



April 8th, 2020

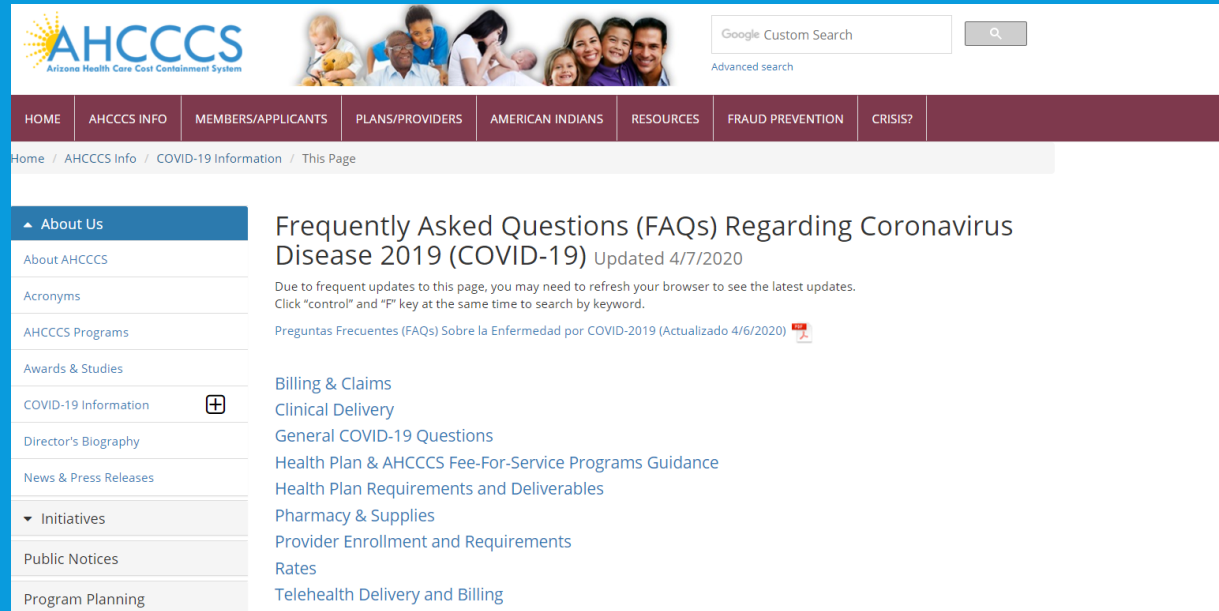
COVID-19 TOWN HALL

Suzanne Berman

Director of Pharmacy
AHCCCS


AHCCCS-Updates

- <https://www.azahcccs.gov/AHCCCS/AboutUs/covid19FAQ.html>




The screenshot displays the AHCCCS (Arizona Health Care Cost Containment System) website. The header features the AHCCCS logo, a family photo, and a search bar. A navigation menu includes links for HOME, AHCCCS INFO, MEMBERS/APPLICANTS, PLANS/PROVIDERS, AMERICAN INDIANS, RESOURCES, FRAUD PREVENTION, and CRISIS?. Below the menu, a breadcrumb trail reads: Home / AHCCCS Info / COVID-19 Information / This Page.

The left sidebar contains a menu with the following items:

- ▲ About Us
 - About AHCCCS
 - Acronyms
 - AHCCCS Programs
 - Awards & Studies
 - COVID-19 Information 
 - Director's Biography
 - News & Press Releases
- ▼ Initiatives
- Public Notices
- Program Planning

The main content area is titled "Frequently Asked Questions (FAQs) Regarding Coronavirus Disease 2019 (COVID-19) Updated 4/7/2020". It includes the following text:

Due to frequent updates to this page, you may need to refresh your browser to see the latest updates. Click "control" and "F" key at the same time to search by keyword.

