# COVID-19 Vaccine Opportunities for LTCF

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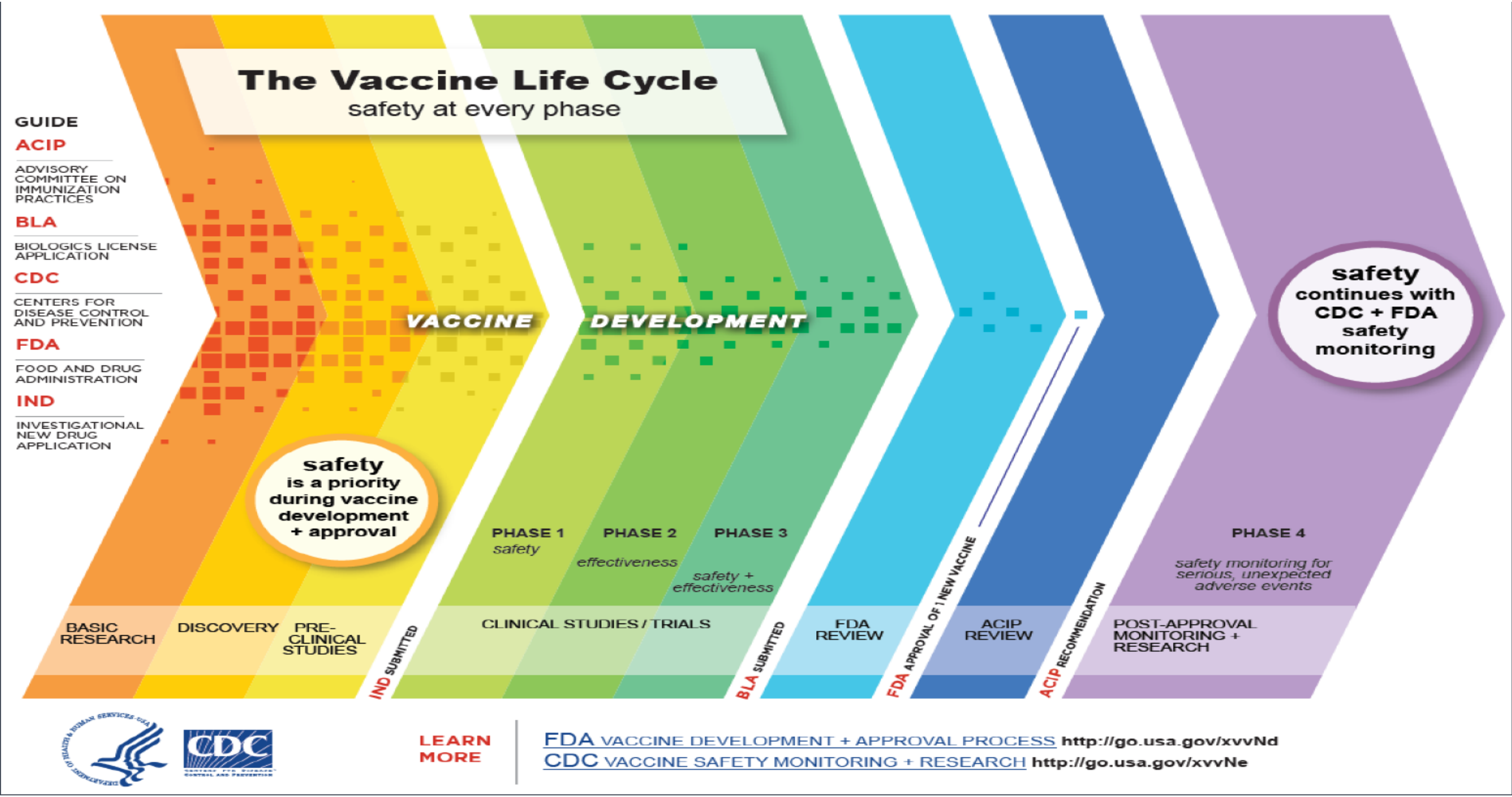
The Vaccine Life Cycle
safety at every phase
GUIDE
ACIP
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
BLA
BIOLOGICS LICENSE APPLICATION
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
FDA
FOOD AND DRUG ADMINISTRATION
IND
INVESTIGATIONAL NEW DRUG APPLICATION
VACCINE DEVELOPMENT
safety is a priority during vaccine development + approval
PHASE 1
safety
PHASE 2
effectiveness
PHASE 3
safety + effectiveness
PHASE 4
safety monitoring for serious, unexpected adverse events
safety continues with CDC + FDA safety monitoring
BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES
IND SUBMITTED
CLINICAL STUDIES / TRIALS
BLA SUBMITTED
FDA REVIEW
FDA APPROVAL OF 1 NEW VACCINE
ACIP REVIEW
ACIP RECOMMENDATION
POST-APPROVAL MONITORING + RESEARCH
LEARN MORE
FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd
CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvvNe

