Current Challenges, Confusion and Concerns Related to COVID-19 Vaccines in Long-Term Care Settings

Current COVID-19 Vaccine Guidance

- CDC has updated (May 1st) its recommendations for COVID-19 vaccines and boosters, including:
  - Removing EUA approval for the monovalent mRNA vaccines
  - Allowing use of the bivalent mRNA vaccines for primary series immunization
  - Approving additional bivalent boosters for:
    - Adults over the age of 65 at least 4 months after bivalent booster dose
    - Immunocompromised individuals at least 2 months after bivalent booster dose AND every 2 months, as recommended by the patient’s care team
  - Novavax vaccines continue to be available for individuals uncomfortable with receiving an mRNA vaccine or booster
• Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.
  • PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.

• Ending of coverage for certain activities.
  • Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
    • COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
    • COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.

• Ending of coverage for routine childhood vaccinations.
  • Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

• No change to coverage for certain prescribing and dispensing of COVID-19 oral antivirals.
  • The PREP Act will continue to offer liability immunity for pharmacists, pharmacy technicians, and pharmacy interns dispensing COVID-19 treatments.

• No change to the “Test to Treat” program.
  • Pharmacists and other providers prescribing tests in the “Test to Treat” program will continue to receive liability protection under the PREP Act.

• With the PHE ending on May 11th, 2023, the Biden Administration, via CMS, has amended requirements related to reporting, including:
  • Ending regulatory requirement for resident and staff COVID-19 testing
    • Facilities are still expected to test per F-880
  • Ending the staff vaccination requirement
    • HOWEVER, the SNF PPS proposed rule proposes to amend the existing COVID-19 vaccination quality measures from “primary series” to “up to date.”
  • Ending, via enforcement discretion and then December 31, 2024, requirement to notify residents and their representatives and families of a single confirmed resident case OR three or more residents or staff with new on-set of respiratory symptoms within 72 hours of each other.
COVID-19 & COVID-19 Vaccine Reporting Requirements

- Facilities are still required to:
  - Report, via the NHSN, the vaccination status of residents and staff (will continue indefinitely)
  - Educate residents and staff on COVID-19 vaccines and assist in immunization (until May 21, 2024)

SNF Enforcement Discretion Relating to Certain Pharmacy Bill

- Under an 1135 waiver, CMS allowed long-term care pharmacists (who were enrolled as mass immunizers) to roster bill Medicare Part B directly for administering:
  - COVID-19 vaccines
  - Influenza vaccines
  - Pneumococcal vaccines

- Per CMS, this enforcement discretion will end on **June 30th, 2023**

- Entire long-term care ecosystem requested preservation through, at least, the 2023-2024 influenza season

- **Concerns:**
  - CMS statements related to ending this enforcement discretion ONLY refers residents in their Part A stay
  - Long-term care facilities are NOT connected with state-run immunizations reporting system (IIS) so:
    - How will vaccines be reported?
    - How will facilities know when a resident needs to receive a booster or second dose in their primary series?
Concerns – nursing home resident:
- Currently:
  - Data from State IIS provides insight to vaccination status of resident
  - Pharmacist can review and recommend
  - Pharmacist reports to State IIS
  - Pharmacy has the flexibility to administer and the responsibility to report if billing for the administration of the vaccine (common during the emergency for Covid-19 and Flu)
- As of June 30th:
  - Pharmacy can no longer roster bill Covid-19 and influenza vaccine, this reverts to the SNF
  - SNF does not report to State IIS
  - Resident’s vaccination history is now compromised and useless to guide recommendations
  - Systems reverts to pre-Covid scenario where SNFs commonly did not manage or bill vaccinations effectively – further challenged by the current staffing situation in SNFs

The Secretary of HHS has the authority to continue the 1135 enforcement discretion waiver.

All SNF stakeholders including medical directors, AHCA, and Leading Age support continuing the 1135 waiver.

Equitable Community Access to Pharmacists Services Act H.R. 1770

- Adds “pharmacists” to the Social Security Act
- Allows for Medicare Part B billing of:
  - Testing for influenza, COVID-19, streptococcal pharyngitis (strep throat) and RSV
  - Treating influenza, COVID-19 and streptococcal pharyngitis (strep throat)
  - Immunizing against influenza and COVID-19
- Bill at 80% of PFS; 85% under PHE
- LTC-specific impact: solves roster billing issue
- AMA critique