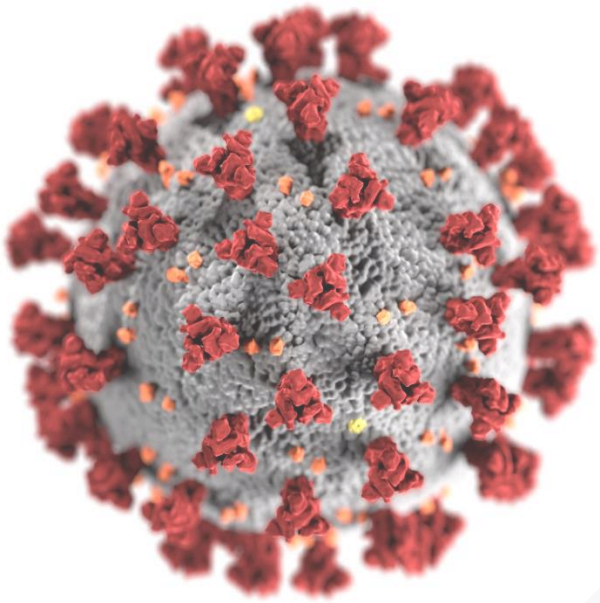

# COVID-19 Vaccination Plan

## TENNESSEE

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Tennessee Department of Health
12/30/20 | VERSION 3.0

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## Record of Changes

**Date of original version: 10/16/2020**

| Date Reviewed | Change Number | Date of Change | Description of Change | Name of Author |
|---|---|---|---|---|
| 10/22/2020 | 2.0 | 12/03/2020 | Updates to prioritization to reflect ACIP recommendations issued 12/1/2020. Updates to VOMS reconciliation and dashboarding. | MFiscus |
| 12/21/2020 | 3.0 | 12/30/2020 | Updates to prioritization to reflect ACIP recommendations issued 12/20/2020. Updates to distribution strategy. | MFiscus |
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| | | | |

## Section 1: COVID-19 Vaccination Preparedness Planning

**A.** ***Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.***

a. The TDH Communicable and Environmental Disease and Emergency Preparedness (CEDEP) division served as lead for the 2009 H1N1 Influenza Pandemic Outbreak response in Tennessee. TDH CEDEP response activities included establishing command and control, defining communication pathways, refining surveillance and epidemiology, revisiting fatality management, expanding laboratory services, coordination of mass vaccination clinics through local, regional, and metropolitan health departments, hiring of temporary staff, vaccine distribution, tracking doses administered, warehousing and distribution of medical countermeasures, deployment of personal protective equipment (PPE), processing contracts (including the state's influenza call center and provision of immunization services to agencies targeting underserved populations), and development of mass media messaging and guidance. There were lessons learned and best practices identified from this response that generated numerous opportunities for TDH staff to deliver abstracts, posters, presentations, and articles. Early vaccine planning activities and lessons learned included:

- Engaging federal officials from CDC, HHS ASPR, and other Region IV states in a gap analysis discussion pertaining to where the federal response ends and the state and local response begins.
- Identification of ancillary supplies (needles, syringes, sharps containers, etc.) needed to mount a massive vaccination response as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
- Identification of both fixed and mobile cold chain capacity (vaccine refrigerators, mobile coolers, fridge freeze units, temperature data loggers, etc.) to store vaccine both centrally and allow for mobile vaccination operations in the community as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
- Identification of external stakeholders with vaccination response expertise to best inform resource allocation decisions and public messaging strategies.
- Identification of surge contract staffing needs for almost every aspect of the vaccination response including clerical, administrative, clinical, epidemiology, and information technology as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
- Identification of essential elements of information and response metrics that will be needed to inform the public and local, state, and federal leadership on a regular basis through situation reporting, data visualization, and dashboarding.

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- Identification of immunization information system enhancements and a multi-tier cohort of knowledgeable staff that can operate all aspects of vaccine systems response from provider enrollment, validation, vaccine allocation, reporting, and technical assistance.
- Conduct outreach to vulnerable populations through non-profit entities and update GIS mapping of known vulnerable populations to target vaccine interventions.
- Identification of proactive administrative preparedness steps and removal of barriers that can be taken to expedite procurement, contracting, and allocation of grant dollars to sub-recipients.

b. The TDH Vaccine-Preventable Diseases and Immunization Program (VPDIP) worked closely with the Emergency Preparedness Program to respond to the hepatitis A outbreak from December 2017-May 2020, involving more than 3,000 cases. Experience gained and gaps identified included:
    - TDH Incident Command System was activated and provided a sustained, coordinated response for 18 months.
    - Local health departments were tasked to complete case interviews, perform contact tracing and monitoring, and provide individual and public communications and needed to reassign duties to meet the demands of that outbreak response.
    - Vaccination strike teams were deployed across the state to reach vulnerable populations at risk of contracting and spreading the virus. More than 23,000 doses of hepatitis A vaccine were provided by six strike teams and nearly 233,000 doses were administered by private and public health providers in medical offices, health departments, jails, prisons, drug rehabilitation centers, medically-assisted opioid treatment programs, homeless shelters and encampments, and other locations where those not routinely seeking healthcare could be reached. These strike teams proved to be a best practice for the successful administration of vaccines to at-risk populations.
    - Challenges included individual concerns regarding the vaccine itself and mistrust of the government, the hiring and supervision of large numbers of contracted workers, coordination of efforts and communication with metro jurisdictions that are not under the umbrella of TDH, and the need for sustained public communication around this prolonged outbreak.

**B.** ***Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.***

a. With the support of executive leadership in 2018 the Tennessee Department of Health initiated a statewide pandemic preparedness vaccination effort known as Fight Flu TN. The goal of the effort was to empower each of our 95 counties to build robust and trusted community partnerships, vaccination plans, trained staff, and ability to operate autonomously in the face of worldwide pandemic. This was coupled with the interest of

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improving vaccination rates and the need to innovate vaccination administration strategies.

- On Dec. 5, 2018, TDH stood up 115 Points of Dispensing (PODs), 113 that were open to the public (of those 84 were walk-through on site, 21 walk-through off site, and 8 drive through) and 2 closed PODs for special populations and a total of nearly 4,500 vaccines were administered in one day across the 95 counties. In total over 1,200 staff were involved in the response efforts which included not only the vaccination PODs but also 14 Health Emergency Operations Centers at the state and local level. Statewide after action reporting and improvement plans were developed with continuous quality improvement in mind.
- On Nov. 19, 2019, TDH increased the number of simultaneously opened PODs from 115 to 175, including 156 open PODs (of those 56 were walk-through on site, 75 walk-through off site, and 25 drive through) and 19 closed PODs for special populations (of those 15 were for vulnerable populations and 4 for first responders), and the number of administered doses of flu vaccine doubled to 9,666. Statewide after action reporting and improvement plans were developed with continuous quality improvement in mind. Additionally, vaccines administered during Fight Flu TN were recorded manually into TennIIS (Tennessee Immunization Information System) after the conclusion of the event.
- On Nov. 19, 2020, TDH activated its public health infrastructure in all 95 counties to Fight Flu TN. All local health departments developed plans that were tailored to accommodate the realities of our current COVID-19 response. In addition, community healthcare partners, universities, and others were engaged in this one-day preparedness event that furthered our movement toward COVID-19 vaccine preparedness. This year's exercise also incorporated real-time reporting of administered doses of vaccine into TennIIS through a new Mass Immunizations Module, which allows for the rapid entering of vaccine administration data during mass immunization events.

- In collaboration with the Tennessee Emergency Management Agency (TEMA), TDH created a series of webinar-based vaccination table-top exercises which were conducted November 9, 10, and 12 in partnership with our Emergency Preparedness and Response Healthcare Coalitions (HCCs). The objectives of the exercises included vaccine assumptions, logistics, administration, and reporting and these exercises were used to educate those involved with vaccinating individuals through hospitals, employee health, and other partnering organizations.
- Tabletop exercises were conducted with Community Health Services week of November 16, 2020.
- Tabletop exercises have been conducted weekly with the UCG and various stakeholders including Commissioners, National Guard and State Highway Patrol leadership, the Governor's Communications Team, TDH leadership and others. These exercises began November 20, 2020 and have continued weekly to ensure Tennessee is prepared for any scenario.

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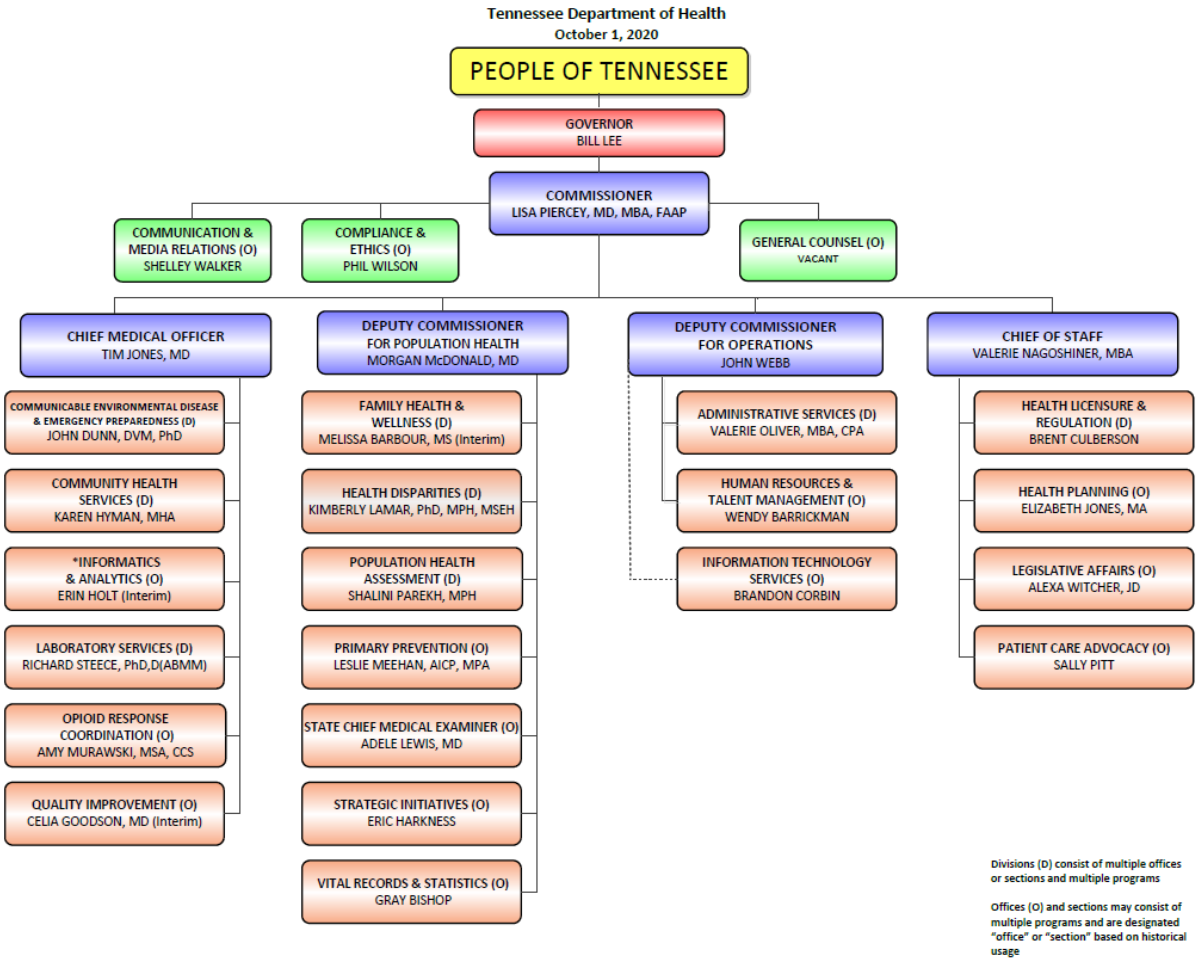
- Tabletop exercises with TN Department of Correction, began December 22, 2020.
- The Tennessee Hospital Association began participating in UCG tabletop exercises in December 2020.