# COVID-19 Vaccine Safety Considerations
## presented by Kathryn Edwards, M.D.

### Conclusions

- An effective vaccine will likely be achieved with at least one of the vaccine approaches
- Vaccine safety will be meticulously assessed
- If enhanced disease occurs it will be carefully assessed and immune mechanisms investigated
- A safe and effective vaccine that is widely available would likely induce herd immunity
- Herd immunity to SARS 2 would allow us to resume normal activities

# More information and links to the Vermont Interim Plan

https://www.healthvermont.gov/covid-19-vaccine

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*"While we look forward to a safe and effective COVID-19 vaccine, we hear the fears expressed by many that political pressure is being applied to rush approval of a vaccine before it has been properly tested. Let me be clear. We stand with science."*

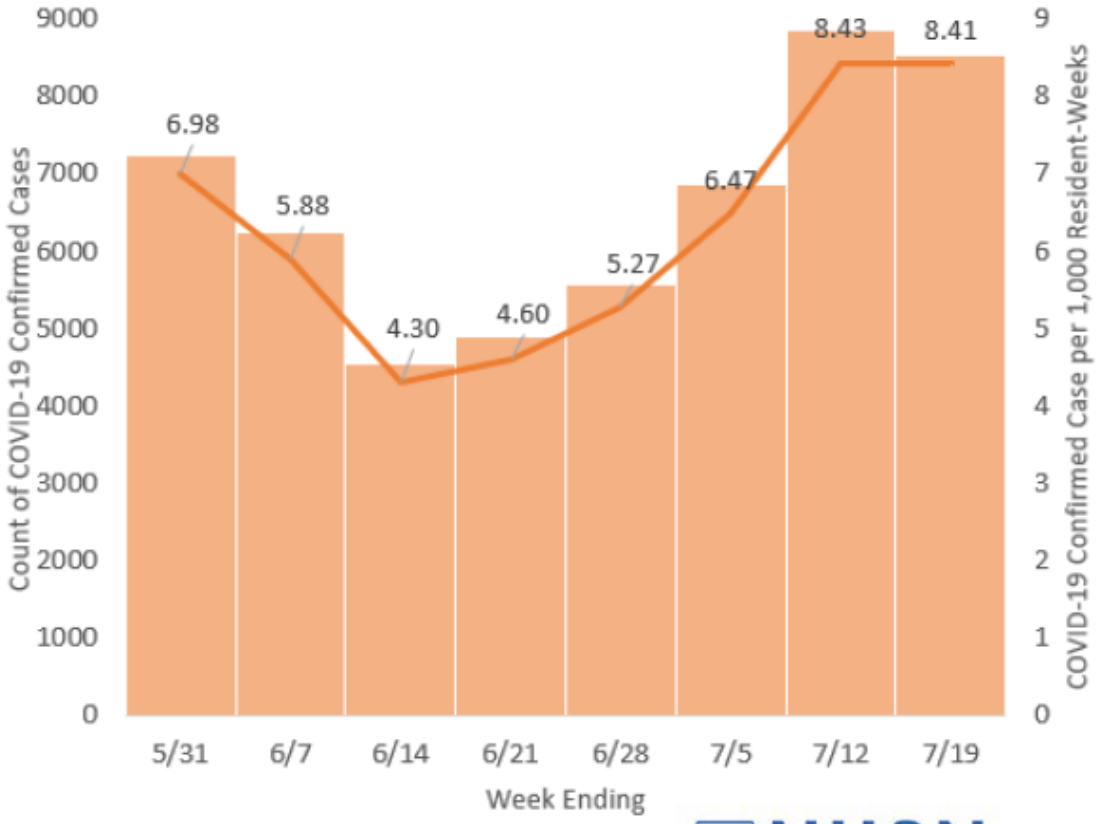
*Mark Levine, MD, Commissioner of Health*

