COVID-19 Public Health Emergency Key Points

- On Feb 4, 2020, HHS declared that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).
- Emergency Use Authorization allows the FDA to offer protection against chemical, biological, radiological, and nuclear threats by facilitating the availability and use of medical countermeasures during public health emergencies.
    - Includes a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.
    - Stays in effect until there is no longer a state of emergency.
    - During the pandemic, EUAs allowed for the use of unapproved COVID-19 vaccines.
- COVID-19 vaccines with EUA approval
    - Pfizer-BioNTech mRNA vaccine: EUA approval on 12/11/20 and was FDA approved on 8/23/21.
    - Moderna mRNA vaccine: EUA approval on 12/28/20 and was FDA approved on 1/31/22.
    - Johnson & Johnson viral vector vaccine: received EUA approval on 2/27/21.
- COVID-19 vaccines pending EUA approval
    - 1/31/22: NovaVax filed for an EUA for use of their 2-dose vaccination series in individuals 18 years or older.
    - 2/1/22: Pfizer-BioNTech began EUA submission for its lower-dose Covid-19 vaccine in children ages 6 months to 4 years old.
    - 2/23/22: Sanofi-GSK announced plans to request emergency authorization for use of their primary 2-dose protein-based vaccine and booster shot in adults ≥ 18 years old.
- Progression of Laws
    - Florida Statute 465.189 states that: Pharmacists may administer immunizations or vaccinations that have been authorized for emergency use by the U.S. Food and Drug Administration as of April 30, 2021 and pharmacists may administer immunizations or vaccinations approved in response to a state of emergency.
    - Emergency Order 20-014: authorized pharmacists and pharmacy interns to administer vaccines approved or licensed by the FDA to **individuals ages 3 to 18 years of age.**
    - Public Readiness and Emergency Preparedness (PREP) Act: allows **pharmacy technicians to vaccinate** in all 50 states under certain conditions which ends on the final day of the Declaration of Emergency OR October 1, 2024.
    - If Emergency Order No. 20-014 is terminated
        - Under Florida state law, pharmacists could still administer the COVID-19 Vaccine to adults
        - Pharmacists would not be able to immunize children 3-18 years old
        - With the exception of the influenza vaccine for children 7 years of age and up
        - Pharmacy technicians would no longer be allowed to immunize under Florida state law

- HRSA Update: Claims for COVID-19 vaccine administration submitted after 11:59 pm on April 5, 2022 will not be adjudicated.
    - This will affect how Guardian Pharmacy operates immunization clinics. Details will be provided once available.
- 3/29/22 CDC booster dose update: Second booster doses of Pfizer-BioNTech or Moderna may be administered to individuals **50 years or older** at least **4 months** after receipt of the first booster dose of any authorized or approved COVID-19 vaccine. This age requirement is reduced to 12 years or older for immunocompromised individuals receiving the Pfizer-BioNTech booster, and 18 years or older for immunocompromised individuals receiving the Moderna booster.
- CMS Update for Skilled Nursing Facilities
    - April 2020 - CMS waived certification and training requirements for nurses aids, allowing them to remain employed longer than 4 months without renewing these requirements.
    - On, April 7, 2022, CMS issued a memo **ending waivers to skilled nursing requirements** for several reasons (i.e. improved COVID vaccination rates, improved ability to respond to outbreaks, and overall care).
    - These waivers will be ending in two groups
        - 30 days from publication of memo
        - 60 days from publication of memo
- COVID-19 available treatments
    - Non-hospitalized patients: Ritonavir-boosted Nirmatrelvir (Paxlovid) and/or remdesivir are first-line therapies; bebtelovimab or molnupiravir may be used second-line.
    - Hospitalized patients: Anticoagulation with UFH or LMWH; corticosteroids (e.g. dexamethasone) for those requiring oxygen; remdesivir, baricitinib, or tocilizumab may be added depending on onset of symptoms, location in hospital, disease progression, and oxygen requirements.
- Dec 8, 2021 the FDA issued an Emergency Use Authorization for AstraZeneca's **Evusheld**, a prevention therapy for certain high-risk individuals that can help protect them from COVID-19 before they are exposed to the virus.
    - Approved for ages 12 and older weighing at least 88 pounds.
    - May NOT be currently infected with COVID or have had recent exposure.
    - Meet one of the following three criteria:
        - Possess health condition that prevents strong response to COVID vaccine.
        - Taking medications that prevent a strong enough response to the COVID-19 vaccine (i.e. chemotherapy).
        - Unable to get the vaccine due to severe allergic reactions (anaphylaxis).
- On January 14, 2022, the Secretary of Health and Human Services renewed the determination that a public health emergency exists due to COVID-19. It expires on April 16, 2022. Another renewal is expected before April 16, and will last an additional 90 days.
- **CS/SB 1892** effective July 1, 2022
    - Authorizes certified pharmacy technicians to administer certain immunizations to **adults** under pharmacist supervision.
    - The bill also updates the statutory list of immunizations and vaccines that pharmacists, registered pharmacy interns, and (under the bill) registered pharmacy technicians may become certified to administer.