## Section 2: COVID-19 Organizational Structure and Partner Involvement

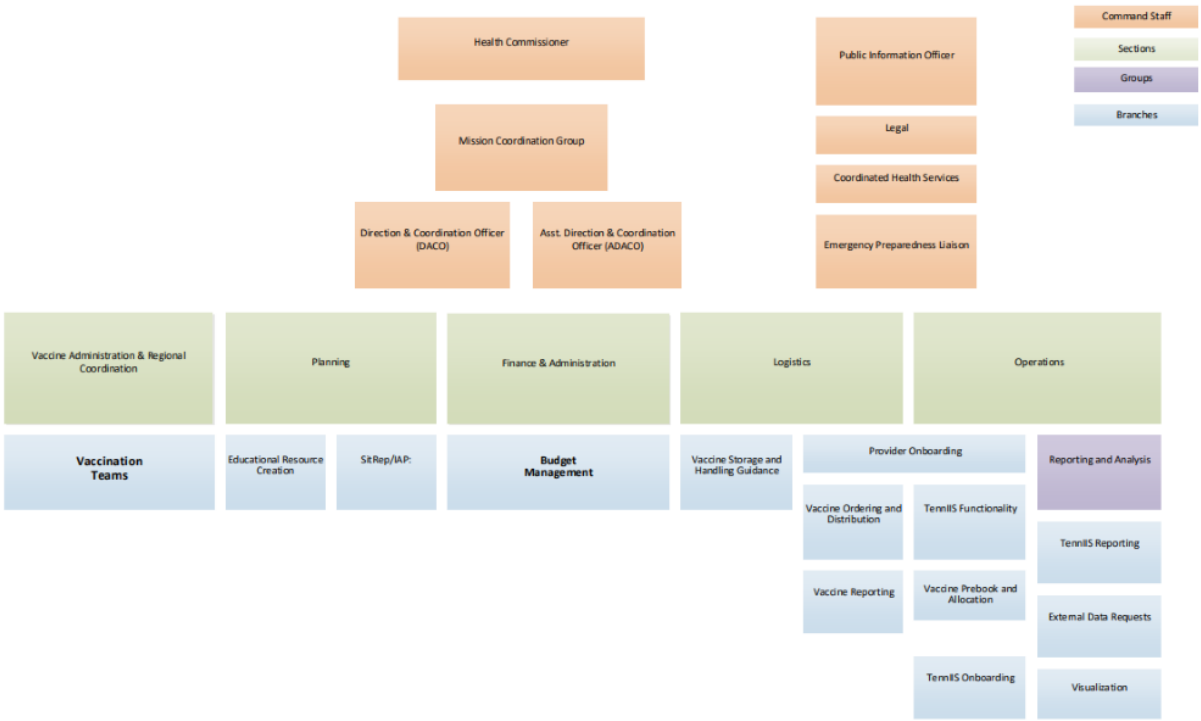
### A. *Describe your organizational structure.*

The Tennessee Department of Health is led by Dr. Lisa Piercey, Commissioner of Health, who reports directly to Governor Bill Lee. The TDH Executive Leadership Team consists of the Chief of Staff, the State Chief Medical Officer, Deputy Commissioner for Population Health, and the Deputy Commissioner for Operations.



**B.** ***Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.***

The initial TDH COVID-19 Vaccination Program Planning Team included members of the Vaccine-Preventable Diseases and Immunization Program team and the Office of Emergency Preparedness. Two of the representatives were with state departments of health during the 2009 H1N1 pandemic. This team began meeting in late June 2020. In late July 2020, leadership of Community Health Services, which oversees the 89 rural health departments, was added, as well as a representative of our overall COVID-19 EP Response team and the TDH Office of Communications and Media Relations. There is enough redundancy of expertise within the planning and coordination team to ensure coverage in the event of a lead member's inability to continue in their role.




**C.** ***Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.***

TDH has convened a Pandemic Vaccine Planning Stakeholder group which meets every two weeks and is leveraged to help inform allocation decisions, define priority populations, and identify gaps in knowledge. The group is comprised of more than 30 different offices, agencies, and departments representing public health, rural health, refugee and other minority populations, legislators, experts in bioethics, medical societies, communications experts, health care coalitions, emergency management, and others. This group will also be used to vet crisis and risk communication messages. In addition, the Unified Command

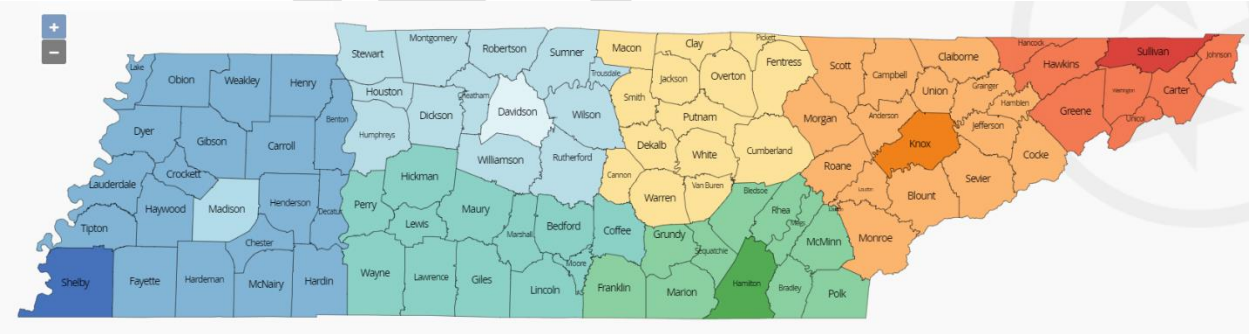
Group (UCG) and the Governor's office are highly engaged in any public communications or messaging campaigns addressing vaccinations. TDH's Office of Minority Health and Disparities Elimination (OMHDE) has conducted open weekly virtual stakeholder meetings since May 2020. The State Plan has been presented six times in November and December 2020 and OMHDE has a representative on the stakeholder group.

**D.** ***Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.***

TDH has convened a Pandemic Vaccine Planning Stakeholder group which meets every two weeks and is leveraged to help inform allocation decisions, define priority populations, and identify gaps in knowledge. The group is comprised of more than 30 different offices, agencies, and departments representing public health, rural health, refugee and other minority populations, legislators, experts in bioethics, medical societies, communications experts, health care coalitions, emergency management, and others. This group will also be used to vet crisis and risk communication messages. In addition, the Unified Command Group (UCG) and the Governor's office are highly engaged in any public communications or messaging campaigns addressing vaccinations.

**E.** ***Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.***

Tennessee is a hybrid state where 89 of its 95 counties report to the State and six metros are independent from the State. Tennessee contracts with these six counties (Shelby, Madison, Davidson, Sullivan, Knox, and Hamilton) to conduct public health activities.




Tennessee does not have territorial authorities. Statewide efforts are coordinated through multiple agencies involved with the State's overall pandemic response and communicated through agency leadership, the Unified Command Group (UCG), and the Governor's office. Coordination between the State and local authorities occurs through numerous channels, including partnering agencies, medical societies, health care coalitions, and emergency management agencies, in addition to multiple opportunities for partners to participate in calls and webinars (bi-weekly COVID-19 update webinar for clinicians, bi-weekly calls between TDH and metro, regional and local health departments; monthly calls with Tennessee Hospital Association, long term care facilities, and others; frequent press conferences that include the Commissioner of Health, and others).

**F.** ***Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.***

Tennessee does not have federally-recognized tribal communities.

**G.** ***List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:***

- *Pharmacies*
- *Correctional facilities/vendors*
- *Homeless shelters*
- *Community-based organizations, including charitable care clinics and Federally-Qualified Health Centers (FQHCs)*

Critical populations will be engaged through the following partners, largely through our Stakeholder Group and professional societies. These include the following:

a. Pharmacies—through our partnership with TN Pharmacists' Association we are engaging pharmacies, especially those in rural areas, to complete the CDC Provider Agreement and Profile and onboarding process to become pandemic vaccine providers in their communities. These pharmacies will assist with vaccination of residents of long-term care facilities that opt out of the federal partnership with Walgreens and CVS, vaccination of high-risk populations, and public vaccination efforts.
b. Correctional facilities—through our partnership within the Stakeholder Group, TN Department of Correction and the TN Sheriffs' Association are part of the planning process for vaccine allocations and distribution to ensure the population housed in correctional facilities is included in planning. Plans are underway to onboard the prison intake facilities to provide COVID-19 vaccine as they have similarly done with hepatitis A vaccine. Additionally, vaccination strike teams will be scheduled to visit jails and other congregate care facilities to ensure these populations are provided the opportunity to receive vaccine. During the hepatitis A outbreak, strike teams delivered hepatitis A vaccine in all county jails across the state at least once, if not on a recurring basis. We will leverage this model and the relationships built by local public health to implement the same vaccination outreach.
c. Homeless shelters—through our partnership with the TDH Office of Disparities Elimination, strike teams will be scheduled to visit locations where individuals experiencing homelessness gather. During the hepatitis A outbreak, strike teams prioritized homeless shelters as one of the target sites for providing vaccine outreach. We will leverage the relationships built by our local public health during this response.
d. Community-based organizations—through our multiple partner agencies, community health centers, federally-qualified health centers, hospitals, home health agencies, K-12 schools, institutes of higher education, large corporations, urgent visit clinics, and private medical providers are being contacted to on-board as pandemic vaccine providers.

