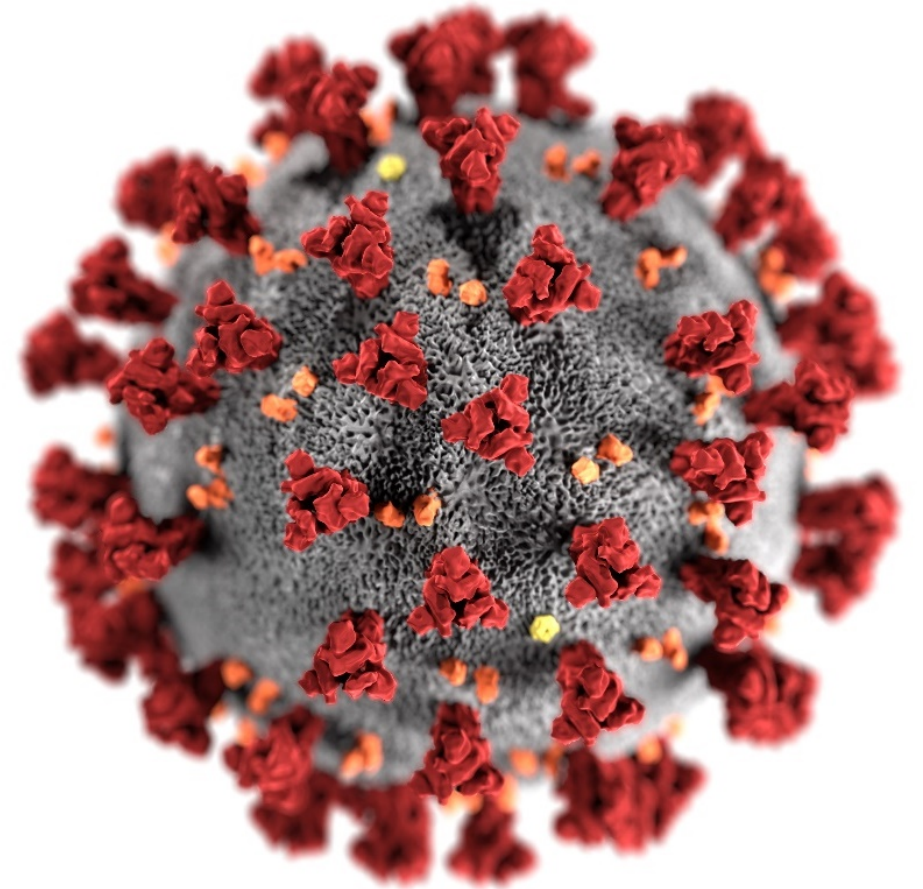


Vaccines and Related Biological Products Advisory Committee Meeting Presentation - Distribution Overview