# Long Term Care Facility Workforce

- Disproportionately lower-wage workers
- **39%** of workers are 50 years of age or older
- **82%** of workers are female, **26%** non-Hispanic Black persons
- Staff can be shared among multiple facilities
- In many instances, COVID-19 activity increases among LTCF **staff** first, and then residents

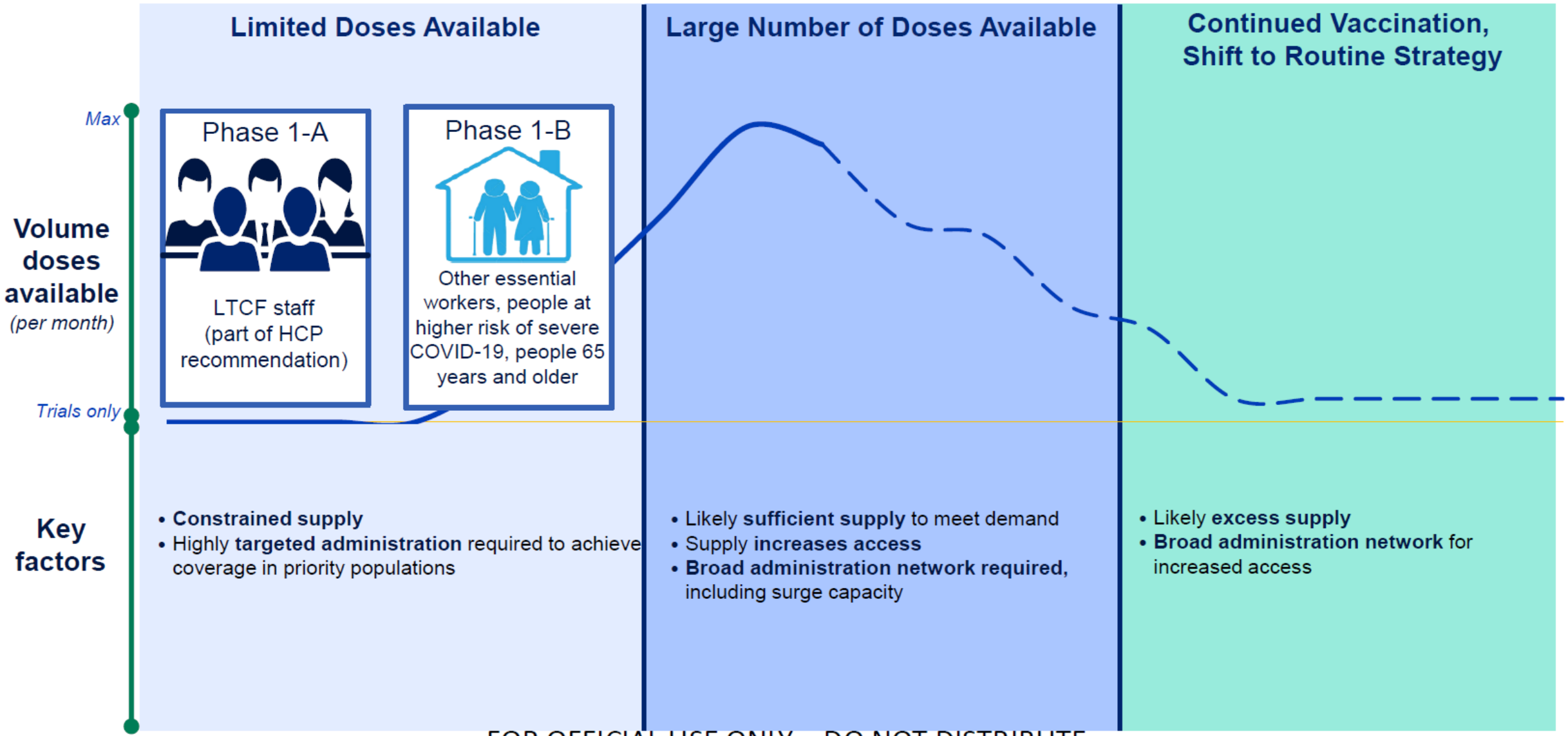
**Cases among Staff at Skilled Nursing Facilities**

Count and Incidence per 1,000 Resident Weeks




Data from NHSN LTCF module:
https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/

NHSN NATIONAL HEALTHCARE SAFETY NETWORK

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# COVID-19 Vaccine Opportunities for LTCF when doses are limited

## Phase 1-A: High-risk health workers

LTCF staff may be vaccinated with other HCP via the state allocation of vaccine (through a hospital or other entity)

This process is still under development and more information will be communicated when available.

