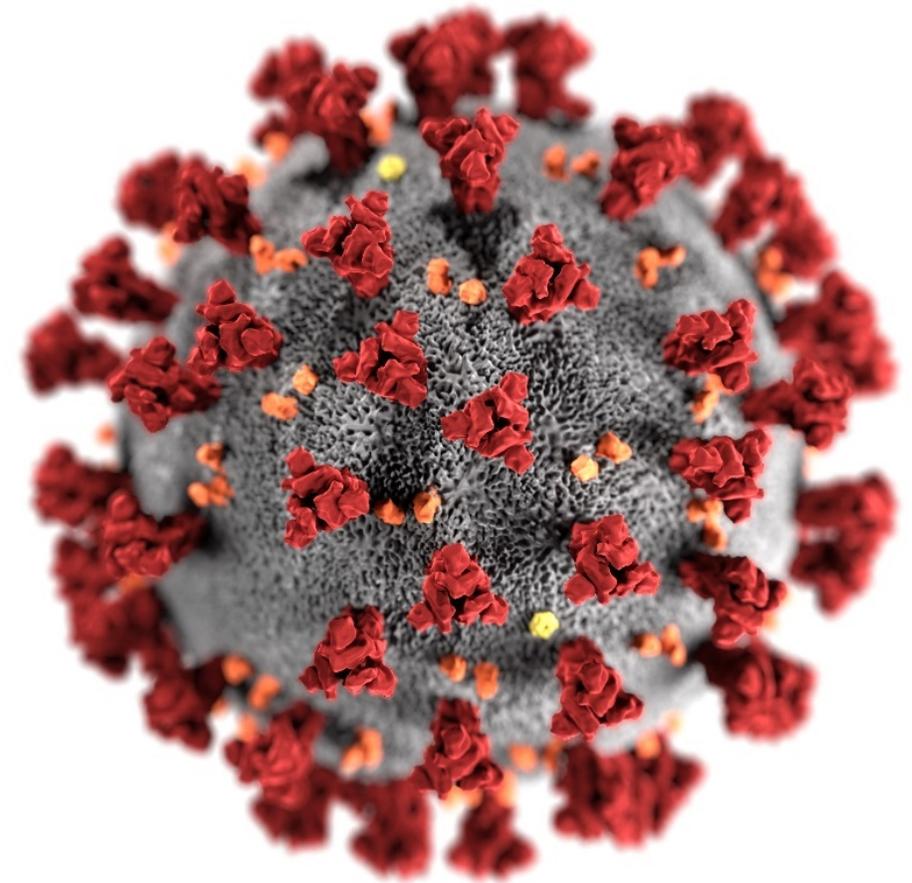


Vaccines and Related Biological Products Advisory Committee Meeting Presentation - Distribution Overview

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.

