Ohio COVID-19 Vaccine Program Provider Enrollment Overview

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Agenda

- **Introductory Remarks**

- **Objectives**

    – COVID-19 Vaccine Planning Assumptions

    – COVID-19 Vaccine Provider Enrollment

    – What to Expect After Enrollment

- Next steps

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Objectives

- Provide you with the latest COVID-19 vaccine planning assumptions.

- Explain to you the provider enrollment platform process that you will access to register.

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Question and Answer Process

Please provide your questions in writing to:

ODH Immunization Program

covidvaccine@odh.ohio.gov

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How Ohio is preparing for COVID-19 vaccine deployment

- Ohio has launched an interagency working team to create and execute a comprehensive vaccination program

- Ohio is focused on the immediate preparedness for:

  - A statewide provider administration framework, which includes launching provider enrollment process, to register all interested vaccine providers in the coming weeks

  - Preparing a central warehouse for repackaging and redistributing vaccines to medium-sized and smaller providers across Ohio

  - Onboarding partners to the immunization registry to track vaccine administration and be able to share progress

  - Message delivery to inform the public of the most up-to-date information on vaccine availability, efficacy, and safety

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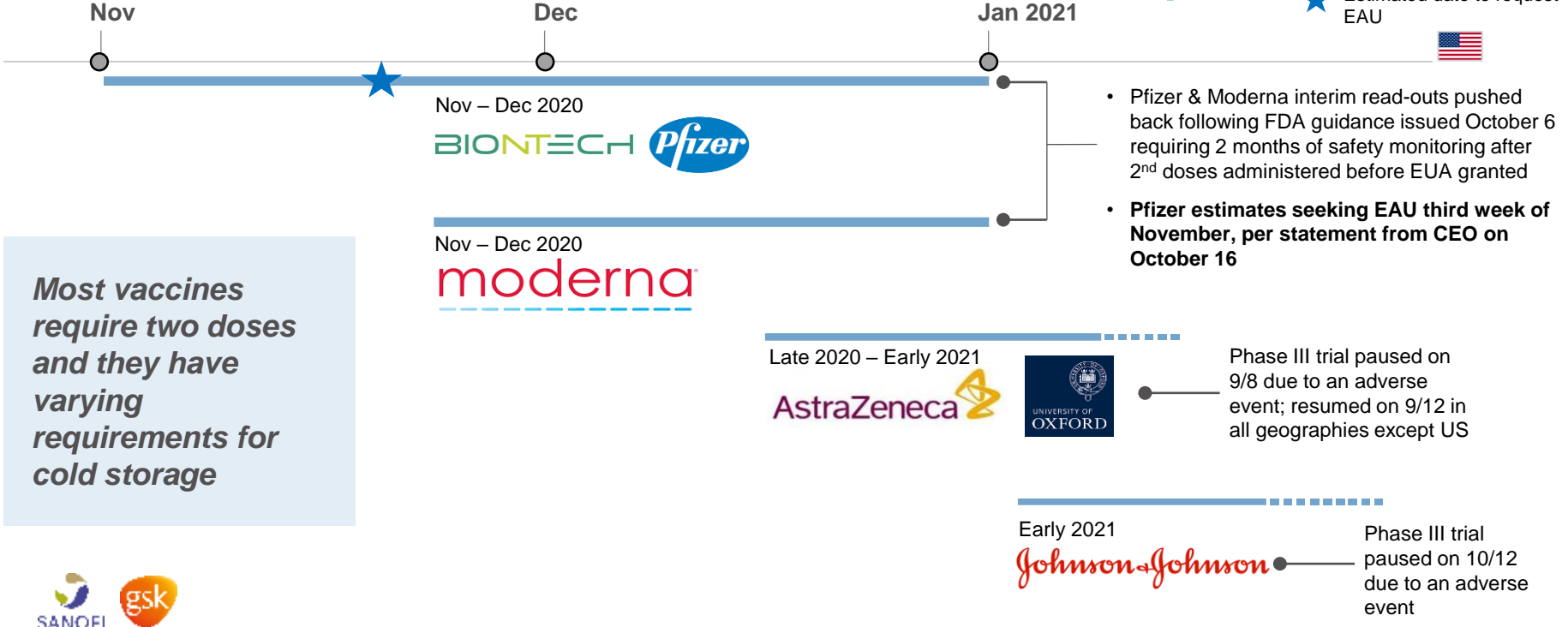
Ohio's Vaccine Framework

- A framework for planning and decision making.