## Phase 1-B: LTCF residents

**(and staff not included in Phase 1-A)**

Option 1: Facility or provider administers through enrollment and receipt of state allocations.

Option 2: On-site vaccination services provided through pharmacy partner (CVS or Walgreens) using direct federal allocations

# Pharmacy Partnership for LTCF COVID-19 Vaccination

## CDC has partnered with CVS and Walgreens for on-site COVID-19 vaccination services at LTCF

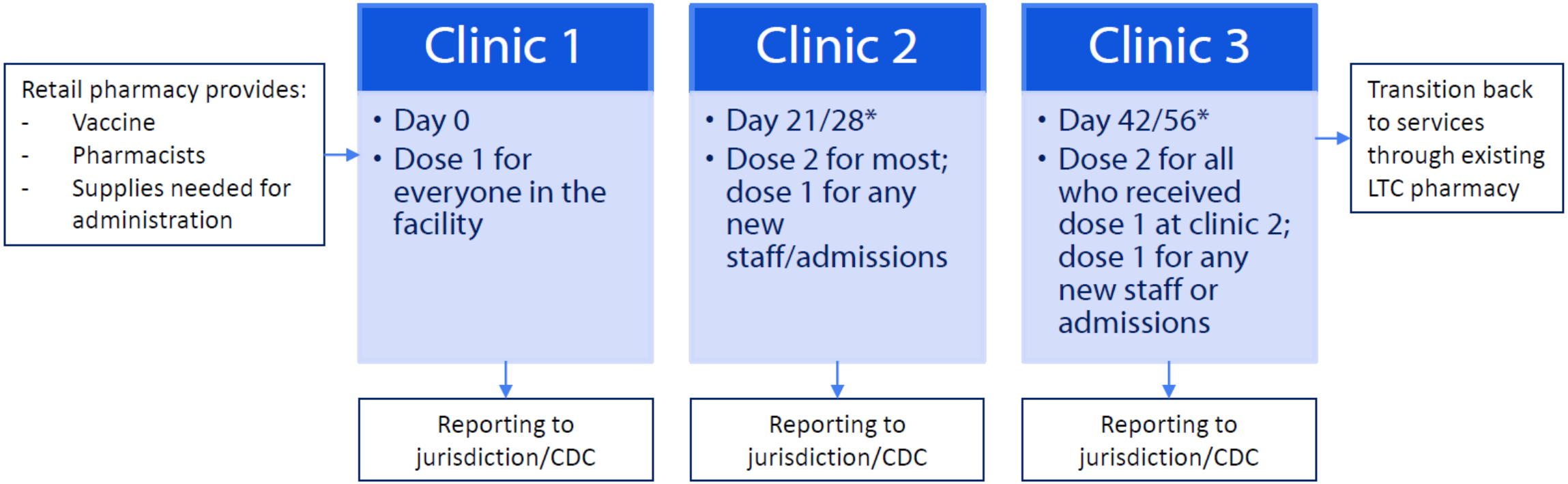
Who is eligible for the partnership?

- *Skilled Nursing Facilities (Nursing Homes)*
  - *Will enroll through the National Healthcare Safety Network (NHSN)*
- *Assisted Living Facilities*
  - *Includes: Residential Care Homes, Assisted Living Communities, and Therapeutic Community Residences*
  - *Will enroll though an online REDcap form*

*Both staff and residents would be able to receive the vaccine at no charge.*

# Federal Planning: Proposed On-Site Pharmacy Administration Services For LTCFs

*Service offerings may change pending discussions with partners*




* Depending on product

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# Signing up for the pharmacy partnership takes much of the burden off your facility.

## On-Site Services Provided by Retail Pharmacy Partners

- On-site clinics will be free to facilities.
- Available to all residents and any staff (full-time, part-time, ancillary, and contract) not already vaccinated.
- End-to-end management by pharmacy partner:
  - Scheduling/coordination (with the LTCF)
  - Ordering, distribution, and cold chain management
  - On-site administration
  - Data reporting to states/CDC

## Self-Administered/Pharmacy or Provider of Choice

- Facility or provider of choice responsible for all steps, including:
  - Working with state to sign provider agreement
  - Meeting facility enrollment criteria
  - Ordering and maintaining vaccine.
  - Maintenance of cold chain.
  - Administration (or coordinating with pharmacy)
  - Data reporting to states/CDC (approx. 20 data fields).

