handed to the customer. Other strategies to limit direct contact with customers include:
  - Avoid handling insurance or benefit cards. Instead, have the customer take a picture of the card for processing or read aloud the information that is needed (in a private location so other customers cannot hear).
  - Avoid touching objects that have been handled by customers. If transfer of items must occur, pharmacy staff should wash their hands afterwards with soap and water for at least 20 seconds or use an alcohol-based hand sanitizer containing at least 60% alcohol. They should always avoid touching their eyes, nose, or mouth with unwashed hands.

**Use strategies to minimize close contact between staff and customers:**

- Use engineering controls where the customer and pharmacy staff interact, such as the pharmacy counter, to minimize close contact:
  - Minimize physical contact with customers and between customers. Maintain social distancing (6 feet between individuals) for people entering the pharmacy as much as possible. Use signage/banners and floor markers to instruct waiting customers to remain 6 feet back from the counter, other customer interfaces, and from other customers and pharmacy staff.
  - To shield against droplets from coughs or sneezes, install a section of clear plastic at the customer contact area to provide barrier protection (e.g., Plexiglass type material or clear plastic sheet). Configure with a pass-through opening at the bottom of the barrier for people to speak through or share items, if feasible.
  - Frequently clean and disinfect all customer service counters and customer contact areas. Clean and disinfect frequently touched objects and surfaces such as workstations, keyboards, telephones, and doorknobs. To disinfect, use products that meet EPA's criteria for use against SARS-CoV-2, the virus that causes COVID-19, and are appropriate for the surface.
  - Discontinue the use of magazines and other shared items in pharmacy waiting areas. Ensure that the waiting area is cleaned regularly.
  - For pharmacies with a co-located retail clinic, use signs to ask customers who have respiratory symptoms to wait for their appointment in a specific part of the store.
  - Promote the use of self-serve checkout registers and clean them frequently. Have hand sanitizer and disinfectant wipes at register locations for use by customers.
- Use administrative controls — such as protocols or changes to work practices, policies, or procedures — to keep staff and customers separated:
  - Promote social distancing by diverting as many customers as possible to drive-through windows, curbside pick-up, or home delivery, where feasible.
  - Large, outdoor signage asking customers to use the drive-through window or curbside pick-up can be useful.
  - Include text or automated telephone messages that specifically ask sick customers to stay home and request home delivery or send a well family member or friend to pick up their medicine.
  - Limit the number of customers in the pharmacy at any given time to prevent crowding at the pharmacy counter or checkout areas.
  - Pharmacists who are providing patients with chronic disease management services, medication management services, and other services that do not require face-to-face encounters should make every effort to use telephone, telehealth, or tele-pharmacy strategies.
  - Close self serve blood pressure units.
CDC updated guidance on providing adult and pediatric vaccinations during COVID-19

Note: recommendation to postpone immunizations with certain exceptions, taking into account benefit vs risk.


▪ Delivery of some clinical preventive services, such as immunizations, requires face to face encounters and in areas with community transmission of SARS-CoV-2, these should be postponed except when:
  ▪ An in-person visit must be scheduled for some other purpose and the clinical preventive service can be delivered during that visit with no additional risk; or
  ▪ An individual patient and their clinician believe that there is a compelling need to receive the service based on an assessment that the potential benefit outweighs the risk of exposure to the virus that causes COVID-19


Health Insurance Providers Respond to Coronavirus (COVID-19)

The health and well-being of millions of Americans remains our highest priority. Health insurance providers are committed to help prevent the spread of the coronavirus strain COVID-19.

We are activating emergency plans to ensure that Americans have access to the prevention, testing, and treatment needed to handle the current situation.

Arizona plan updates posted on AzPA website
<table>
<thead>
<tr>
<th>PBM</th>
<th>Effective Date</th>
<th>Proof of Delivery (common log)</th>
<th>Mail Allowances</th>
<th>Audits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carvernak</td>
<td>03/01/2020</td>
<td>May require a signature log with &quot;COVID&quot; in the delivery and time stamp.</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Express Script</td>
<td>05/15/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Humana</td>
<td>05/15/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Medicare</td>
<td>06/01/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
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<tr>
<td>MedImpact</td>
<td>06/15/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Monarch</td>
<td>06/23/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
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<tr>
<td>Optimole</td>
<td>06/30/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Pathways</td>
<td>06/15/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
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<tr>
<td>Pernova</td>
<td>06/23/2020</td>
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</tr>
<tr>
<td>Plus Therapeutics</td>
<td>06/01/2020</td>
<td>Acceptable documentation may take many forms (e.g., faxed or electronic confirmation in your system).</td>
<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>ProCare Rx</td>
<td>06/23/2020</td>
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<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
<tr>
<td>Quest Diagnostics</td>
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<tr>
<td>Synergy</td>
<td>06/15/2020</td>
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<td>Mail will arrive at mailroom or pharmacy.</td>
<td>New audits as of 03/14/2020</td>
</tr>
</tbody>
</table>

*New audits as of 03/14/2020. New audits to be reviewed by the PBM and/or mailroom providers for potential improvements.*

_Newsfeed Networks (PBM’s) do not assume any legal liability or responsibility for the accuracy, completeness or usefulness of any information in this document._

*PBM’s are responsible for specific requirements mandated by the PBM or any state or federal regulations._
COVID-19 Guidance for Long-Term Care Facilities

A new respiratory disease — coronavirus disease 2019 (COVID-19) — is spreading globally and there is community spread in the United States, including in Arizona. Long-term care facilities should assume COVID-19 is in their community and restrict all non-essential visitors to their facilities.