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## Section 3: Phased Approach to COVID-19 Vaccination

**A.** ***Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:***

***Phase 1: Potentially Limited Doses Available***

***Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand***

***Phase 3: Likely Sufficient Supply, Slowing Demand***

After careful review of the CDC Playbook, the National Academies' of Sciences, Engineering and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine, the recommendations of the Advisory Committee on Immunization Practices (ACIP), and discussion with the Stakeholder Group, TDH leadership, and the Unified Command Group, the following structure has been adopted for the allocation and prioritization of COVID-19 vaccines:

- Pfizer vaccine: Operation Warp Speed (OWS) required the "pre-positioning" of a minimum of one tray (975 doses) of the State's allocation of Pfizer vaccine with delivery scheduled to occur between the time of the Emergency Use Authorization and the release of recommendations by ACIP. As the allocation of pre-positioned vaccine could involve sites with ultra-cold storage capability, the presence of which is unevenly distributed across the state, TDH elected to pre-position the minimum of one tray at a TDH location where it could be maintained in ultra-cold storage while the remainder of the State's allocation of vaccine made its way to Tennessee. TDH maintained possession of the tray of vaccines until the remainder of the vaccine shipments were confirmed to have reached their destinations in good condition, and then the tray was allocated to an under-resourced hospital that did not have enough Phase 1a population to be able to receive the Pfizer vaccine without assistance. The initial Pfizer vaccine doses were allocated to hospitals that are able to administer 975 doses of vaccine to Phase 1a individuals within 14 days. The State received 58 trays (56,550 doses) of Pfizer vaccine with the first allocation. A second allocation was awarded on December 18, 2020 and distributed to facilities in need of additional vaccine doses to vaccinate their Phase 1a1 population. Matching allocations are anticipated in early January to provide the second doses of vaccines to the first vaccinated cohorts.
- Moderna vaccine: The initial allocation of Moderna vaccine was 115,000. The CDC required that 36,200 doses from this allocation be provided to initiate the federal partnership with Walgreens and CVS to begin vaccinating residents and staff of skilled nursing facilities (SNFs). The remainder and was distributed to all 95 counties between December 21 and December 28, 2020. Each county health department received a minimum of one box (100 doses) of vaccine from the first allocation (approximately 10% of the remaining allocation after doses were diverted to the federal pharmacy partnership). Approximately 85% of the remaining doses were allocated to the 95 counties according to their populations. The remaining doses (approximately five

percent of the State's remaining allocation) were allocated to selected county health departments to provide vaccine doses in excess of the county's population-based allocation. These additional allocations were awarded based upon the Social Vulnerability Index (SVI) and the State of Tennessee's list of distressed counties. Twenty-nine of Tennessee's 95 counties have a SVI of .68 or greater (range .68-.97), placing them at higher risk than more than two-thirds of counties. Eleven of these counties are designated as "distressed" by the State of Tennessee. Additional doses of the initial vaccine allocation were provided to these counties to ensure sufficient quantity to vaccinate at least 50% of the counties' Phase 1a populations. In this way, counties that are disadvantaged and slower to recover from adversity will be able to protect a larger portion of their citizens from COVID-19 more quickly than counties that are better resourced and able to recover more readily. Future allocations of Moderna vaccine will be allocated in similar fashion until these disadvantaged counties have vaccinated all willing residents. The 29 counties receiving supplemental vaccine doses due to their high social vulnerability index include: Benton, Bledsoe, Campbell, Carroll, Claiborne, Cocke, Crockett, Grundy, Hamblen, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Lake, Lauderdale, Lawrence, Madison*, McNairy, Morgan, Obion, Perry, Rhea, Scott, Shelby*, Unicoi, Warren and Wayne.

- For all other vaccine manufacturers: Five percent of the State's allocation of COVID-19 vaccines will be earmarked by the State for use in targeted areas with high Social Vulnerability Index (SVI) values. Approximately ten percent of the State's allocation of COVID-19 vaccines will be distributed equitably among all 95 counties. Eighty-five percent of the State's allocation of COVID-19 vaccines will be distributed among all 95 counties based upon their populations.

With a cross-cutting focus on equity, the overarching principle in determining all phasing decisions is **RISK** –

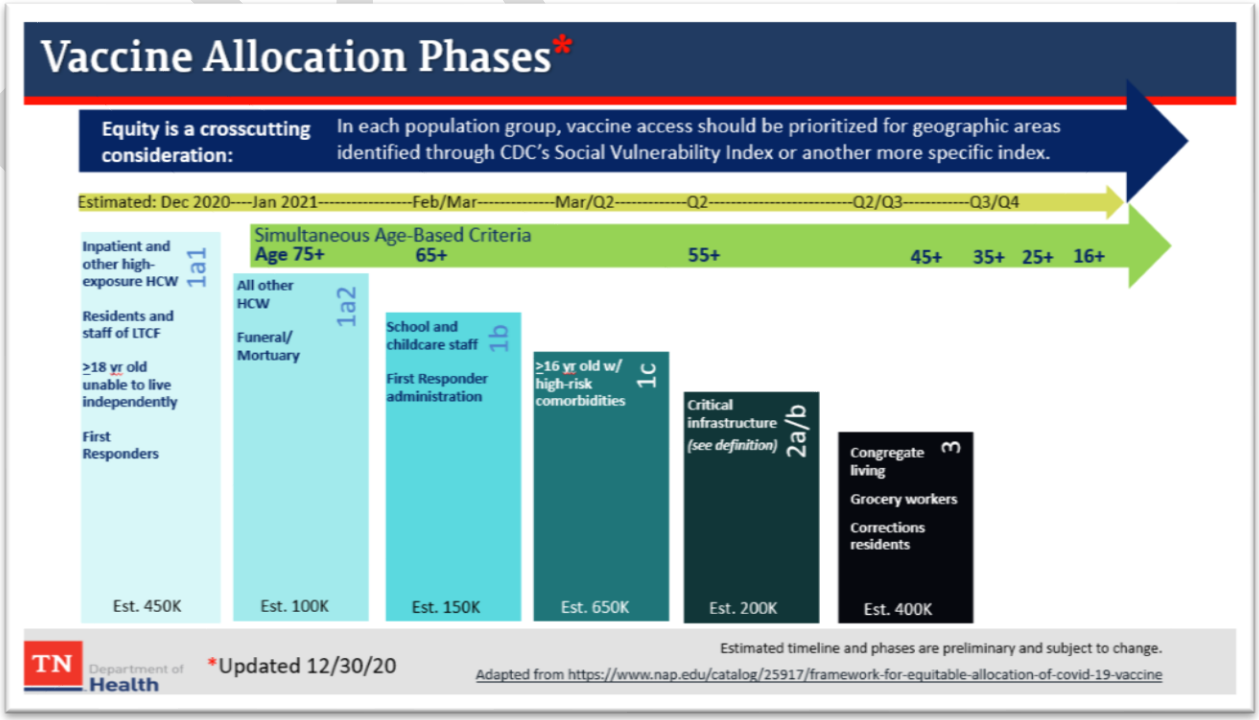
- Risk to our healthcare infrastructure – keeping frontline healthcare workers at the bedside, while reducing demand on hospital capacity
- Risk to individual health outcomes – protecting the most vulnerable Tennesseans first
- Risk to our society/economy – preserving workforce in our highest risk areas

Populations are prioritized based upon risk of contracting and spreading the virus, as well as their risk of morbidity and mortality from COVID-19. Tennessee has worked through several iterations of allocation phases, based upon changing recommendations of the ACIP and discussions with the Governor, the UCG, and the Stakeholder Group. Tennessee's plan has been updated to include three allocation phases, based upon risk and informed by the NASEM's Framework. The Tennessee phases differ from those proposed by federal agencies in several ways. Phase 1a of the Tennessee plan is sub-divided into two phases: one for in-patient health care providers, first responders with direct exposure to the public, and staff and residents of long term care facilities, and a second for those primarily working in out-patient health care settings.

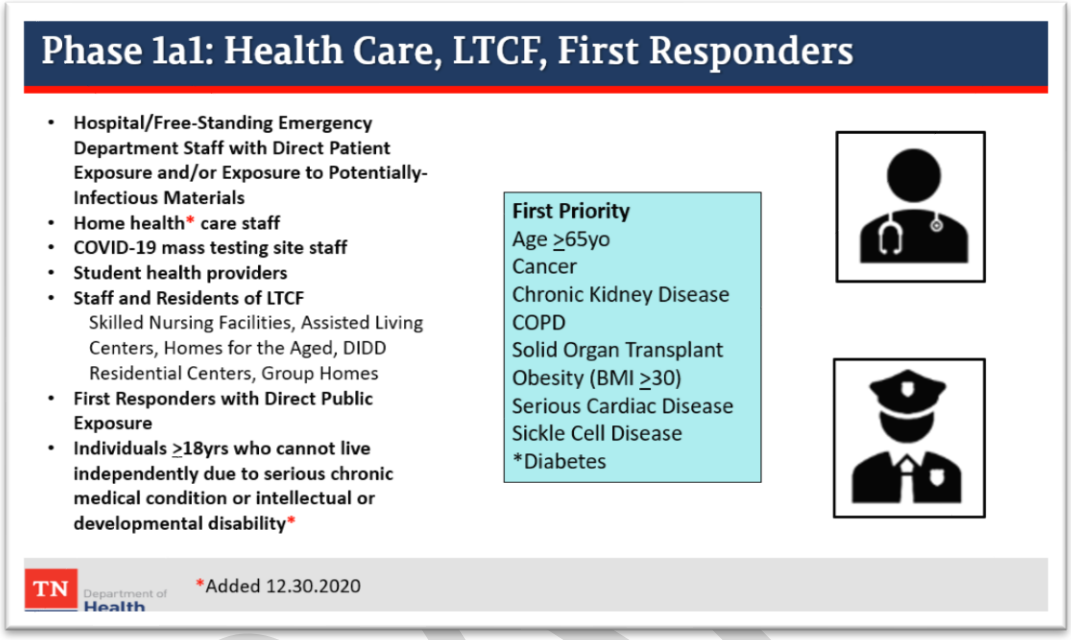
*Madison and Shelby Counties are large metropolitan counties that, due to limited vaccine supply, were provided supplemental doses in excess of their population-based allocations, but not enough to cover 50% of the Phase 1a population.