Preguntas Frecuentes (FAQs) Sobre la Enfermedad por COVID-2019 (Actualizado 4/6/2020) 

The list of FAQs includes:

- Billing & Claims
- Clinical Delivery
- General COVID-19 Questions
- Health Plan & AHCCCS Fee-For-Service Programs Guidance
- Health Plan Requirements and Deliverables
- Pharmacy & Supplies
- Provider Enrollment and Requirements
- Rates
- Telehealth Delivery and Billing

KAM GANDHI

Executive Director
AZ Board of Pharmacy

BOARD OF PHARMACY UPDATE

- [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 **STRICTLY** 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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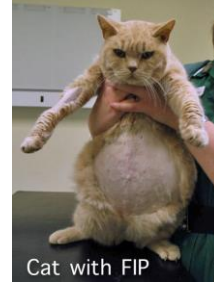


Burning Questions from Front Line Providers

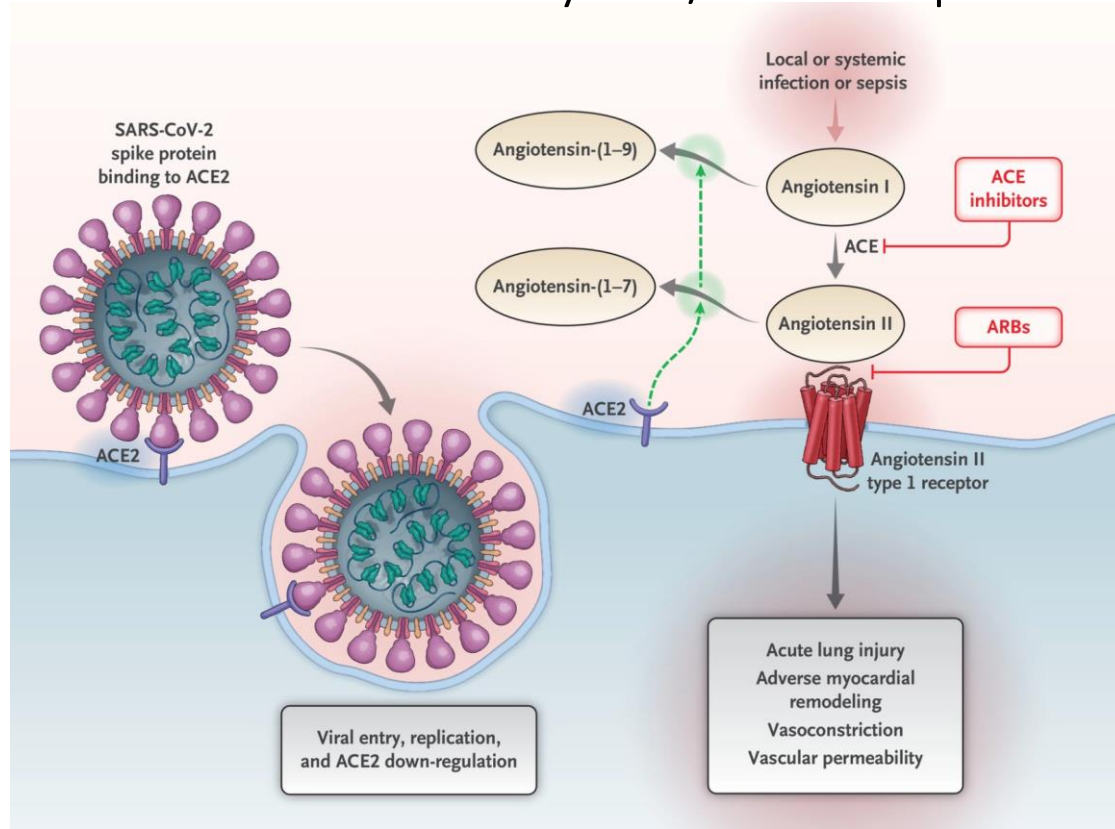
1. What are the neurologic implications of COVID-19 infection?
2. Assuming CQ/HCQ has efficacy against COVID-19, would its greatest role be in prophylaxis, treatment of mild disease, treatment of moderate disease, or treatment of severe disease?
3. What is the theory behind why (or if) azithromycin (an antibacterial agent) could have a positive role in COVID-19 treatment/recovery?