- Provider organizations, local leaders and health care experts will be engaged for input and logistical planning.

- The framework submitted to the CDC is a living document that will be updated as vaccine development advances, logistics capacities are identified and stakeholder input is gathered.

In development:

- Critical population segmentation
- Allocation
- Distribution and shipment
- Metrics
- Data reporting

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Current COVID-19 vaccine landscape

Announced target interim data to inform EUA

★ Estimated date to request EUA

🇺🇸

Nov — **Dec** — **Jan 2021**

Nov – Dec 2020

BIONTECH *Pfizer*

Nov – Dec 2020

moderna

- Pfizer & Moderna interim read-outs pushed back following FDA guidance issued October 6 requiring 2 months of safety monitoring after 2nd doses administered before EUA granted

- **Pfizer estimates seeking EUA third week of November, per statement from CEO on October 16**

Most vaccines require two doses and they have varying requirements for cold storage

Late 2020 – Early 2021

AstraZeneca | UNIVERSITY OF OXFORD

Phase III trial paused on 9/8 due to an adverse event; resumed on 9/12 in all geographies except US

Early 2021

Johnson&Johnson

Phase III trial paused on 10/12 due to an adverse event

SANOFI **gsk**

Source: BioCentury; ClinicalTrials.gov; Milken Institute COVID-19 Treatment and Vaccine Tracker, FDA/ Operation Warp Speed, NY Times, Moderna, Pfizer, and J&J press releases & public statements

Preliminary – Not meant to communicate clinical, legal, or regulatory advice

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COVID-19 Vaccine Planning Assumptions

- CDC does not know when a vaccine(s) will be available or how many doses may be available.

- CDC expects limited vaccine supply in the initial phase.

- Vaccine will be distributed in a phased approach.

- States should anticipate that allocations may shift during the response based on supply, demand, and risk.

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COVID-19 Vaccine Planning Assumptions

Phase Approach to COVID-19 Vaccination:

- Phase 1: Potentially limited doses available.

- Phase 2: Large number of doses available.

- Phase 3: Sufficient supply of doses available.

- We don't know yet which of the vaccines will be available or how quickly vaccine supply will be scaled up to meet demand after the initial allocation.

- More information will be provided as it becomes available.

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COVID-19 Vaccine Planning Assumptions

- The Advisory Committee on Immunization Practices (ACIP), with input from the National Academies of Sciences, Engineering, and Medicine (NASEM), is considering recommendations for who should receive early doses of COVID-19 vaccine when supply may be limited.

- As more vaccine quickly becomes available, the goal is to provide easy access to vaccination for everyone who wants to be vaccinated. More information will be shared as soon as it is available.

COVID-19 Vaccine Planning Assumptions

- Initial supply of COVID-19 vaccine may be under an Emergency Use Authorization (EUA) issued by the FDA.

- Cold Chain requirements will vary from refrigerated (2 C to 8 C) to frozen (-20 C) to ultra-cold (-60C to -80 C). Stability testing is ongoing that may impact requirements.

  - The CDC currently is not recommending purchase of ultra-cold storage.

- Some products may require 2 doses, separated by 21 or 28 days.

- Products will not be interchangeable, so both doses must be with the same product.

- Some products may require reconstitution with diluent or adjuvant.

COVID-19 Vaccine Planning Assumptions

- Vaccine shipment amounts will vary based on the vaccine.

- The minimum order size and increment for federally distributed vaccines will be 100 doses per order; though early in the response, some may be shipped in larger quantities.

- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs.

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COVID-19 Vaccine Planning Assumptions

- Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders.