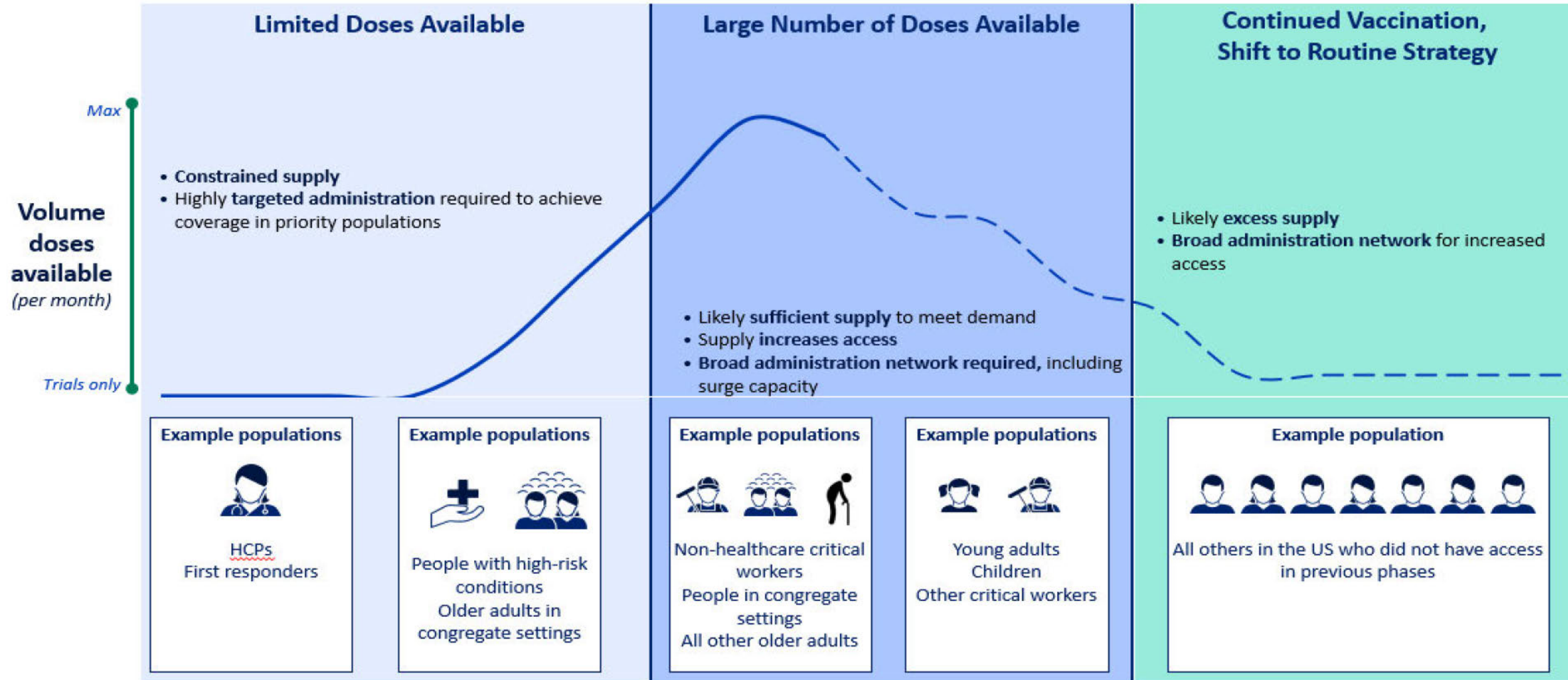
Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