Translational Model for Exploring COVID-19 Infection: Coronavirus in Felines

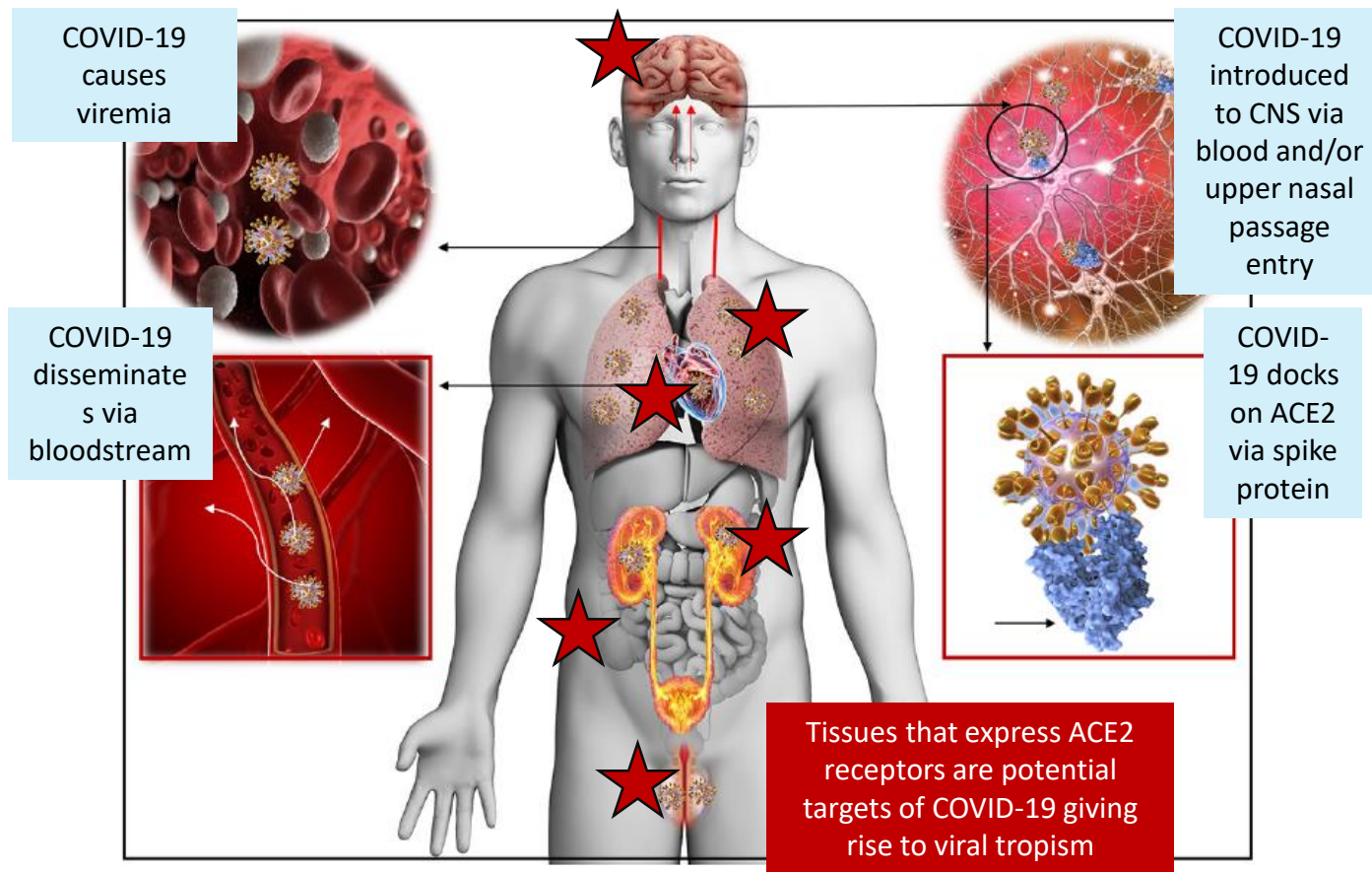
- Mark Olsen has been studying feline coronavirus
- Felines can be infected with coronaviruses:
 - Feline infectious peritonitis (FIP)
 - SARS-CoV-1
 - SARS-CoV-2 – A tiger at Bronx zoo tested positive for COVID-19 and has been symptomatic with dry cough over past month <https://www.bbc.com/news/world-us-canada-52177586>
- 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