For more information, please see the CDC LTCF Recommendations.

The “prevent spread within your facility” section:

• Per CMS Guidance released on April 2, “For the duration of the state of emergency in [Arizona], all LTCF personnel should wear a face mask while they are in the facility.” and “When possible, all long-term care facility residents, whether they have COVID-19 symptoms or not, should cover their noses and mouths when staff are in their room. Residents can use tissues for this. They could also use cloth, non-medical masks when those are available. Residents should not use medical face masks unless they are COVID-19-positive or assumed to be COVID-19-positive.”

Update to “if a resident in my facility is diagnosed with COVID-19” section:

• Healthcare personnel should wear all recommended PPE (gown, gloves, eye protection, face mask) for the care of all residents, regardless of presence of symptoms. Implement protocols for extended use of eye protection and facemasks.

If possible, designate a ward or section of the facility for COVID-19 patients.

Patient/Resident Transfers from Higher Acuity Facilities Update:

• Public Health strongly recommends that long-term care facilities and nursing facilities accept their residents back from hospitals after they no longer require acute care. Hospitals are encouraged not to keep patients for isolation because the county will run out of inpatient bed capacity if patients cannot be discharged.

• Please keep all patients/residents with COVID-19 isolated until 7 days after their last positive test AND until they have not had fever or symptoms for 72 hours (without the use of fever-reducing medications).

• Please do NOT require that patients/residents have a negative COVID-19 test before accepting them back into your facility.

PPE Plan Update:

• Your commitment to patient care is critical. To support you in the midst of this pandemic response, Maricopa County Department of Public Health is trying to prioritize long-term care and nursing facilities for PPE distribution from the very limited county supply. We encourage all facilities to follow all of the guidance below to optimize your PPE supplies during this critical time.

Updated – Long-term Care Facility Guidance

Additions to the “prevent spread within your facility” section:

• Per CMS Guidance released on April 2, “For the duration of the state of emergency in [Arizona], all LTCF personnel should wear a face mask while they are in the facility.” and “When possible, all long-term care facility residents, whether they have COVID-19 symptoms or not, should cover their noses and mouths when staff are in their room. Residents can use tissues for this. They could also use cloth, non-medical masks when those are available. Residents should not use medical face masks unless they are COVID-19-positive or assumed to be COVID-19-positive.”

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NEW Resources from ASHP

Open Access to ASHP's Interactive Handbook on Injectable Drugs
- Free access to our Interactive Handbook on Injectable Drugs
- The Interactive Handbook on Injectable Drugs includes compatibility and stability information for 400 parenteral medications, including sedatives, neuromuscular blockers, opioids, and vasopressors.

New Free Service Helps Alleviate Potential Staffing Shortages During Pandemic
- ASHP CareerPharm Rapid Connect is a new online service that unites healthcare facilities with pharmacy personnel who can provide surge support, remote medication order review and verification, remote clinical pharmacy specialist services, pharmacy technician support, and temporary onsite staffing.
- Candidates (pharmacists or pharmacy technicians) who are willing and able to work are encouraged to create a profile and post their CV. There is no fee for this service.
APhA Continuing Education

APhA's 15 on COVID-19 Series is designed to provide you with the answers you need to educate yourself, your colleagues, and your patients about COVID-19.

Topics Include:

▪ Role of remdesivir in treatment of COVID-19
▪ Connections between ACE-i/ARB therapy
▪ Facts and Myths of NSAIDs in COVID-19
▪ Broad overview of COVID-19
▪ Real of two older antimalarial drugs in COVID-19

Link: https://www.pharmacist.com/coronavirus/resources-training
The Center for Drug Evaluation and Research (CDER) is engaged in numerous activities to protect and promote public health during the COVID-19 pandemic, ranging from the acceleration of development for treatments for COVID-19, maintaining and securing drug supply chains, providing guidance to manufacturers, advising developers on how to handle clinical trial issues, and keeping the public informed.

Descriptions of efforts led by CDER are below. Please visit the links below for contact information and to learn more about each area of activity.

**Coronavirus Treatment Acceleration Program (CTAP)**
CTAP will use every available method to move new treatments to patients as quickly as possible, balancing patient needs for medicine while supporting trials to gather evidence and weighing the risks and benefits.

**Drug Shortages**
Monitoring drug supply chain for impact of COVID-19 pandemic, and working with industry to prevent and alleviate shortages.

**Compounding**
Providing guidance on compounded drugs.

**Manufacturing and Supply Chain**
Providing clarity on manufacturing and supply chain changes, including expediting changes as needed.

**Drug Registration and Listing**
Ensuring companies manufacturing drugs to address the COVID-19 public health emergency can quickly register and list products with FDA.
THANK YOU!

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