- Each kit will contain supplies to administer 100 doses of vaccine, including:

  - 105 needles (various sizes for the population served by the ordering vaccination provider).

  - 105 syringes.

  - 210 alcohol prep pads, four surgical masks and two face shields for vaccinators.

  - 100 COVID-19 vaccination record cards for vaccine recipients.

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Pharmacy Partnership for Long-term Care (LTC) Program

- CDC is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for residents of nursing homes and assisted living facilities

- Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the vaccination process

- As part of this program, which is free of charge to facilities, the pharmacy will:
  - Schedule and coordinate on-site clinic dates directly with each facility and provide on-site administration of vaccine
  - Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment) and ensure cold chain management for vaccine.
  - Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 72 hours of administering each dose.

- If interested in participating, LTCFs should sign up via National Healthcare Safety Network www.cdc.gov/nhsn/index.html

Source: CDC

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COVID-19 Vaccine Provider Enrollment
High-level process ahead

■ Focus today   *Additional details on other steps will be covered in later phases*

• **Enrollment**	• **Approval**	• **Training**	• **Distribution**
• Online form submission	• Validation of provider registrations	• Completion of relevant training	• Reception of vaccines

COVID-19 Vaccine Provider Enrollment

- To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their State's immunization program.

- Enrolled COVID-19 vaccination providers must be credentialed/licensed in the state of Ohio, and sign and agree to the conditions in the CDC and Ohio COVID-19 Vaccination Program Provider Agreements.

- Due to the phased approach for vaccine delivery, providers may be prioritized in the enrollment process.

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How To Become an Ohio COVID-19 Vaccine Provider

- Visit OHID webpage: https://ohid.ohio.gov/ Log-in using your OHID, or create a new account.

- Then click the *Sites & Applications* tab and search the App Store for "Vaccination Program (COVID-19)" to request access.

- Complete, sign and submit all required forms electronically through OHID.

COVID-19 Vaccination Enrollment Required Agreements

1. (Section A) CDC COVID-19 Vaccination Provider Agreement

   – This agreement must be electronically signed by your Facility's Chief Medical Officer and Chief Fiduciary Officer, or equivalents.

2. (Section B) CDC COVID-19 Vaccination Provider Profile

   – This agreement collects Vaccination Provider Profile elements.

3. ODH Outbreak Response Immunization Initiative Agreement

4. Impact Statewide Immunization Information System Security Agreement (if not a registered facility)

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How To Become an Ohio COVID-19 Vaccine Provider

- You must complete a (Section A) COVID-19 Provider Agreement before you can begin any other required form.

- You will need your site's Terminal Distributor License (TDDD) number. This number will be used to link the individual forms.

- For more information on TDDDs or to find your Organization's TDDD Number please visit the State of Ohio Board of Pharmacy: https://elicense.ohio.gov/oh_verifylicense.

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(Section B) COVID-19 Vaccination Program Profile Elements

- Address for receiving site and vaccination site, if different.

- Contact information for primary and back-up vaccination coordinator.

- Days and times vaccine coordinators are available for receipt of vaccine shipments.

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COVID-19 Vaccination Provider Profile Elements

- Vaccination provider type (e.g. urgent care, hospital, occupational health).

- Vaccination setting (e.g. school, pharmacy store, workplace, mobile clinic).

- Number patients routinely served, by age group.

- Peak week of influenza vaccination doses administered in previous season.

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COVID-19 Vaccination Provider Profile Elements

- Population served (e.g. pregnant women, pediatric, persons over 65 years of age).

- If organization already reports to jurisdiction's immunization information system (IIS).

- Storage capacity (along with temperature monitoring devices) at various temperature ranges, based on number of 10 dose multidose vials.

- List licensed healthcare providers at this location who have prescribing authority with license number.

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After Agreements are Submitted

- You will receive an email after you have submitted each required document to ODH.