# Information for Assisted Living Facility use of REDcap

- Only a 3-page survey
- Completion of the survey is non-binding but opting in later may be cumbersome.
- Assisted Living Residences will be in a drop down.
- Residential Care Homes and Therapeutic Community Residences should choose "Other" and enter facility name.
- All facilities required to enter facility info and have a point of contact.
- If you choose to opt-out, or have another pharmacy partner you wish to use, you will be asked to specify alternative plans.
- Requires **number of certified beds** in facility and **total staff** (include all full-time, part-time, ancillary, and contract staff)

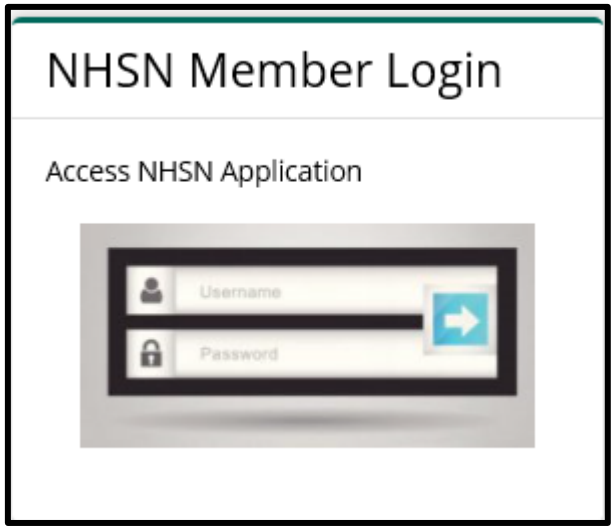
*Please complete the survey even if you choose not to participate in the partnership.*

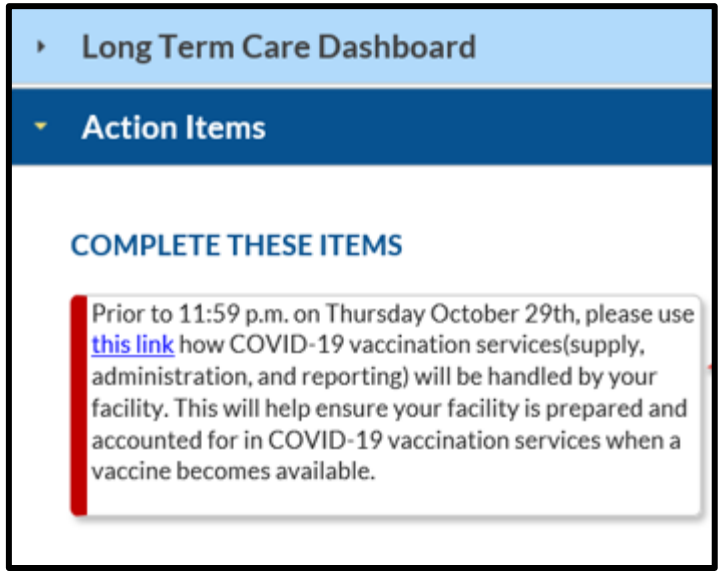
https://redcap.link/LTCF

# Information on Nursing Homes signing up with NHSN

Nursing Homes (SNFs) must sign up for the partnership though the National Healthcare Safety Network (NHSN).

https://www.cdc.gov/nhsn/index.html





# Survey will close on November 2nd , so don't wait!

- The Vermont Immunization Program needs to know about your plan
  - Please send an E-mail to AHS.VDHImmunizationProgram@vermont.gov stating:
    - Your facility name and point of contact
    - Which pharmacy (CVS/Walgreens) you selected or if you opt out
    - Post clinic 3 plan (onsite pharmacy or other pharmacy partners to enroll with the state, work with a pharmacy/practice enrolled with the state/policy to confirm vaccination status of all new residents)
- CDC will try to accommodate the pharmacy of your choosing, but changes may be required.
- The pharmacy will reach out to you directly for scheduling and logistics of the clinics.

# Conclusion

A baseline fully vaccinated status will allow your facilities to focus on later plans to continue vaccinating new staff and residents.

Plans for Phase 1-A are still in process.  Enrolling in the partnership will ensure that your staff has **easy access** to a vaccine.

# Thank you!

Questions about the partnership can be sent to
eocevent494@cdc.gov

Confirmation of survey completion or questions about the state vaccine program
AHS.VDHImmunizationProgram@vermont.gov