# April 8, 2020
# COVID-19 Update

Sponsored by Kansas Pharmacists Association

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## Agenda

- Introduction
- State Action Update
- Compounding Clarification from FDA
- Face Masks / Coverings Guidance
- Questions - Moderated
- Open Discussion - Moderated

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# State and Federal Resources

- Please visit our website https://kansaspharmacistsassociation.wildapricot.org/COVID-19/ to view a list of resources and the latest information from:
  - KDHE
  - The CDC
  - US Department of Labor
  - The White House
  - OSHA
  - World Health Organization
  - US Food and Drug Administration
  - CMS
  - National Institutes of Health
  - National Institute of Allergies and Infectious Disease
  - USP

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# State Action Update

- Gatherings Limits
  - EO adjusted to include limiting gatherings for all funerals and religious services to more than 10 participants, excluding those conducting the services, assuming they maintain appropriate social distancing
- Connecticut added to travel sites requiring self-quarantine upon return
- Kansas Essential Functions Requests
  - https://governor.kansas.gov/keff/
  - Allows for businesses to submit an "Essential Functions" inquiry for determination on if they meet the criteria

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# State Action Update

- Self-Service Food Guidelines
  - NO self-service food are allowed
  - NO self-serve coffee pots
    - No reuse of cups or use of cups brought from home
  - NO self-service fountain drink stations
  - NO condiment stations
  - NO unwrapped utensils
  - NO self-serve straws or lids
  - Screen all employees at the beginning of each shift
  - Surfaces open to patrons cleaned and sanitized every 30 minutes
  - Line management should be enforced (6 feet between patrons)

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# FDA Compounding Clarification

- The US Food and Drug Administration (FDA) late Monday clarified a few policies related to drug compounding
- FDA clarifies that a draft guidance has not taken effect and will be revised.
  - FDA will not take action as long as drugs are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a one-mile radius of the compounding pharmacy.
- FDA also says that 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 the agency has finalized a Memorandum of Understanding (MOU) and given states an opportunity to sign it.
- FDA also clarifies guidance from 2018 that says that compounders may compound drugs on FDA's shortage list or if they have been discontinued or are no longer marketed, and that they 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. They also said they do 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.

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## CDC Face Mask and Coverings Guidance

- CDC guidance now recommends cloth face coverings in public settings where other social distancing measures are hard to maintain, especially in areas of significant community-based transmission
- Coverings should:
  - Fit snugly but comfortably against the sides of the face
  - Be secured with ties or ear loops
  - Include multiple layers of fabric
  - Allow for breathing without restriction
  - Be able to be laundered and machine dried without damage or change of shape
  - Washed routinely based on frequency of use
  - Washed in a washing machine
  - Be removed carefully, to not touch the eyes, nose, or mouth when removing

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# QUESTIONS

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# Q1

- Has the Kansas Medicaid program made any headway on delivery fees?
  - Not yet. Last we heard; the state was waiting on a response from CMS.

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# Q2

- Does KPhA have any UPDATED guidance on home testing for COVID 19?
  - In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable.
    - This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met.
    - The FDA issued this policy to allow early patient access to certain serological tests with the understanding that the FDA has not reviewed and authorized them.
  - The FDA can also authorize tests for COVID-19 under an Emergency Use Authorization (EUA). To date, FDA has authorized one EUA for a serological test that is intended for use only by clinical laboratories.
  - Since the FDA issued the policy, over 70 test developers have notified the agency that they have serological tests available for use. However, some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that they can diagnose COVID-19. The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

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# DISCUSSION

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