Phase 1b includes teachers and staff of childcare centers and K-12 schools, as schools have been disproportionately impacted by COVID-19 outbreaks, learning has been lost, and parents rely on consistent school schedules in order to remain in the workforce.

Phase 1b also includes other first responders not previously vaccinated in Phase 1a1. Subsequent phases are informed by federal recommendations but differ in that critical infrastructure industries are more narrowly defined due to scarcity of early vaccine supply. Persons ages sixteen years and older who have high-risk health conditions are included in Phase 1c, which occurs earlier than in the federal recommendations. In addition, simultaneous age-based criteria run concurrently to the phases in ten-year age brackets beginning with 75-year-olds. Collectively, the allocation phases and simultaneous age-based criteria place priority on those most at risk of morbidity and mortality due to COVID-19 and, further, recognize certain critical infrastructure workers who have direct public exposure or work in environments presenting higher risk of exposure. The placement or omission of any sector or industry within the phases is not a reflection of importance or worth to society or the economy; rather, a narrow definition of critical infrastructure for purposes of allocation is necessitated by the scarcity of vaccine supply at present and is informed by assessment of risk. Employees in industries not enumerated in the phases will become eligible as their age group is reached, while persons with high-risk health conditions are included in Phase 1c, regardless of employment or industry. These updated phases are as follows and are subject to additional changes pending further recommendations from the ACIP and other federal agencies and the recommendations of the State's UCG and COVID-19 Vaccine Stakeholder Group:

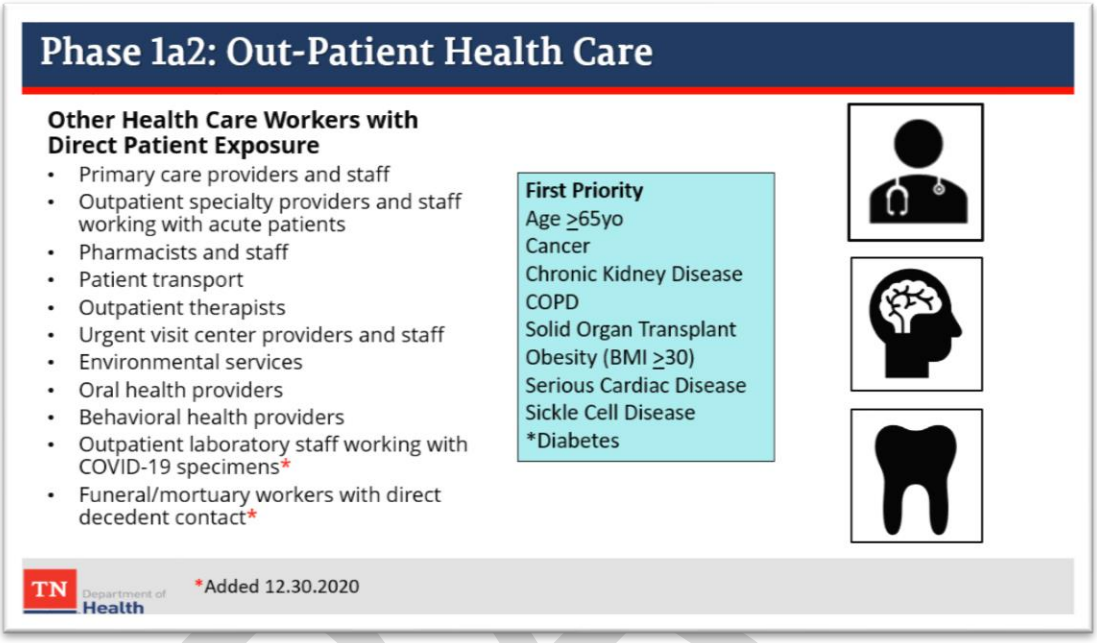


Equity remains a crosscutting consideration of the State's plan, with attention given to ensure unlicensed health care workers, low wage earners and those with limited access to health care resources will have access to vaccination. The timeline depicted in the image above is an estimation and likely to change as it is subject to vaccine supply, shipping, administration and uptake.




Hospitals and county health departments began vaccinating the Phase 1a1 population in mid-December 2020. This phase includes those working or volunteering, full or part-time, in hospitals and free-standing emergency departments where they have direct patient exposure and/or exposure to potentially-infectious materials. Phase 1a1 also includes those providing home health services to patients, those working COVID-19 mass testing sites where no other clinical service is offered, those providing student health services in K-12 schools, colleges and universities, and first responders with direct public exposure. Also included in Phase 1a1 are the staff and residents of long-term care facilities including skilled nursing facilities, assisted living centers, homes for the aged, congregate care centers for individuals receiving services provided by the Tennessee Department of Intellectual and Developmental Disabilities. Additionally, residents of group homes and other individuals ages ≥18 years who cannot live independently due to a serious chronic medical condition or intellectual or developmental disability are eligible for vaccination under Phase 1a1. While vaccine supply is limited, vaccination of Phase 1a1 individuals who are age ≥65 years and those with high-risk health conditions (current cancer treatment, chronic kidney disease (including renal failure, polycystic kidney disease and those with only one kidney), chronic obstructive pulmonary disease (COPD), those with history of solid organ transplant (e.g., liver, kidney, pancreas, heart, lung), those with serious cardiac disease (excluding hypertension), those with sickle cell disease (excluding sickle cell trait), those requiring treatment for type 1 or 2 diabetes, and those with body mass index ≥30 should be prioritized over healthier and younger individuals.

Individuals qualifying for vaccination under Phase 1a1 may be offered vaccine by their employer (if the employer is administering vaccines), through their local health department, or through a partnering hospital. Staff and residents of long-term care facilities will be provided vaccinations through the federal partnership with Walgreens and CVS, in partnership with a local pharmacy, or via TDH vaccination strike teams. Phase 1a1 individuals should check with their employer or contact their local health department for more information.




Tennessee divided the federal Phase 1a for health care into two phases (Phase 1a1 and 1a2) in order to prioritize the protection of the hospital system infrastructure. Phase 1a2 includes individuals working in any aspect of out-patient health care, including outpatient laboratory staff working with COVID-19 specimens and funeral and mortuary workers with direct decedent contact. As with Phase 1a1, individuals at higher risk due to age or health condition should be vaccinated ahead of younger and healthier individuals in the Phase.

Individuals qualifying for vaccination under Phase 1a2 may be offered vaccine by their employer (if the employer is administering vaccines), through their local health department, or through a partnering hospital. Local pharmacies are being onboarded to provide vaccinations, but likely will not be in significant number during Phases 1a2. Phase 1a2 individuals should check with their employer or contact their local health department for more information.

## Age-Based Vaccination*

| Begins+ | Age Group | Est. Pop |
|---|---|---|
| January 2021 | ≥75 years | 448K |
| Feb/March | ≥65 years | 1.1M |
| Q2 | ≥55 years | 2M |
| Q2/Q3 | ≥45 years | 2.9M |
| Q2/Q3 | ≥35 years | 3.7M |
| Q3/Q4 | ≥25 years | 4.7M |
| Q3/Q4 | ≥16 years | 5.4M |

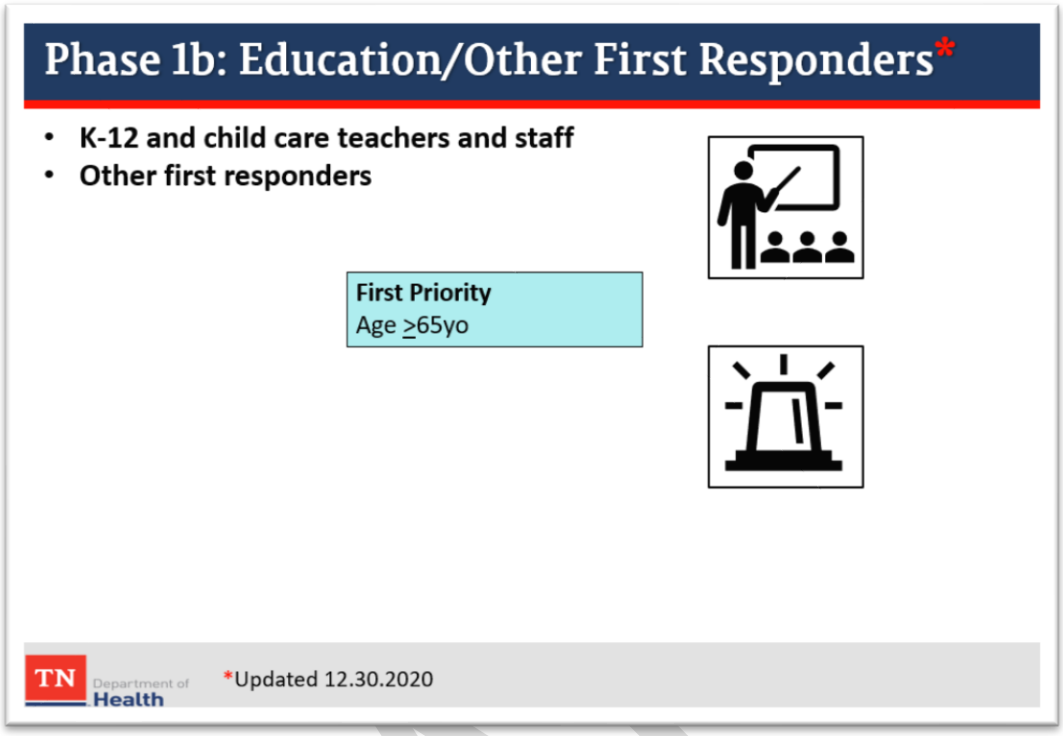
TN Department of Health

*Added 12.30.2020

+Dates are estimates and subject to change

Tennessee's COVID-19 morbidity and mortality is significantly higher in older age groups, with 68% of deaths occuring in individuals ages ≥70 years and 57% of those ages ≥75 years who are hospitalized with COVID-19 not surviving to discharge. As the primary goal of the overarching COVID-19 response is to reduce morbidity and mortality, the vaccination plan must prioritize those individuals at greatest risk for those outcomes. As age-based prioritization excludes others who may be at higher risk of morbidity and mortality due to their occupation, work environment, or history of chronic conditions, the simultaneous use of age-based prioritization along with prioritization of special populations allows the State to address both categories of risk at the same time.