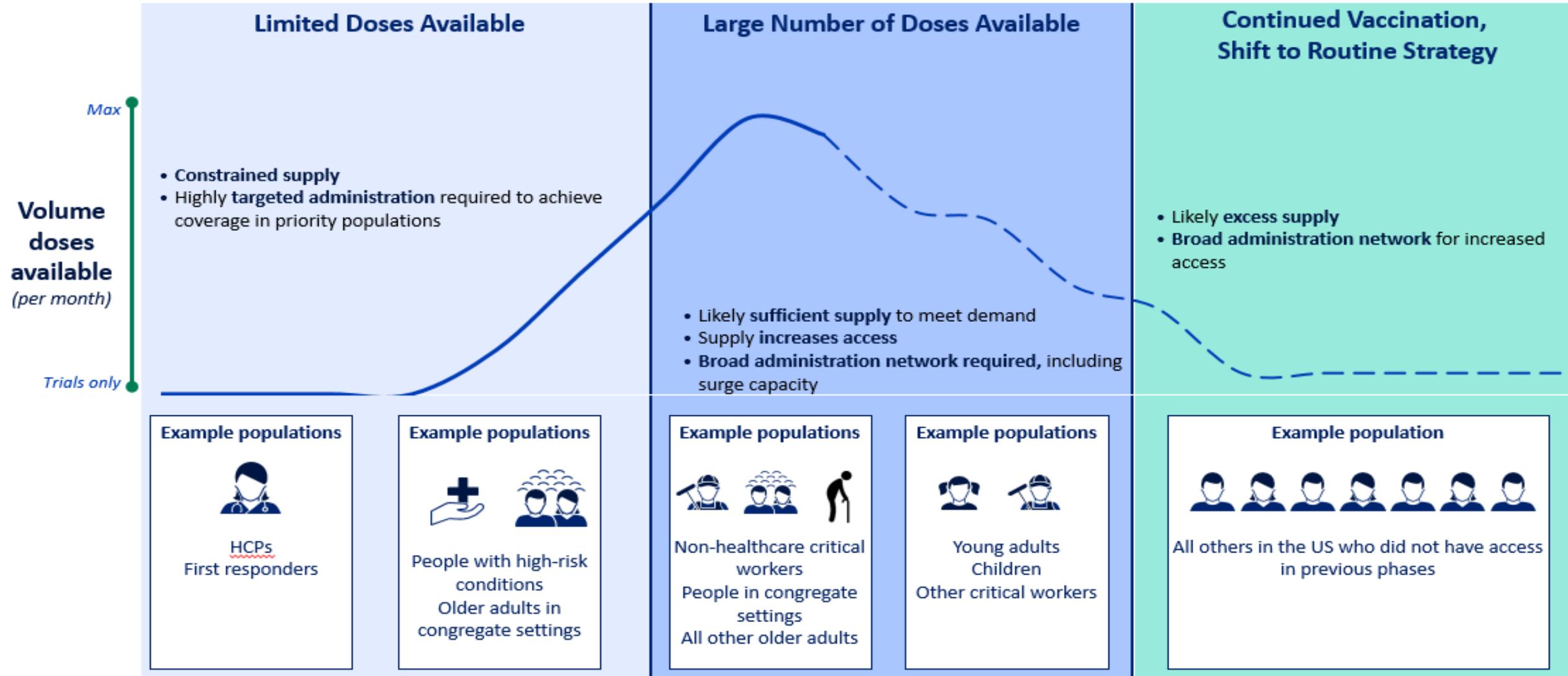
Distribution Overview

Anita Patel, PharmD, MS
Deputy, Vaccine Task Force

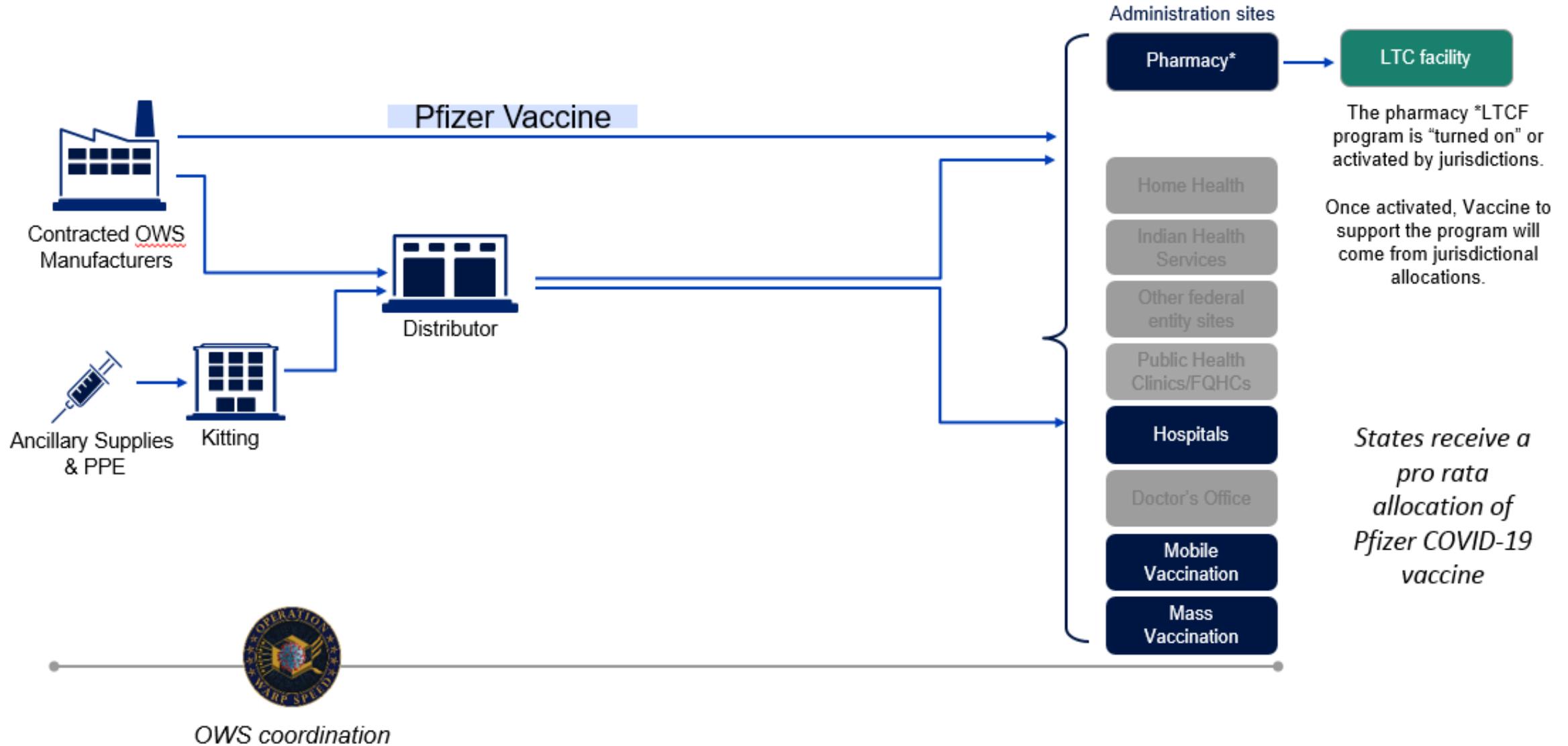