Renin-Angiotensin-Aldosterone System (RAAS): Focus on ACE2 enzyme / co-receptor



Sites of ACE2 Expression and SARS-CoV-2 Infection





Burning Questions from Front Line Providers

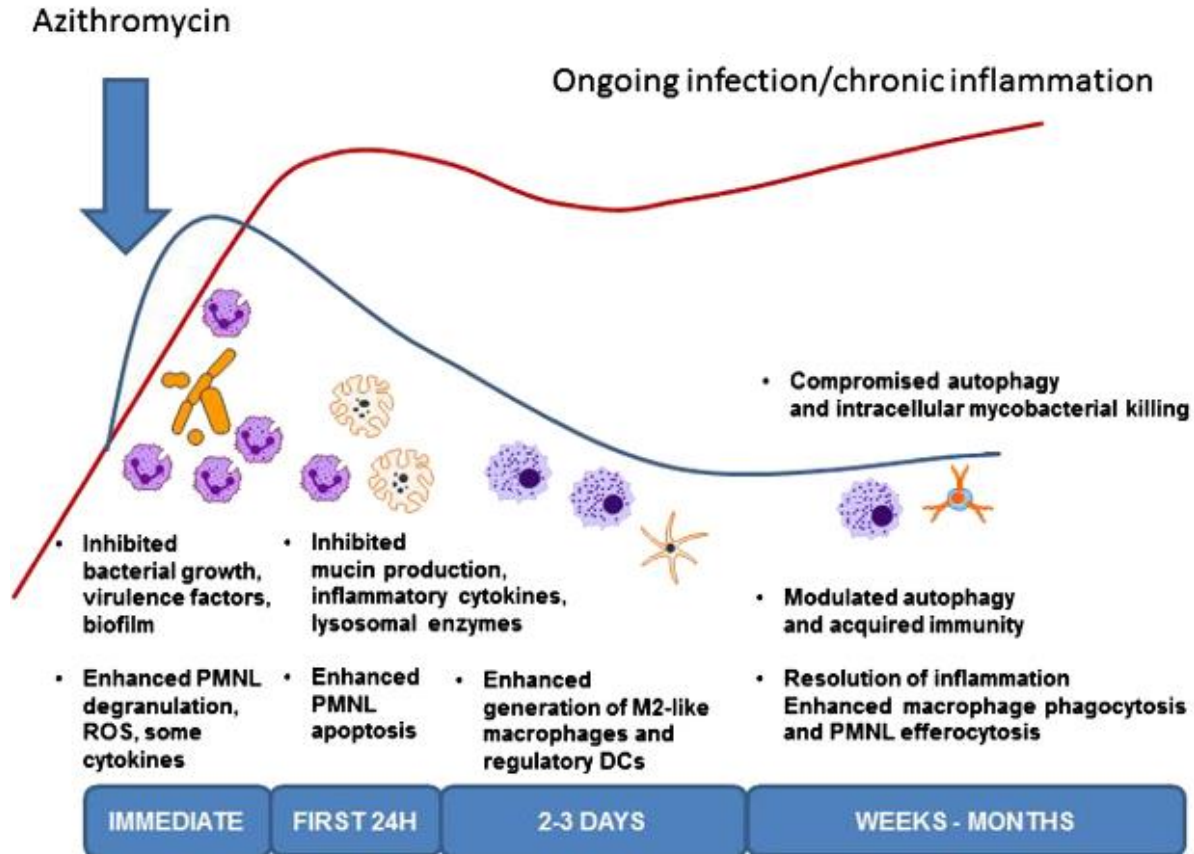
1. What are the neurologic implications of COVID-19 infection?
2. Assuming CQ/HCQ has efficacy against COVID-19, would its greatest role be in prophylaxis, treatment of mild disease, treatment of moderate disease, or treatment of severe disease?
3. What is the theory behind why (or if) azithromycin (an antibacterial agent) could have a positive role in COVID-19 treatment/recovery?

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

- 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.

Frontiers in immunology. 2018; 9:302.