The timeline depicted above is an estimate based upon population size and what is understood of vaccine allocation and distribution to the State by CDC and the supply chain. This timeline may lengthen if vaccine supply slows, or accelerate if additional vaccine manufacturers are able to contribute to vaccine supply or if uptake of vaccine by the population is lower than anticipated. Due to the enlarging population covered by the age-based prioritization, coupled with prioritization of special populations, this draft timeline above lengthens to two months per age bracket after February 2021.




Due to the ongoing impact of COVID-19 upon education in Tennessee and to support the need for parents and guardians to continue to work, childcare, pre-school, and kindergarten through twelfth grade teacher, school staff, and school bus drivers, will be prioritized for vaccination in Phase 1b. Also included in Phase 1b are other first responders, including dispatch and other emergency communications personnel not included in Phase 1a1.

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## Phase 1c: High-Risk Chronic Disease*

**Persons ages ≥16 years old w/ high-risk health conditions**

- Current cancer treatment
- Chronic renal disease
- COPD/pulmonary fibrosis/Cystic Fibrosis/moderate-severe asthma
- Obesity (BMI ≥30)
- Heart failure/CAD/cardiomyopathies/hypertension
- Sickle cell/thalassemia
- Diabetes
- Cerebrovascular disease/stroke
- Immunocompromise
  - HIV, taking chronic steroids or immunomodulators, history of solid organ, blood or bone marrow transplant
- Dementia
- Liver disease

**First Priority**
Age ≥65yo

TN Department of Health

*Updated 12.30.2020

Phase 1c includes anyone ages 16 years and older who have been diagnosed with one of the listed chronic disease conditions. This phase is prioritized by age and individuals ages 65 years and older should be vaccinated before younger individuals.

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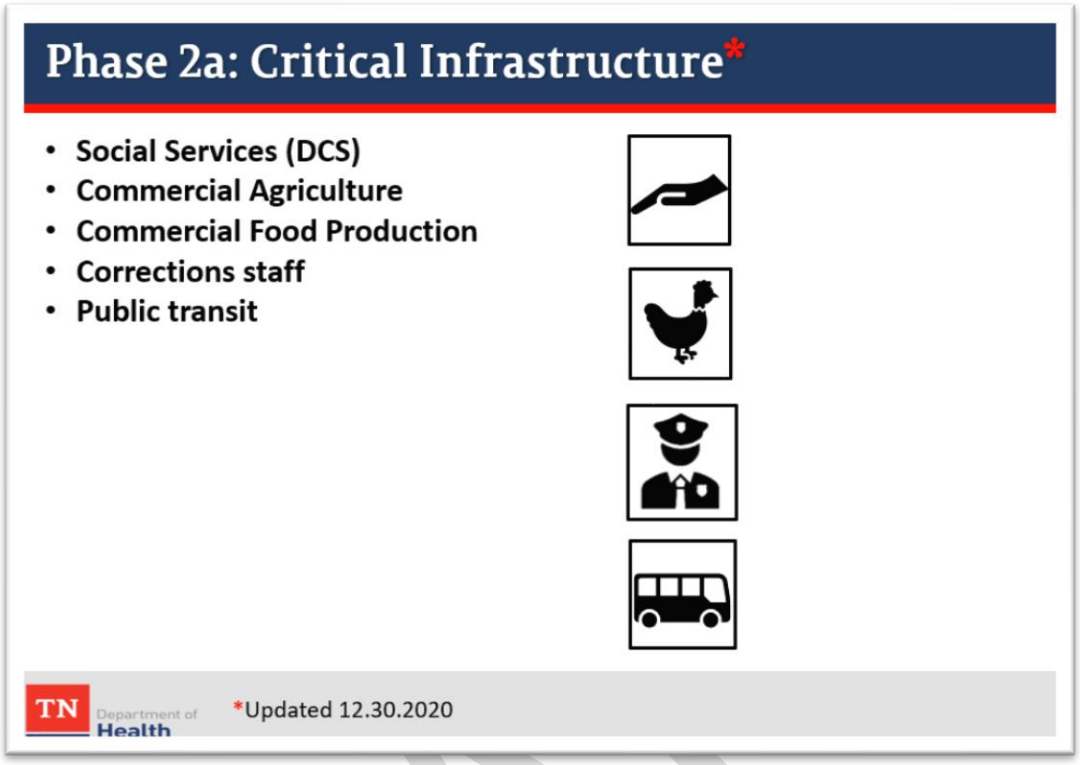


The Advisory Committee on Immunization Practices (ACIP) has made recommendations to include certain "essential employees" in the phases of state plans. Tennessee's focus has been on "critical infrastructure" employees needed to continue state operations and on those who are at highest risk of moridity and mortality due to their age, health condition, or occupation. While there is considerable overlap between the ACIP recommendations and the State's prioritization, there are differences. Tennessee's Phase 2a includes child welfare agency personnel with direct public exposure, commercial food manufacturing workers, commercial agriculture workers involved in production of food supplies and commodities, individuals working in the corrections system with direct exposure to the inmate population, and public transit drivers and maintenance personnel. These individuals work in settings that have experienced high numbers of COVID-19 infection clusters and their work is critical to the continuation of state operations.

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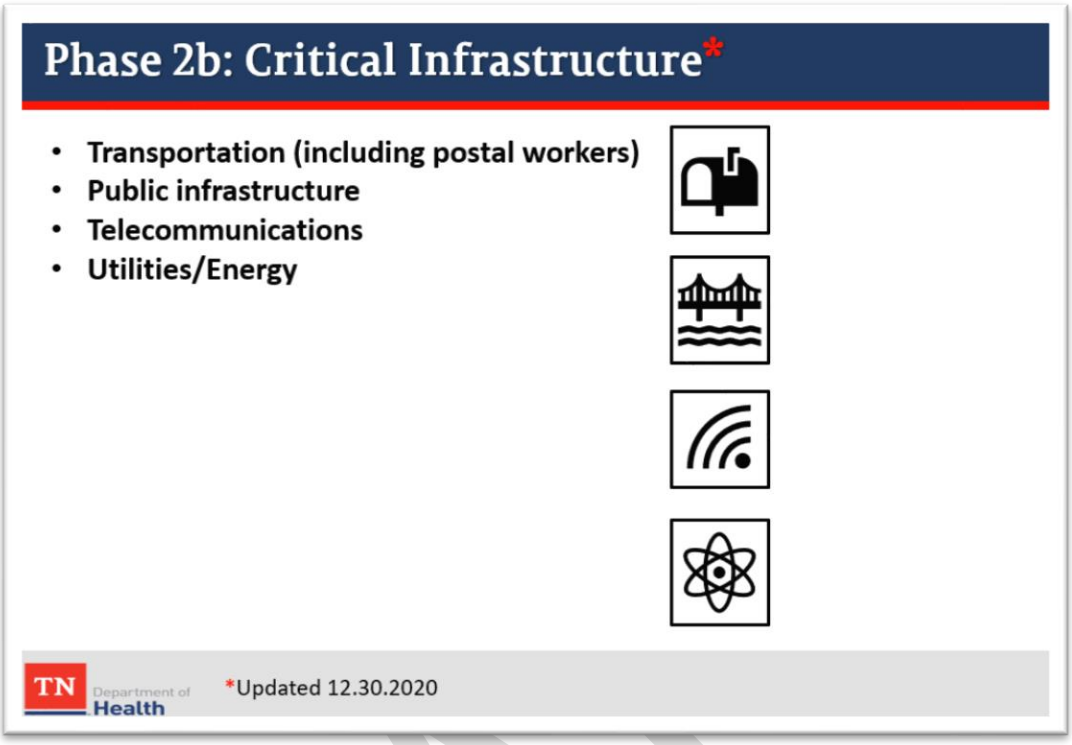


Tennessee's Phase 2b includes those working in additional sectors that are critical to the continuation of state operations. These include transportation, mechanical, and engineering personnel for freight railroad, maritime cargo, and commercial or cargo service airports; transportation, mechanical, and engineering personnel for courier and parcel delivery service; telecommunications industry technicians and engineers involved in installation, operations and maintenance functions; and mechanical and engineering personnel for utilities and energy sector operations.

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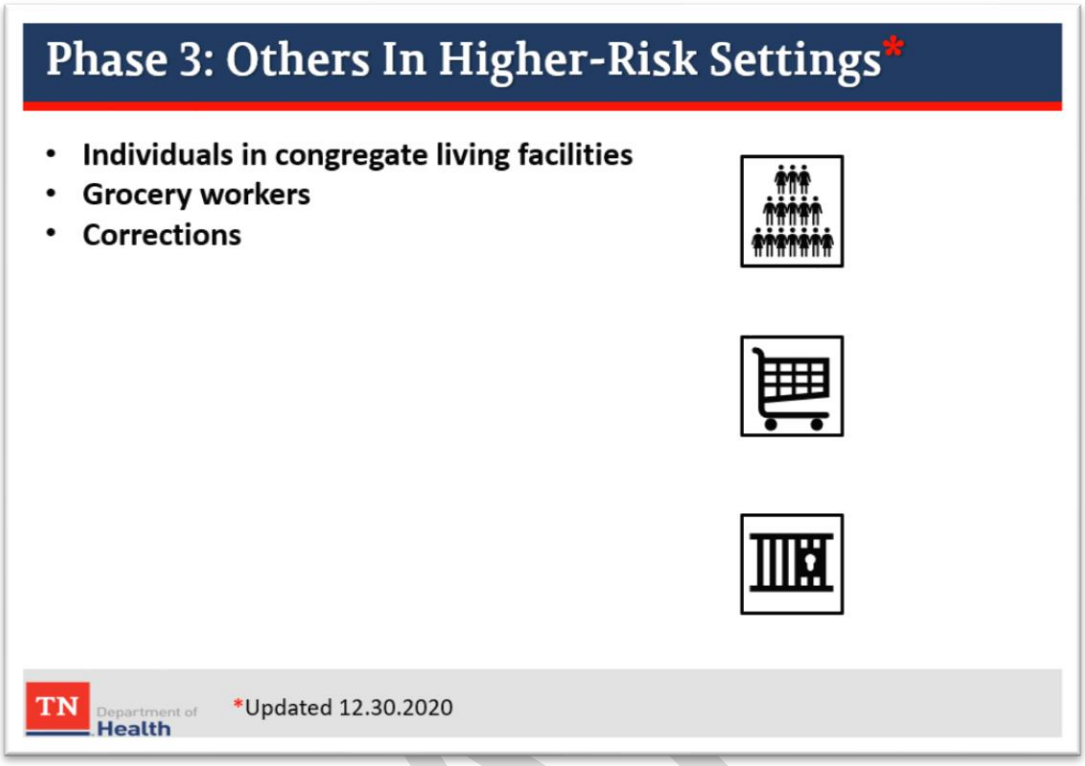


Phase 3 includes residents and staff of congregate living facilities, including dormitories and other group college and university campus housing, group homes and shelters serving those in transition, and other group housing environments that provide temporary or semi-permanent shelter to individuals who are capable of returning to independent living. Phase 3 also includes those working in grocery stores as these individuals are at high risk of exposure to the pandemic coronavirus and provide critical community services. Inmates of corrections facilities are also included in Phase 3 due to the high numbers of COVID-19 infection clusters that have occurred within these facilities.