For more information: www.cdc.gov/COVID19

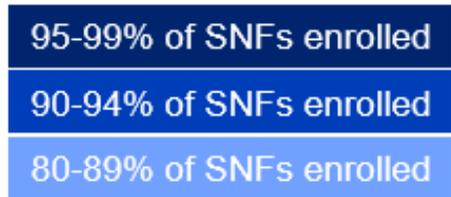
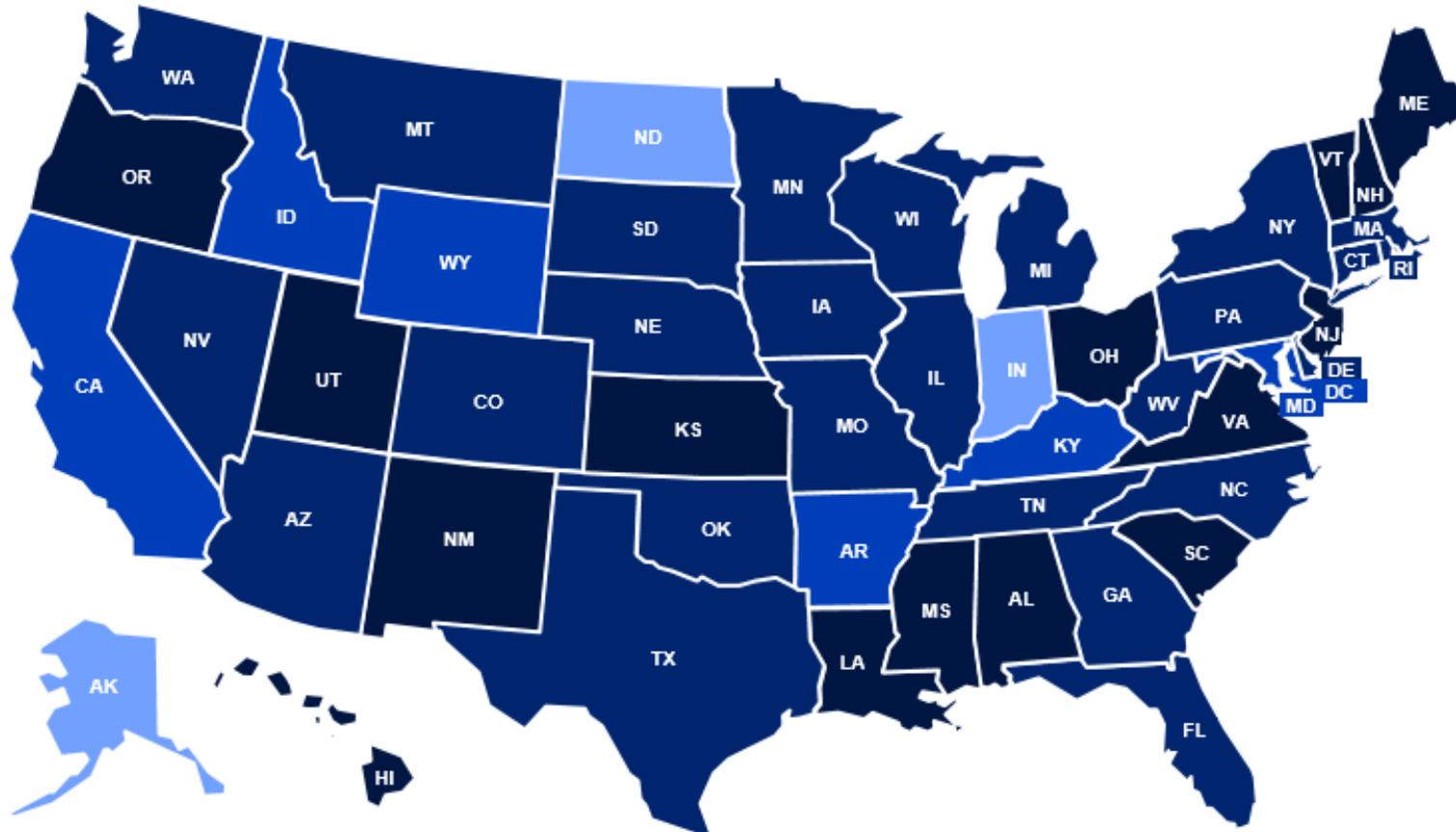
Distribution will adjust as volume of vaccine doses increases