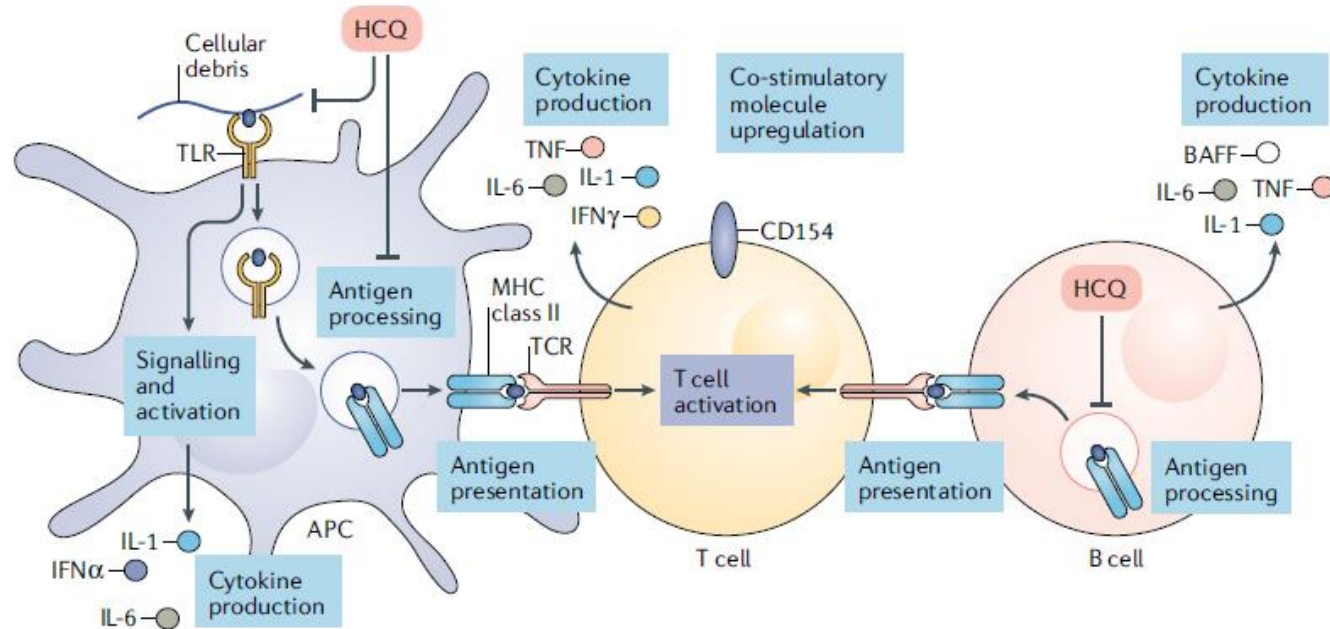
Antimicrob Agents Chemother. 2019 Sep 16. doi: 10.1128/AAC.00394-19.

The European respiratory journal. 2010;36(3):646-54.

Journal of medical virology. 2017;89 (12),2239-43.

Pediatric pulmonology. 2008,43(2):142-9.

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, TNF α
 - → perhaps more effective when used in combo with IL-6R antagonist mAB tocilizumab (Actemra®)

Central nervous system agents in medicinal chemistry. 2011;11(4):285-95.

Inflammopharmacology. 2015;23(5):231-69.

Antiviral research. 2019;169:104547.

Virology journal. 2005;2:69.

Frontiers in immunology. 2015;6:550.

International journal of antimicrobial agents. 2020:105954.

Biosci Trends. 2020;14(1):72-3.

International journal of antimicrobial agents. 2020:105949.



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 other 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

FDA Compounding Policy Clarifications

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.

CDC Guidance to Pharmacies and Pharmacy Staff

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.


- <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-resources/pharmacies.html>

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 and between 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/barriers 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., Plexiglas 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.