## Section 4: Critical Populations

**A.** ***Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:***

TDH plans to use Geographic Information System (GIS) mapping and Tiberius functionality to locate/map all critical populations.

- *Healthcare personnel*—Data obtained from the Bureau of Labor Statistics, Occupational Employment Statistics May 2019, the hospital Joint Annual Report, and by health care facility direct reporting.
- *Other essential workers*—Data obtained from the Bureau of Labor Statistics, Occupational Employment Statistics May 2019 and the North American Industry Classification System.

- *Long-term care facility residents (e.g., nursing home and assisted living facility residents)*—Data obtained from the CDC Tiberius Database, communications from Operation Warp Speed, and the Tennessee State Licensure Database.
- *People with underlying medical conditions who are risk factors for severe COVID-19 illness*—Data obtained from Tennessee Office of Vital Records and Statistics and the Tennessee Behavioral Risk Factor Surveillance System and communications from the Advisory Committee on Immunization Practices.
- *People 65 years of age and older*—Data obtained from Tennessee Office of Vital Records and Statistics, the Tennessee Department of Health, Division of Population Health Assessment, and CDC Tiberius Database.
- *People from racial and ethnic minority groups*—Data obtained from Tennessee Office of Vital Records and Statistics, US Census Bureau, and CDC Tiberius Database.
- *People from tribal communities*—TN has no federally-recognized tribal communities
- *People who are incarcerated/detained in correctional facilities*—Data obtained from the TN Department of Corrections and the TN Sheriffs' Association county jail census September 2020.
- *People experiencing homelessness/living in shelters*—National Coalition for the Homeless (state-level data).
- *People attending colleges/universities*—Data obtained from Tennessee Higher Education Commission.
- *People living and working in other congregate settings*—Data obtained from Tennessee Departments of Correction, Mental Health and Substance Abuse Services, Child Services, and Corrections.
- *People living in rural communities*—Data obtained from U.S. Department of Agriculture, Economic Research Services (ERS) 2013 Urban Influence Codes (UIC).
- *People with disabilities*—data obtained from the CDC's Social Vulnerability Index and the TN Department of Intellectual and Developmental Disabilities.
- *People who are under- or uninsured*— Data obtained from US Census, CDC's Social Vulnerability Index.

**B. *Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.***

Tennessee includes the following among its critical infrastructure workforce (in addition to health care workers): social services (child welfare field workers), commercial food production, commercial agriculture production, corrections staff, public transportation, transportation of goods, utilities/energy, the postal service, and telecommunications. Refer to allocation phase details above for specified workers within the defined sectors/industries. In addition, K-12 and childcare teachers, staff and school bus drivers, funeral/mortuary workers with direct decedent contact, first responders, and grocery store workers are separately identified in allocation phases. Estimates are obtained through the Department of Labor and Workforce. The critical infrastructure workforce was identified, in part, through Cybersecurity and Infrastructure Security Agency (CISA) guidance but was narrowed as described in Section 3.A above.

**C.** ***Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.***

Tennessee will further stratify critical populations by prioritizing those with comorbid conditions or situations placing them at increased risk for poor outcomes from COVID-19. When vaccine supply is limited, these subpopulations will be identified at the facility level.

**D.** ***Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.***

TDH has longstanding relationships with medical societies, the Tennessee Hospital Association, and the Tennessee Pharmacists Association, all of which are assisting with the identification of POCs in facilities that will be receiving the first allocations of vaccines. The State's Economic Recovery Group (ERG) has agreed to assist the Program by making first contact with leaders within critical infrastructure employers and large corporations so that these entities may serve as a conduit for communications to their employees. Additionally, the members of the Stakeholder Group serve as a resource for connecting with critical populations and connecting them with opportunities for vaccination.

## Section 5: COVID-19 Provider Recruitment and Enrollment

**A.** ***Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.***

VPDIP developed a REDCap survey to gauge the interest of facilities in becoming pandemic vaccinating providers. This survey was deployed on April 6, 2020 to all licensed physicians and pharmacists in Tennessee and the full TennIIS provider list including pharmacies and urgent care sites. This REDCap survey assessed for the facilities':

- Interest in becoming a pandemic provider
- Provider type
- Patient population
- Storage capacity
- Number of staff
- Storage and handling information

From the list of >1000 respondents, VPDIP started approving facilities' storage units and verifying their status in TennIIS.

Once the Provider Agreement (PA) was released by CDC, the REDCap survey was updated to mirror the document. Surveys containing previously-collected information were then sent to the points of contact for hospitals in Phase 1a. All elements of the PA can be completed within the

REDCap survey; however, facilities are also able to complete the fillable PDF and VPDIP staff will enter the information into REDCap for the facility.

Tennessee Hospital Association has assisted with relaying communications from TDH to hospital leadership and pharmacists, while the Tennessee Pharmacists Association has worked to relay communications to and recruit local pharmacies. As a result, every hospital in the State and many of the local pharmacies will be onboarded to provide vaccine to identified populations.

**B.** ***Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.***

VPDIP's first priority was to enroll hospitals with emergency departments and intensive care units that would see the highest acuity patients. Enrollment then expanded to include all hospitals in the state so that they may provide vaccine to qualifying staff. The next priority was to ensure all health departments had completed the CDC Provider Agreement and were ready to receive vaccines, and then to focus on pharmacies, especially those in rural areas that do not have hospitals or other opportunities to access vaccines outside of the health departments. By enrolling these pharmacies, we are able to provide vaccine to many of the priority patients. The State will also be deploying vaccination strike teams across the state that will be able to conduct on-site vaccination events for targeted populations that may not have ready access to another vaccine provider. Once hospitals and pharmacies are onboarded, the focus will shift to large employers, urgent care clinics, and community providers that will be able to reach additional individuals within these priority populations.

**C.** ***Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.***

Tennessee generates a CSV file from the Provider Agreement REDCap project. The file is converted into the CDC-provided format in SAS and uploaded to SAMS twice weekly.

**D.** ***Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.***

Provider licensure information is pulled from the Provider Agreement REDCap project into a CSV file. A preexisting SAS code compares this file to Tennessee's Licensure Board's database for MD, DO, PA, RPh, and NP. The code matches providers on Name, License Type, License Number, Group Number, and contact information. Providers that have a license in good standing are then compared to Tennessee's Office of the Inspector General's Exclusion List. This check identifies any providers who are barred from participating in federal healthcare programs.

Any provider who is not able to be verified through the automated code is contacted by VPDIP staff to request the provider's license number and manually check against the Licensure List and Office of the Inspector General's Exclusion List.

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**E.** ***Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.***

TDH has identified staff who have developed training for:

a. Completing the Provider Agreement and Profile
b. Storage and handling
c. Vaccine Ordering and Management System (VOMS) training
    - Ordering and receiving vaccine
    - Reconciling vaccine counts
d. TennIIS training
    - Entering vaccine
    - Mass Immunization Module
e. Providing a strong vaccine recommendation
f. EUA Fact Sheets
g. Reporting to the Vaccine Adverse Events Reporting System (VAERS)
h. Conducting offsite vaccination clinics
i. Submitting facility information to CDC's Vaccine Finder
j. Vaccine Administration

**F.** ***Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).***

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution is unavoidable. Redistribution is coordinated centrally to ensure the integrity of the cold chain and vaccine is only be redistributed with the approval and involvement of the VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

**G.** ***Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.***

Tennessee is in the process of onboarding more than 1,300 volunteer vaccine providers, located across the state's 95 counties. Every county has at least one provider among this initial priority group of organizations. In partnership with the TN Pharmacists Association, local pharmacies will be onboarded as vaccine providers with priority given to those that are in counties where the local health department is currently the only provider of vaccine and to those who will partner to vaccinate residents of long term care facilities. Additionally, multiple vaccination strike teams are being deployed across the state to provide additional vaccination opportunities—particularly at locations where vulnerable populations are housed or congregate. In each population group prioritized for vaccination, additional prioritization will be given to geographic areas identified through CDC's Social Vulnerability Index or other index that indicates higher risk of disease burden or severity of outcomes.

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**H.** ***Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.***

VPDIP has a strong relationship with the Tennessee Pharmacists Association (TPA). TPA serves as the central point of contact for pharmacists and provides a conduit for communication to that group of providers. Local pharmacies, especially those in rural regions, will play an important role in providing COVID-19 vaccine in their communities and this group is the second priority for onboarding to the process. VPDIP has already collected information from hundreds of pharmacists that will be pre-populated into individual REDCap records that parallel the CDC's Provider Agreement.

## Section 6: COVID-19 Vaccine Administration Capacity

**A.** ***Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.***

In April of 2020, Tennessee began collecting information from organizations that had interest in partnering to administer pandemic vaccines. An initial interest survey was sent to all TennIIS users and licensed physicians and pharmacists. The survey included questions about the capacity to store vaccine and the willingness to vaccinate staff and/or the community. This information paired with GIS mapping of approved vaccine administrators and estimates of priority populations will help VPDIP understand the capacity to provide vaccines. Additionally, the recruitment of rural pharmacists and large corporations that will be able to vaccinate large numbers of individuals from priority populations will provide substantial capacity across the state.

**B.** ***Describe how your jurisdiction will use this information to inform provider recruitment plans.***

GIS mapping has been used to identify the locations of more than 1,300 organizations that have expressed interest in becoming pandemic vaccine providers. This has allowed the planning team to visualize gaps in access and recruit providers in specific regions. The initial goal was to onboard every hospital, with priority to those with emergency departments and/or intensive care units, followed by local pharmacies that will ensure at least two vaccine administration sites per county. The onboarding of local pharmacies is estimated to add hundreds of vaccine administration sites across the state and provide expanded access to rural communities. All health department sites have also been onboarded to accept vaccine. Additionally, maps that indicate populations with higher prevalence of conditions or circumstances that increase the risk of significant morbidity and mortality from COVID-19 will be utilized. Particular attention will be paid to those identified areas to ensure vaccine providers are recruited in those geographic areas in sufficient number to vaccinate those at-risk populations. Vaccination strike teams and closed PODs will also be used in these areas to target high-risk populations that may be reluctant or unable to proactively seek out the opportunity to receive the vaccine.