Distribution Overview

Anita Patel, PharmD, MS
Deputy, Vaccine Task Force

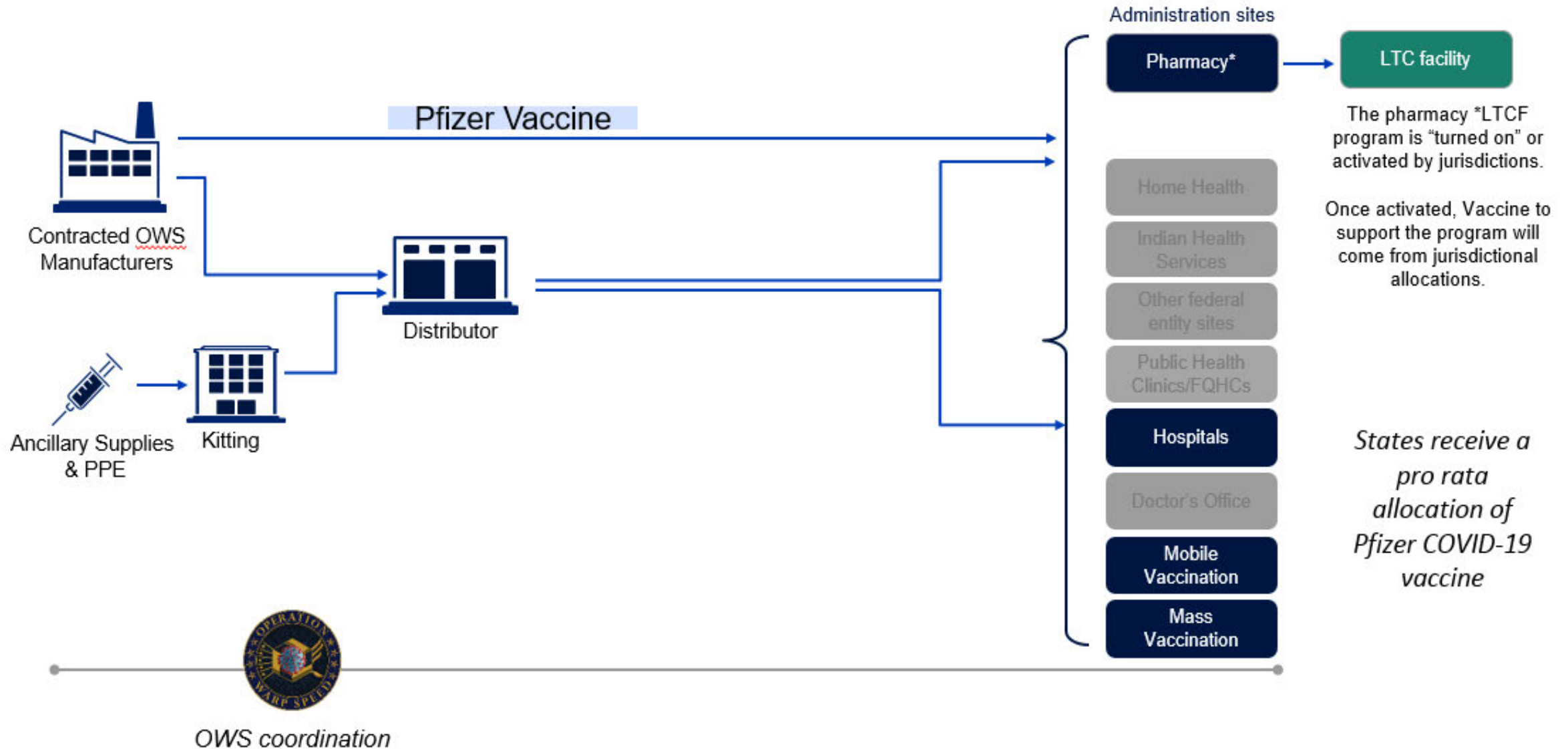


Distribution will adjust as volume of vaccine doses increases

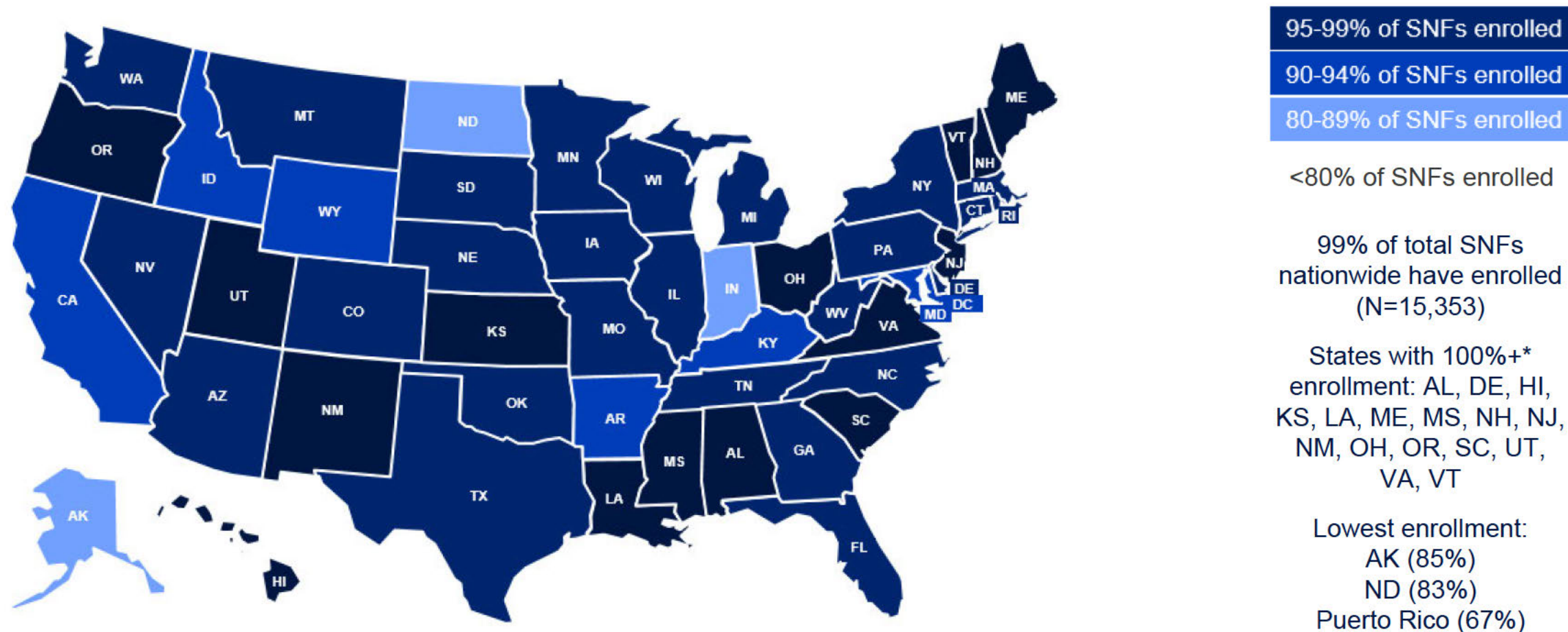


DO NOT DISTRIBUTE

Overview of Early Distribution for Pfizer Vaccine



SNFs enrolled in pharmacy partnership for long term care program (as of 11/15)



* States >100% enrollment: numerator may include non-CMS-certified SNFs. Denominator is only CMS-certified.

Pfizer vaccine requirements:

Distribution, storage, site , administration

Distribution requirements

- Vaccine must be kept at ~ -75° throughout supply chain
- Product is direct shipped in ultra low temperature 'Thermal shippers' to maintain ultra cold chain
- Minimum order/ship quantity = 195 vials = 975 doses
- Reverse logistics to return reusable shippers

Site storage requirements

- Product can be stored in ultra low temperature freezer or temporarily in Thermal shipper
- Thermal shipper must be re-charged with 23kg dry ice within 24 hrs once opened
- If opened 2x/day (3 min / opening) and used for longer-term storage, shipper must be refilled with dry ice every 5 days – max life of 30 days
- Vaccine can be stored at 2-8°C for 5 days; cannot refreeze

Administration requirements

- At-site mix with diluent (0.9% saline USP)
- Thawed product must be used or disposed of within 6 hours
- Atypical, 0.3mL dose volume
- Dilution, mixing ancillary supplies required (0.9% saline USP, 3mL syringes, etc.)
- Full course = 2 doses, separated by ~21 days

Pfizer vaccine requires additional planning for distribution, storage, handling, and use