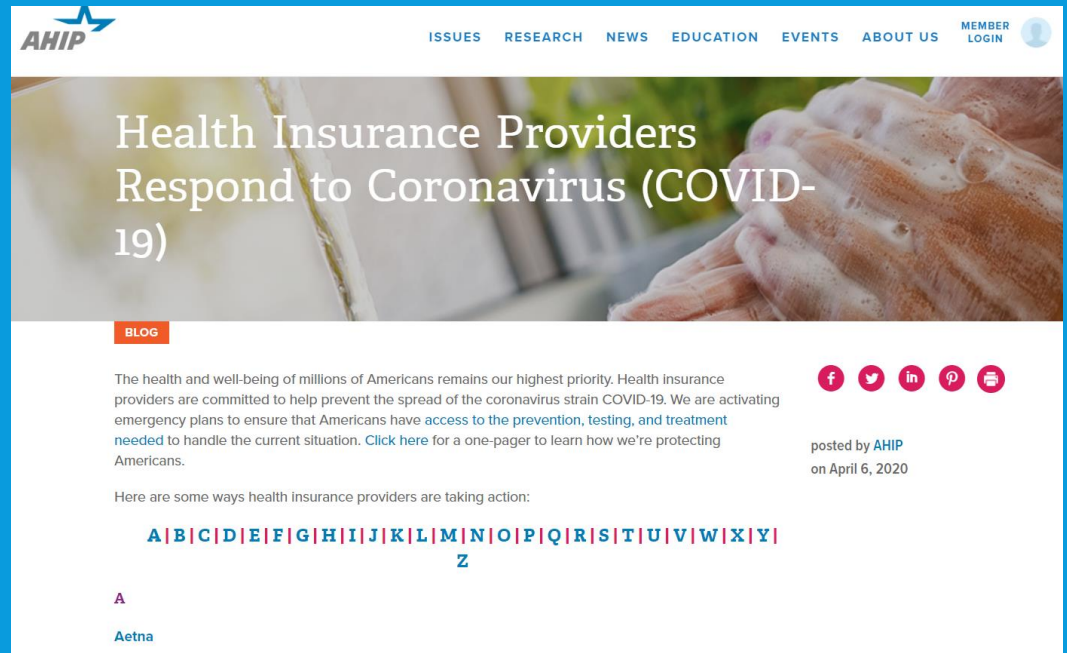
- Delivery of Adult Clinical Preventive Services, Including Immunizations, During the COVID-19 Pandemic* <https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-checklists.html>
- Delivery of some clinical preventive services, such as immunizations, requires face to face encounters and in areas with 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
- Guidance on pediatric preventive healthcare during the COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html>
- Maintaining Childhood Immunizations During COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html>
- Guidance on adult preventive healthcare during the COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-checklists.html>

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



The screenshot shows the AHIP website's blog page. At the top, the AHIP logo is on the left, and navigation links for ISSUES, RESEARCH, NEWS, EDUCATION, EVENTS, and ABOUT US are on the right, along with a MEMBER LOGIN button. The main header features a large image of hands being washed with soap, with the title "Health Insurance Providers Respond to Coronavirus (COVID-19)" overlaid in white text. Below the header, a red "BLOG" tag is visible. The main text of the post states: "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. Click here for a one-pager to learn how we're protecting Americans." To the right of the text are social media sharing icons for Facebook, Twitter, LinkedIn, Pinterest, and Print. Below the text, it says "Here are some ways health insurance providers are taking action:" followed by a horizontal list of letters A through Z, each in a different color. The letter 'A' is highlighted in purple, and below it, the word "Aetna" is written in purple.

Health Insurance Providers Respond to Coronavirus (COVID-19)

BLOG

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. [Click here](#) for a one-pager to learn how we're protecting Americans.

Here are some ways health insurance providers are taking action:

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

A

Aetna

posted by AHIP on April 6, 2020

NEW RESOURCES-PBM's

PBM	Proof of Delivery ("signature log")	Mail Allowances	Audits
Caremark	Effective 03/01/2020, until further notice In-store: Signature log with "COVID" + delivery date and time Delivery: Signature log with "COVID Delivery" + delivery date and time (maintain tracking information that links to Rx # and date of fill if using common courier) Source: Caremark memo 03/20/2020	Will allow mail from retail pharmacies Source: Caremark memo 03/16/2020	
EnvisionRx	Specific for Medicare Part D, unclear for other lines of business In-store: Signature log with "COVID" or "C" Delivery: Not otherwise specified Sources: EnvisionRx Quarterly Communication Q1 2020 03/24/2020 & EnvisionRx memo 03/20/2020	Mailing is allowed for pharmacies that have a previously established relationship with the member if agreed to/requested by member. Source: Email correspondence between EnvisionRx and PAAS 03/17/2020	
Express Scripts	Effective 03/18/2020 to 04/30/2020 In-store: Acceptable documentation may take many forms (e.g. log book with Rx # and date of service, POS with Rx #, note on hardcopy, or an electronic annotation in your system). Delivery: Documentation must contain member name, prescription number and date of service or delivery. Source: ES memo 03/20/2020 and 03/18/2020		Desk audits suspended as of 3/23/2020 Field audits suspended as of 3/13/2020 (audit suspensions do not apply to FWA investigations or other exceptions that may be required by law) Source: ES memo 03/23/2020
Humana	In-store: Humana will accept Point-of-sale documentation showing the date and time Rx was sent out for delivery for claims in March-April 2020 in lieu of a patient signature Delivery: Not otherwise specified Source: Humana memo 03/21/2020	Humana will waive any mail or home delivery restrictions for retail-only pharmacies for March-April 2020. Source: Humana memo 03/21/2020	Humana will not initiate new desk/onsite audits and will suspend all in-progress desk/onsite audits until April 30, 2020 (except for audits requested by CMS or initiated due to FWA concerns). Source: Humana memo 03/21/2020
Medicare Part B (DMEPOS)	Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19. Source: 2019-Novel Coronavirus (COVID-19) Provider Burden Relief FAQs March 2020		CMS has suspended most Medicare Fee-For-Service (FFS) medical review. This includes pre- and post-payment medical reviews conducted by MACs, TPE reviews, SMRC, and RAC reviews. Targeted Probe and Educate reviews that are in process will be suspended and claims will be released and paid. Current postpayment MAC, SMRC, and RAC reviews will be suspended and released from review. However, CMS may conduct medical reviews during or after the PHE if there is an indication of potential fraud. Source: 2019-Novel Coronavirus (COVID-19) Provider Burden Relief FAQs March 2020
MedImpact	Effective 03/13/2020 In-store: Signature log with "COVID-19" along with the date, time, and full name of person picking up AND relationship (if not beneficiary) Delivery: "Best practice" is to include a delivery confirmation card and instruct patient to sign, date and mail document to pharmacy or return it as a later date. Alternatives include (a) document "COVID-19" and include delivery date and time, AND full printed name of delivery person or (b) Copies of carrier delivery confirmations that link between the Rx # and fill date with the carrier's tracking number. Source: MedImpact memo 03/20/2020	MedImpact allows local delivery (within 50 miles) by courier, mail or other common carrier Source: MedImpact memo 03/18/2020	Onsite Audits cancelled through 04/30/2020, however Desk audits will continue, and pharmacies should work with auditor if difficulty responding due to the emergency Source: MedImpact memo 03/16/2020
Navitus	Valid through end of April 2020 In-store: Pharmacy staff should capture the date and time of pick-up and write "COVID-19" and pharmacy staff initials Delivery: Notate delivery with date and time (if using courier such as FedEx, UPS or USPS, the electronic tracking and delivery time stamp will suffice) Source: Navitus memo 03/20/2020	Valid through end of April 2020 Waiving restrictions of mail/home delivery; must be licensed where Rx is shipped Source: Navitus memo 03/20/2020	Onsite audits have been suspended. However, desktop audits will proceed. Source: Unofficial email from industry source 04/02/2020
OptumRx	Effective 03/01/2020 In-store: "Impacted by COVID-19" and pharmacy staff initials Delivery: "Impacted by COVID-19" as well as a means to tie the signature log to the specific prescription (e.g. Rx # and fill date)" is adequate Source: OptumRx memo 03/20/2020	Effective 03/10/2020 Retail pharmacies can mail via common carrier (USPS, UPS FedEx or local carrier) Source: OptumRx memo 03/20/2020	Onsite and desk audits have been suspended (except FWA investigations) Source: Unofficial email from industry source 03/30/2020
PerformRx	In-store: When a member picks up a medication, the point of sale transaction will be used in lieu of the signature. Delivery: No differentiation specified Source: PerformRx memo 03/23/2020		
Prime Therapeutics	In-store: "COVID-19" on the hardcopy or a date and time stamped notation in pharmacy's POS system Delivery: Electronic delivery records should include the patient name, address, prescription order number, fill date, name of person receiving medication, and the date and time of delivery. Source: Prime Therapeutics memo 03/27/2020	Pharmacies can mail medications if they are licensed in the states that they are mailing or delivering to. Prime requires tracking of the prescription. Source: Prime Therapeutics memo 03/27/2020	Onsite audits cancelled as of 03/16/2020 Daily and historical desktop claim audits are suspended as of 03/24/2020 (other than FWA investigations and essential audits that may be required by federal or state law) Source: Prime Therapeutics memo 03/27/2020
ProCare Rx	In-store: Signature log with "COVID" + delivery date and time Delivery: Signature log with "COVID Delivery" + delivery date and time Source: ProCare Rx memo 03/25/2020		Temporarily postpone all pharmacy audits, including those that were recently notified or that were to be notified in the next day. Source: ProCare Rx memo 03/25/2020
SS&C Health aka DST Pharmacy Solutions	Effective 03/23/2020 In-store: The pharmacist or technician records "COVID-19" on the signature log when the prescription has been dispensed Delivery: A date and time stamp of delivery is added to the prescription record Source: SS&C Health (DST) memo 03/26/2020		
WellDyne	In-store: If a patient is unable to acknowledge receipt of delivery, the pharmacy must indicate the reason on the hardcopy or within dispensing software Delivery: Not otherwise specified Source: WellDyne memo 03/19/2020		No new notification letters regarding desktop audits have been sent as of Monday, March, 23, 2020. However, any open audits must be responded to and closed out. Source: Unofficial email from industry source 04/02/2020