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## Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

**A.** ***Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.***

Initially, VPDIP intended to use allocation code adapted from its current influenza vaccine allocation process to determine county, and then facility, allocations. On October 7, 2020, the Program was introduced to the Tiberius application, which appeared to be able to make allocation based on several variables easier to determine. A combination of the Program's vaccine allocation code and Tiberius have been used to determine early vaccine allocations, but Tiberius has been found to have some important limitations, such as the inability to plan for more than one vaccine manufacturer on the same planning document. Additionally, the time it takes to enter individual allocations into Tiberius makes the use of this application in its current form unsustainable. During Phase 1a allocation (when vaccine supply is restricted), front line health care workers, residents and staff of long-term and other congregate care facilities and first responders are provided the first opportunity to be vaccinated. As such, initial vaccine allocations were sent to hospitals with emergency departments and intensive care units, as they care for patients with the highest acuity and risk for transmission to their staff. At the same time, county health departments have received limited doses of vaccine to provide to their first responders, and the federal agreement with Walgreens and CVS has been initiated to vaccinate residents and staff of long-term care facilities. Hospitals and health departments prioritize health care workers and first responders meeting certain criteria that place them at higher risk of severe morbidity and mortality from COVID-19. Additionally, supplemental doses of vaccines are being given to geographic areas identified through CDC's Social Vulnerability Index or other index that indicates higher risk of disease burden or severity of outcomes. Due to the large minimum quantity of Pfizer vaccine and the cold chain challenges, Pfizer vaccine is carefully allocated across qualifying facilities in order to minimize the need to relocate vaccine and minimize vaccine wastage. Moderna vaccine is more easily managed and is allocated by algorithm. During this early Phase of vaccine distribution, local pharmacies will continue to be onboarded to assist with vaccination of residents and staff of long-term care facilities and in anticipation of the need to vaccinate expanded numbers of individuals in Phases 2 and 3.

**B.** ***Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving orders.***

Tennessee's VFC Coordinators and Epidemiologists assess each storage unit listed by providers on the COVID-19 Provider Agreement. Every storage unit's make and model number is researched to ensure it meets minimum CDC requirements for vaccine storage, as outlined in the CDC Storage and Handling Toolkit. If a storage unit cannot be located through research, the provider is asked to send photos of the storage unit. The VFC team may request photos of the thermostat and the unit's interior and exterior, as well as temperature monitoring documentation to ensure the documented storage unit meets CDC requirements and can

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maintain appropriate vaccine storage temperatures. All providers are required to submit Digital Data Logger (DDL) Certificates of Calibration for each storage unit, and the VFC team reviews each certificate to ensure it meets recommendations outlined in CDC's Storage and Handling Toolkit.

DDLs are required to have the following features:

- Detachable buffered probe
- Alarm for out of range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature display
- Uncertainty of +/- 0.5°C
- Logging interval that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Ability to easily download data for review
- Ability to report temperatures in Celsius

DDL Certificates of Calibration must not be expiring within the next six months and must include the following:

- Model/device name and/or number
- Serial number
- Date of calibration
- Confirmation the instrument passed testing
- Uncertainty of +/- 0.5°C

The VFC team assesses the estimated storage capacity of each vaccine storage unit and reviews the availability of the vaccine coordinator for receipt of COVID-19 vaccine shipments as documented on the Provider Agreement. Documentation of the provider's vaccine storage and temperature monitoring equipment and capacity is maintained in a REDCap database. Following review of the provider's vaccine storage and handling capacity, the VFC team indicates "approved" or "not approved" in REDCap for each provider's cold chain capacity for refrigerated and frozen vaccine. A provider may be approved to store refrigerated vaccine, frozen vaccine, or both.

COVID-19 vaccine is allocated to providers based on identified storage capacity and approval status for storage of refrigerated or frozen vaccine. These variables are analyzed by Program epidemiologists to appropriately allocate the amount and presentation of COVID-19 vaccine for each provider enrolled in the COVID-19 Vaccination Program. Tennessee leverages its existing seasonal influenza allocation SAS code and allocation functionality through the new Tiberius platform to allocate COVID-19 vaccine to providers, and orders are approved based on allocated amounts. Once vaccine is available in sufficient quantities to allow providers to place orders instead of receiving vaccine allocations, orders will be approved only after review of a provider's profile information.

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**C.** ***Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.***

Tennessee's Vaccine Ordering Management System (VOMS) Team utilizes existing processes to update provider information in VTrckS. Tennessee's epidemiologists have written SAS code to pull information from the REDCap database (where all COVID-19 Vaccination Program provider information is documented) to create a VTrcks provider profile form export, allowing new provider information to be uploaded into VTrcks en masse. The Tennessee Immunization Information System (TennIIS) team continues to utilize its existing onboarding process for enrolling new providers into the IIS or updating existing providers in the IIS.

For Phase 1, Tennessee has leveraged existing seasonal influenza vaccine allocation code and allocation information from the Tiberius platform to output the VTrckS order file for COVID-19 vaccine. The Program's Central Office VOMS staff manually place the order in the IIS based on the allocation. Orders are entered or uploaded and approved based on amounts allocated through code for Phase 1. Once vaccine is available in sufficient quantities to allow providers to place orders instead of receiving vaccine allocations, orders will be approved only after review of a provider's profile information.

**D.** ***Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.***

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution is unavoidable. Redistribution is coordinated centrally to ensure the integrity of the cold chain and vaccine will only be redistributed with the approval and involvement of the State's VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

Tennessee will follow existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All providers receive an educational packet including this expectation and Program contact information upon enrollment into the COVID-19 Vaccination Program. All COVID-19 vaccine transfers are conducted with the assistance of a Regional Immunization Representative (RIR). RIRs are located in each rural and metro region in Tennessee and are trained in conducting VFC Program activities, including the safe transfer of vaccines. To ensure cold chain is maintained, RIRs follow established vaccine transport procedures and use either a portable vaccine refrigerator/freezer or a qualified container and pack-out. DDLs remain with the vaccine at all times before, during, and after the transfer. All transport requirements and recommendations outlined in section 6 of CDC's Storage and Handling Toolkit are followed. As vaccine is being retrieved, a final inventory reconciliation is conducted and documented in the IIS' Vaccine Ordering and Management System (VOMS). Once the vaccine transfer is complete, the reconciled inventory is transferred

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to the receiving facility's VOMS inventory by the RIR or Central Office VOMS team and accepted by the provider.

**E.** ***Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.***

For accurate monitoring of vaccine inventory levels, it is crucial that providers routinely reconcile and accept vaccine orders into their inventory within TennIIS/VOMS. Providers enrolled in the COVID-19 Vaccination Program are required to reconcile their inventory in VOMS daily as well as accept new orders into their inventory upon receipt of the vaccine. Daily inventory levels are reported to Vaccine Finder by VPDIP on behalf of participating providers.

Program epidemiologists leverage existing SAS code used to monitor VFC Provider ordering and inventory management practices to evaluate adherence to COVID-19 vaccine reconciliation and inventory requirements. If an order is not accepted into a provider's inventory within two business days, the provider will receive an auto-generated email asking them to accept their vaccine order. The VOMS epidemiologist runs a daily report using IIS data to generate a list of providers who have not accepted an order into their VOMS inventory within four business days. This report is sent to the VOMS team for immediate follow-up with the provider. The VOMS epidemiologist generates a monthly report utilizing TennIIS data to identify providers that are not reconciling their inventory for VOMS team follow up at least every 30 days. Additionally, VPDIP will use data from CDC on providers who are not updating their inventory appropriately to conduct follow up.

The VOMS epidemiologist creates code to monitor the reconciliation reasons submitted to the TennIIS by providers to monitor for high levels of wastage and for any inventory discrepancies that require follow up. The VOMS epidemiologist will also use TennIIS data and SAS code to generate reports identifying provider locations that have COVID-19 vaccine inventory set to expire within 30 days so vaccine can be repositioned, if needed, to prevent wastage. This report will be limited to providers utilizing ultra-cold freezers for the Pfizer vaccine, but it will be applicable to all other vaccine presentations. VPDIP will require providers utilizing the thermal shipping containers for Pfizer vaccine storage to notify the program of vaccine expiring within 5 days so it may be repositioned.

An unforeseen challenge to accurate monitoring of inventory and wastage has been the extra doses of vaccines that have been drawn from approximately 80% of vaccine vials. While good news for vaccine supply, these extra doses cannot be precisely accounted for and wastage will likely be overestimated as a result. The Program is developing a process for accounting for these extra vaccine doses.

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## Section 8: COVID-19 Vaccine Storage and Handling

**A.** ***Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:***

a. Individual provider locations

Cold chain maintenance at individual provider locations requires appropriate vaccine storage and temperature monitoring equipment, a trained provider staff, and consistent, accurate inventory management as already discussed. All enrolled providers are required to report TEs to the Program's VFC Team. Providers are also expected to label vaccine that has undergone a TE as "Do Not Use" and cease administration of the vaccine until stability has been determined by the Program. The VFC Team has two primary TE contacts assigned to handle incoming TEs per program protocols each day, and support will be provided by TN's VFC Coordinators should the primary TE contacts require assistance. Some facilities have the capacity to store vaccines under ultra-cold storage conditions. These facilities are largely located in large medical centers and at the State Public Health Laboratory locations in Nashville and Knoxville. Facilities storing vaccines under ultra-cold conditions are required to monitor unit temperatures with equipment that is appropriate for the monitoring of vaccines stored in that environment. Facilities that fail to report temperature excursions within one business day will be at high risk for wasting vaccine and the need to re-vaccinate patients. Facilities failing to report a temperature excursion and facilities with repeated temperature excursions will be closely monitored and required to submit weekly data logger reports to the program. Facilities identified as having these issues will be reviewed on a case-by-case basis and will risk having their vaccines reallocated to other facilities if these issues are not corrected or if it is determined that the facility is negligent in their handling of vaccines.