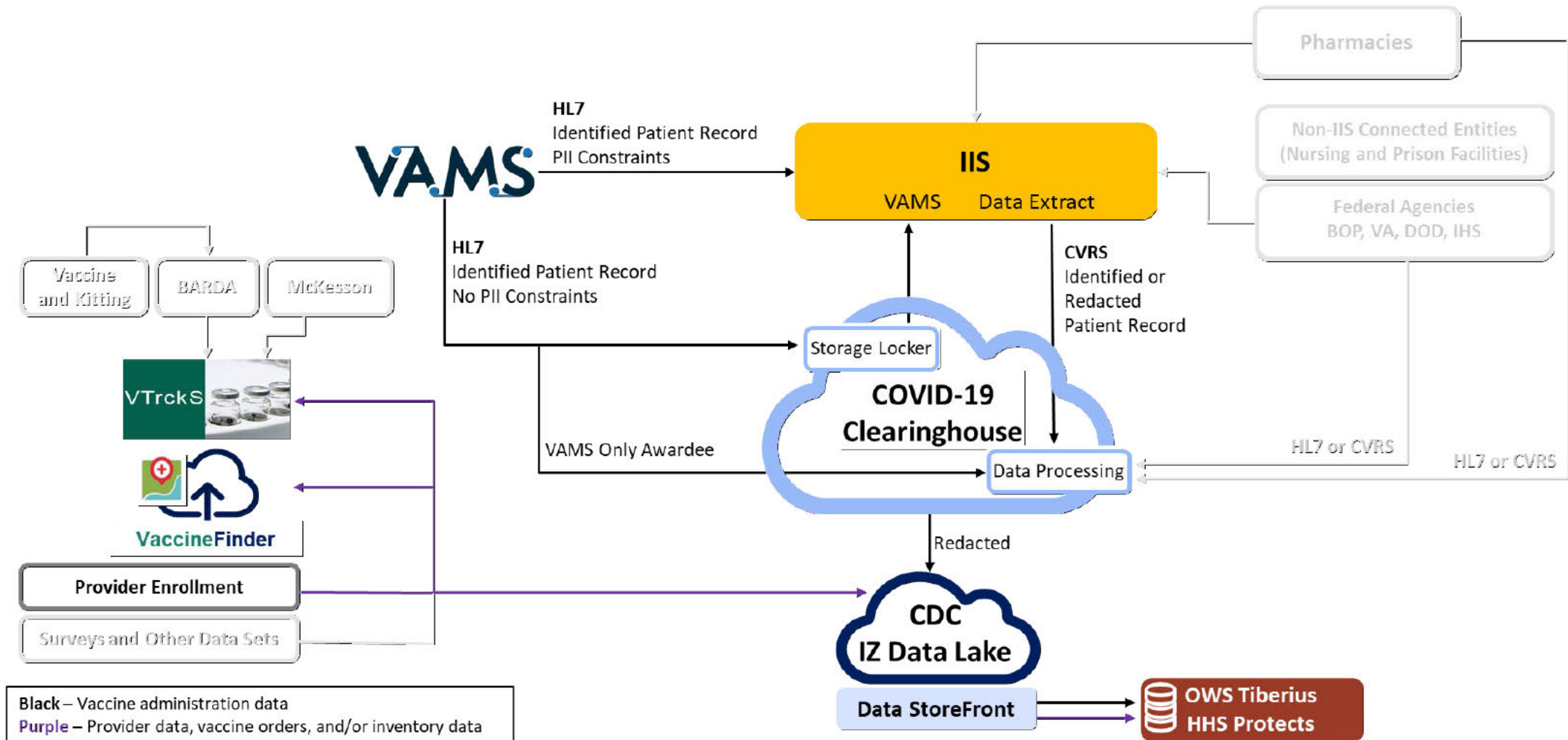
- **Dedicated cold chain:** Product requires dedicated operations throughout supply chain to appropriately ship, receive, and store at ultra low temp
- **Timing:** Timing of vaccine, ancillary supplies, and dry ice replenishment must arrive and be received at sites near
- **Minimum order/ship quantity:** Requires re-distribution to less populated geographies, local level, or less equipped sites
- **Thermal shipper:** Training for staff in sites using thermal shipper to manage ultra low temperature monitoring, dry ice replenishment, and to administer product before expiry or risk of waste
- **Mixing, use:** Unique administration requirements will require detailed training for clinical personnel
- **Inventory planning:** Sites must plan inventory to ensure sufficient supply for administration of boost doses, while reminding patients to return

Extra Slides



COVID-19 Immunization Data Architecture – Day 1

For reporting provider, inventory, and vaccine administration data on Day 1, the data will follow the paths depicted in the Data Architecture below.



OWS IT Architecture