Overview of Early Distribution for Pfizer Vaccine



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



<80% of SNFs enrolled

99% of total SNFs nationwide have enrolled (N=15,353)

States with 100%+* enrollment: AL, DE, HI, KS, LA, ME, MS, NH, NJ, NM, OH, OR, SC, UT, VA, VT

Lowest enrollment:
AK (85%)
ND (83%)
Puerto Rico (67%)

* 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

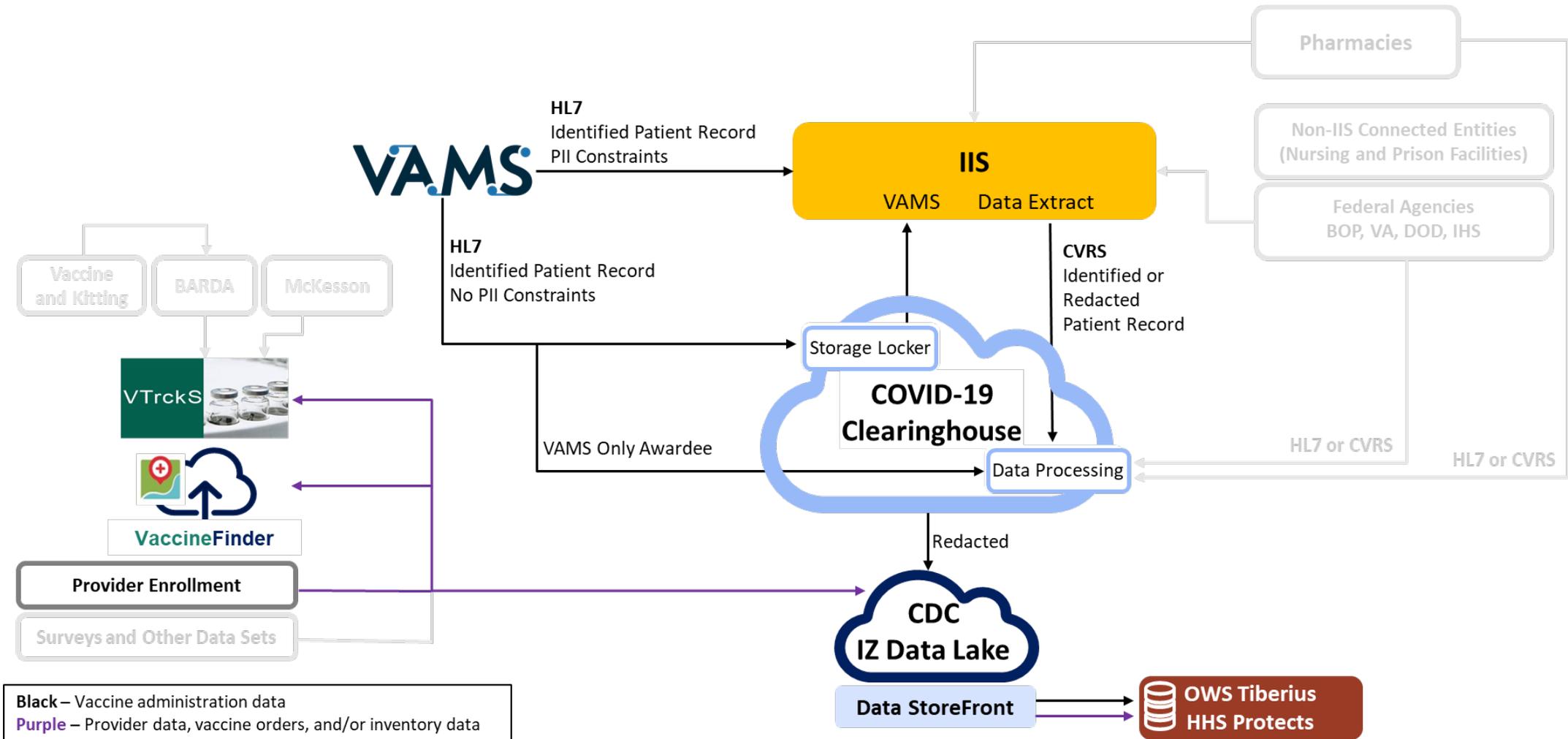
- **Dedicated cold chain:** Product requires dedicated operations throughout supply chain to appropriately ship, receive, and store at ultra low temp
- **Timing:** Timing of vaccine, ancillary supplies, and dry ice replenishment must arrive and be received at sites near
- **Minimum order/ship quantity:** 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