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COVID-19 Guidance for Long-Term Care Facilities (Updated 4/3/20)

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](#).

Prevent the introduction of respiratory germs INTO your facility:

Ill visitors and healthcare personnel (HCP) are the most likely sources of introduction of COVID-19 into a facility. MCDPH and CDC recommends aggressive visitor restrictions and enforcing sick leave policies for ill staff, even before COVID-19 is identified in a community or facility.

- **Restrict all visitation** except for certain compassionate care situations, such as end of life situations.
 - Decisions about visitation during an end of life situation should be made on a case by case basis, which should include careful screening of the visitor for fever or respiratory symptoms. Those with symptoms should not be permitted to enter the facility.
- **Restrict all volunteers and non-essential HCP**, including non-essential healthcare personnel (e.g., barbers, consultants).
- **Cancel** all group activities and communal dining.
- **Implement active screening** of residents and healthcare workers for fever and respiratory symptoms.
- Ensure sick leave policies **allow employees to stay home if they have symptoms** of respiratory infection.

Prevent the spread of respiratory germs WITHIN your facility:

Employee-specific guidance

- **Develop a system** to regularly monitor all employees 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**.
- 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.**”
- Per CMS Guidance released on April 2, “**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.”
- Identify dedicated employees to care for COVID-19 patients and provide infection control training.
 - Guidance on implementing recommended infection prevention practices is available in CDC’s free online course — [The Nursing Home Infection Preventionist Training](#) — which includes resources and checklists for facilities and employees to use.
- Provide the right supplies to ensure easy and correct use of PPE.

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.”

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.

New – 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.

New – 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.

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>

Coronavirus (COVID-19) | Drugs

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Coronavirus (COVID-19) | Drugs

Coronavirus Treatment Acceleration Program (CTAP)

Clinical Trial Conduct During the COVID-19 Pandemic

Drug Shortages Response | COVID-19

Hand Sanitizers | COVID-19

Compounding Activities | COVID-19

Fraudulent Activity and Unlawful Sales of Unapproved and Misbranded Drug Products | COVID-19

Manufacturing and Supply Chain | COVID- 19

Registration and Listing Assistance for Non- Traditional Manufacturers of Hand Sanitizer and Related COVID-19 Drugs

Import of Drugs for Potential COVID-19 Treatment

FDA Coronavirus Disease 2019 (COVID-19) and Frequently Asked Questions

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

Clinical Trial Conduct

Coordinating and managing responses to stakeholder inquiries on Clinical Trial Conduct during the COVID-19 pandemic

Hand Sanitizers

Help meet the increased demand for hand sanitizers during the COVID-19 public health emergency

Fraudulent Activity

Protecting Americans from fraudulent/unproven products for the treatment or prevention of COVID-19

Drug Registration and Listing

Ensuring companies manufacturing drugs to address the COVID-19 public health emergency can quickly register and list products with FDA

Drug Imports

Supporting regulatory flexibility for imports related to the COVID-19 pandemic

Content current as of:
04/07/2020

Regulated Product(s)
Drugs

Health Topic(s)
Infectious Disease
Coronavirus

FDA CDER COVID-19 Webpage

The Food and Drug Administration's Center for Drug Evaluation and Research (CDER) is engaged in numerous activities to protect and promote public health during the COVID-19 pandemic

Click [here](#) for the link

THANK YOU!

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