- Once your agreements have been approved, you will receive communications from ODH regarding training for staff and temperature verification procedures.
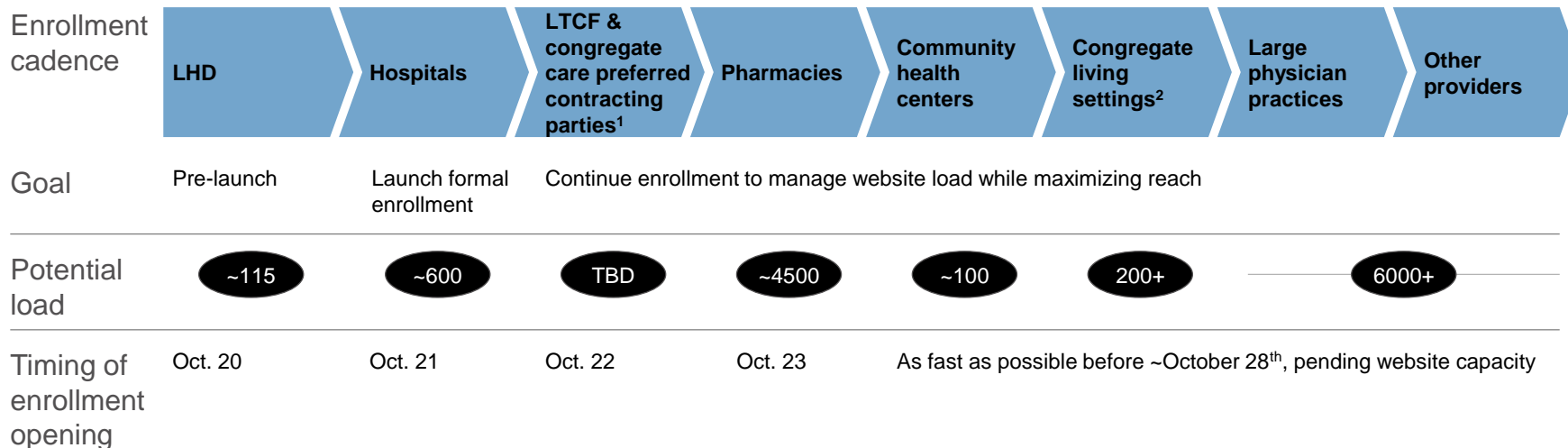
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After Agreements are Submitted

- In order to receive COVID-19 vaccines, all providers must attest to participation or review of COVID-19 vaccine training.
  - Providers must submit verification of training.
  - Once your enrollment documents have been approved, you will receive further instructions regarding training and verification submission requirements.

- All locations that will store COVID-19 vaccine must provide verification of required temperature monitoring devices and stable temperatures for a defined period of time.
  - Providers will submit stability data to ODH prior to delivery of vaccines.
  - Once your enrollment documents have been approved, you will receive further instructions regarding how to submit temperature verification documents.

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After Providers Are Enrolled

- ODH will send you a final confirmation via e-mail after your site is enrolled and information about when your facility may order COVID-19 vaccine.

- Given phased vaccine distribution, providers should expect subsequent communications at different times.

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Provider enrollment phasing

Enrollment cadence	LHD	Hospitals	LTCF & congregate care preferred contracting parties[1]	Pharmacies	Community health centers	Congregate living settings[2]	Large physician practices	Other providers
Goal	Pre-launch	Launch formal enrollment	Continue enrollment to manage website load while maximizing reach					
Potential load	~115	~600	TBD	~4500	~100	200+		6000+
Timing of enrollment opening	Oct. 20	Oct. 21	Oct. 22	Oct. 23	As fast as possible before ~October 28th, pending website capacity			

1. That are not addressed by LHD, hospitals, and / or pharmacies; applies to BH/DODD/Veteran Homes congregate sites
2. Congregate living settings include homeless shelters, jails, youth services, SUB facilities, etc.

Source: Ohio OneSource Facility Lookup portal

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Next steps

Visit https://ohid.ohio.gov/ following this webinar.

More information available on CDC website.

Contact us for questions or follow-up:

ODH Immunization Program
covidvaccine@odh.ohio.gov

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