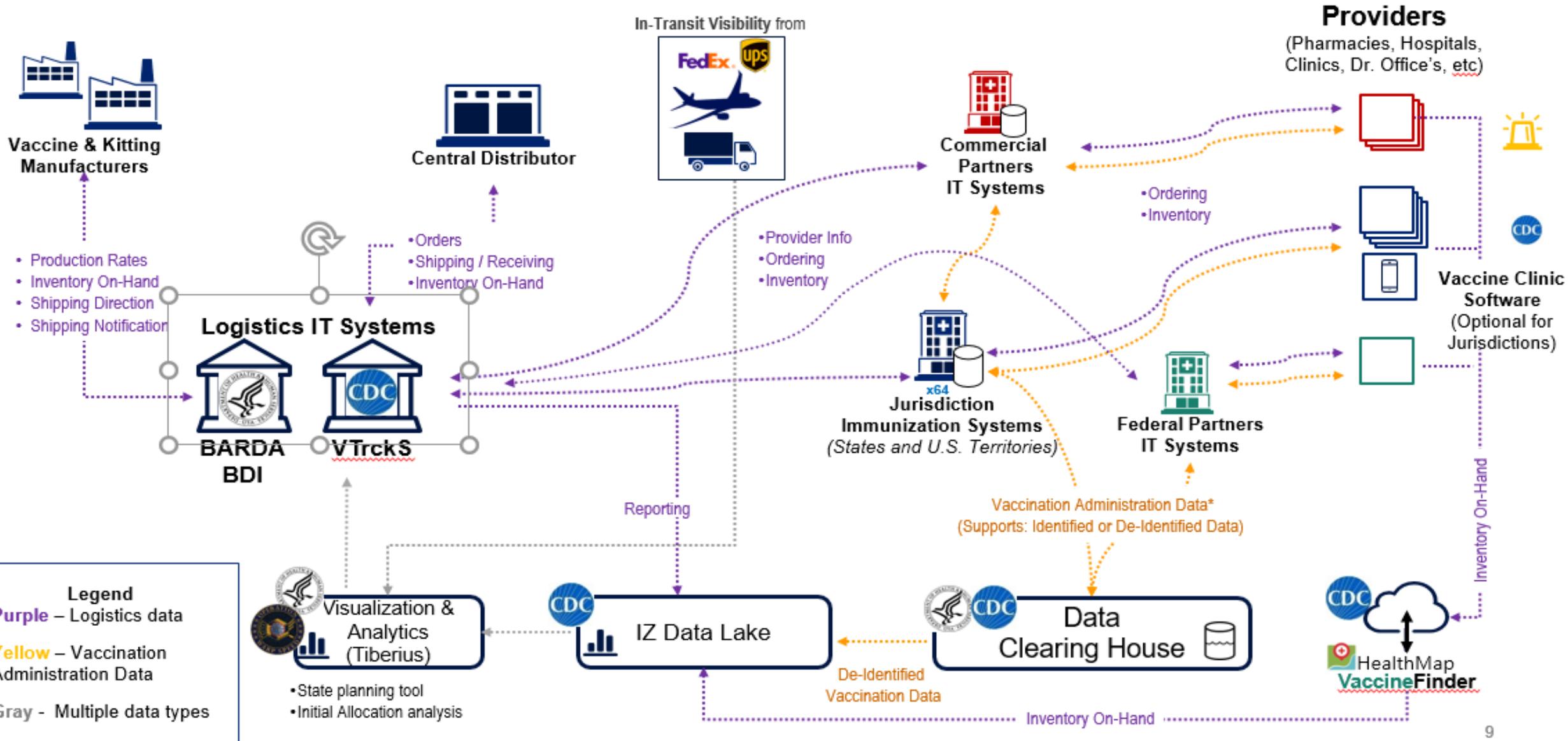


COVID-19 Immunization Data Architecture – Day 1

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



*Admin Data reported per COVID-19 Vaccine Reporting Specification