Pfizer vaccine requires ultra-cold storage and will be shipped in containers that will require up to 300 lbs. of pelleted dry ice to maintain those conditions for as long as 30 days. Tennessee Emergency Management Agency and the Unified Command Group have identified the supply chain and delivery of that resource to ensure maintenance of the cold chain. CDC has indicated it will provide the initial re-charge of dry ice, but the State is prepared to supply the dry ice in case there is a delay in the federal shipments.

b. Satellite, temporary, or off-site settings

Satellite, temporary, or off-site vaccine administration settings require additional care to ensure appropriate vaccine storage and handling is maintained. Tennessee limits the transport of frozen or ultra-cold vaccine products and encourages providers to have frozen or ultra-cold vaccine shipped directly to the vaccination site or utilize refrigerated vaccine for mass vaccination events. Providers are required to adhere to all requirements outlined in CDC's Storage and Handling Toolkit Section Six: Vaccine Transport. Upon enrollment into the COVID-19 Vaccination Program, providers receive an electronic educational packet that details the requirements for satellite, temporary, or off-site settings.

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Providers are encouraged to review CDC's Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations and CDC's Vaccination Guidance during a Pandemic for additional considerations necessary for vaccination during COVID-19. These documents are provided to all enrolling providers.

c. Planned redistribution from depots to individual locations and from larger to smaller locations

Tennessee plans to have the ability to store vaccine requiring ultra-cold storage vaccines at two depots, if necessary. Both depots are located within TDH's State Public Health Laboratories and will be utilized in the event that there is need to store quantities of ultra-cold vaccine within the state for the purpose of mass vaccination events and closed PODs. The Nashville location also received pre-positioned vaccine that Operation Warp Speed (OWS)required be shipped prior to the recommendations of the Advisory Committee on Immunization Practices being released. Vaccine temperatures are continuously monitored according to established protocols. Vaccine received as part of OWS pre-positioning was transported to an under-resourced hospital for use. This hospital did not have the ability to receive and store vaccine under ultra-cold conditions without the assistance of TDH.

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution will be unavoidable. Redistribution between individual facilities is coordinated centrally to ensure the integrity of the cold chain and vaccine is only redistributed with the approval and involvement of the VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

d. Unplanned repositioning among provider locations

Tennessee follows existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All providers receive an educational packet including this expectation and Program contact information upon enrollment into the COVID-19 Vaccination Program. All COVID-19 vaccine transfers are conducted with the assistance of a Regional Immunization Representative (RIR). RIRs are located in each rural and metro region in Tennessee and are trained in conducting VFC Program activities, including the safe transfer of vaccines. To ensure cold chain is maintained, RIRs follow established vaccine transport procedures and use either a portable vaccine refrigerator/freezer or a qualified container and pack-out. DDLs remain with the vaccine at all times before, during, and after the transfer. DDL reports are evaluated for TEs prior to vaccine transport, as well as after transport to the receiving facility is completed. All transport requirements and recommendations outlined in section 6 of CDC's Storage and Handling Toolkit are followed.

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**B.** ***Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities***

Tennessee will not allow providers to redistribute COVID-19 vaccine through depots and has no intention of distributing vaccines from the TDH depots to providers outside of TDH's oversight.

## Section 9: COVID-19 Vaccine Administration Documentation and Reporting

**A.** ***Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.***

Tennessee uses the Tennessee Immunization Information System (TennIIS) to collect COVID-19 vaccine doses administered by providers. TennIIS is a Software as a Service (SAAS) platform that is maintained by STChealth. STChealth maintains TennIIS on Amazon Web Services (AWS) and provides the patches and fixes to the STChealth proprietary code. The VPDIP program manages TennIIS and supports its users. As of October 2020, TennIIS holds +8.2 million patients and +78 million vaccinations. TennIIS has +13,500 users across +5,700 facilities. Of these 5,700 facilities, 44% report data to TennIIS via direct data entry using the TennIIS iWeb web portal, 35% report data electronically sending HL7 messages via a batch process, and 21% report data via real-time HL7 messaging.

Below is a visual overview of how TennIIS functionality is used to collect vaccine doses administered:

- During the Limited Vaccine Availability Phase, TennIIS' Mass Immunization Module is leveraged by those providers who do not have an electronic interface in place between their Electronic Health Record system (EHR) and TennIIS.
- During the phases where vaccine will be more widely available, TennIIS' iWeb Module will be used by those providers who do not have an electronic interface in place between their Electronic Health Record system (EHR) and TennIIS.

**B.** ***Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.***

COVID-19 vaccine information is collected through TennIIS. The TennIIS vendor, STC, produces a daily file following the COVID-19 Vaccine Reporting Specification (CVRS). The VPDIP epidemiologists pick this file up from the STC SFTP server and upload the data to the CDC IZ Data Clearinghouse. The longer term plan is to send this data to the CDC via the IZ Gateway.

The TennIIS team implemented the IZ Gateway Connect and Share components. The Connect component acts as a provider sending update and query messages to TennIIS, while the Share component has TennIIS acting as the initiator of update and query messages based on patient address. TennIIS currently receives patient and vaccine information from the IISs in Mississippi and Indiana when these IISs receive vaccine updates for patients with

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Tennessee addresses. It is our goal to build these connections with all of Tennessee's neighboring states and eventually with all states in the US.

For the implementation of the Connect component, the Immunization Gateway utilizes the CDC WSDL transport mechanism that we have in place at Cloverleaf. The connections between IZ Gateway Connect, Cloverleaf and TennIIS have been established in the Test, Staging and Production environments.

For the implementation of the Share component, a modified WSDL that includes a "destination ID" in the SOAP header has been implemented.

**C.** ***Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.***

Ensuring that each COVID-19 vaccination provider is ready and able to report the required COVID-19 vaccine administration data elements to TennIIS is a part of the COVID-19 provider onboarding process. As COVID-19 providers are going through the onboarding process, the VPDIP onboarding team makes sure that every provider meets three overall requirements:

a. The COVID-19 Provider Agreement and Profile has been completed and signed
b. The facility where the vaccine will be stored meets the Storage and Handling Requirements
c. The facility and its staff are registered as TennIIS users

If the provider is linked to a facility or organization that is already registered in TennIIS, the TennIIS team checks and makes sure that the facility is active, that active users are associated with the facility (if direct data entry provider) and that electronic messages are being exchanged (if HL7 electronic data exchange provider). Communications from the TennIIS team to the existing providers inform these providers of the requirement to report COVID-19 vaccine data within 24 hours of the administration of the vaccine.

If the provider is linked to a facility or organization that is not already registered in TennIIS, the TennIIS Registration team registers the organization or facility and the users that are linked to these entities. Next, the TennIIS Registration team sends out a "welcome" email that includes the TennIIS Quick Reference Guide for Medical Office Users. If the provider is interested in building an electronic connection between the provider's EHR system and TennIIS, the TennIIS Electronic Data Exchange team will work with the provider and the EHR vendor to implement an electronic connection.

The TennIIS epidemiologists create reports that evaluate timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility levels. These reports include flags for follow-up that are based on the percentage of errors and delays in reporting. Reports are viewed on a daily basis by the TennIIS Registration (direct data entry COVID-19 providers) and Electronic Data Exchange (electronic data exchange COVID-19

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providers) teams. These teams reach out to the COVID-19 providers who are not reporting every 24 hours and help with troubleshooting barriers to successful reporting.

**D.** ***Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.***

The satellite, temporary and off-site clinics use TennIIS' Mass Immunization Module to document COVID-19 vaccine administration at the time of the mass vaccination event. All public health clinics have been trained on TennIIS' Mass Immunization Module and used this module during last fall's flu mass vaccination events and during the Fight Flu TN event. This prepared public health users for documenting COVID-19 vaccines administered later this year. Any non-public health site that will be hosting a mass vaccination event may access the Mass Immunization Module Quick Reference Guide and reach out to TennIIS.Training@tn.gov when in need of additional assistance.

**E.** ***Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 72 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.***

The TennIIS epidemiologists create reports that evaluate timeliness and completeness of the reporting of COVID-19 vaccine administration at the organization and facility levels. These reports include flags for follow-up that are based on the percentage of errors and delays in reporting. Vaccine administration data that are submitted more than 72 hours after the vaccine administration date will be flagged as will providers who have not reported data within the past 48 hours.

The TennIIS Registration (if direct data entry COVID-19 providers) and Electronic Data Exchange (if electronic data exchange COVID-19 providers) teams review reports on a daily basis. Below is the process that the TennIIS Registration and Electronic Data Exchange teams follow when troubleshooting vaccine reporting issues with COVID-19 providers:

Ongoing: monitor organizations that are submitting immunizations and identify gaps within their submissions. Gaps are identified in the above-mentioned report. Reports are stored on the shared network.

**Step 1:** Navigate to the most recent spreadsheet. The most recent spreadsheet is uploaded daily, Monday through Friday. Dates are indicated in the filename.

**Step 2:** Filter for highest priority groups .

**Step 3:** Check practices with >72 hour delay in reporting and/or last submission date over 48 hours ago, use email to reach out to that provider and (if electronic trading partner) their EHR vendor.

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**F.** ***Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.***

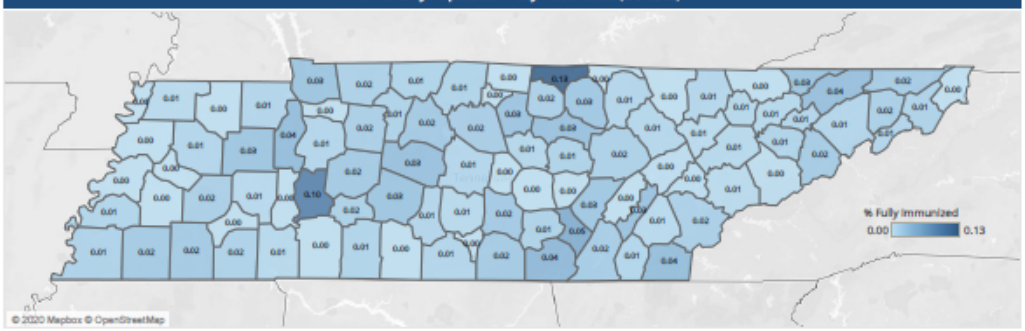
Every day, Monday through Friday, an internal coverage report is generated from TennIIS. The report reflects patient demographics and organization/facility information, incorporating census data for coverage and geographic estimates.

Below are proposed COVID-19 Vaccine coverage reports:

## Tennessee COVID-19 Vaccine Reporting

| Total Vaccines Reported | Vaccines Reported <= 1 day | Vaccines Reported <= 7 days |
|---|---|---|
| 255,519 | 3,027 | 39,486 |

### % of County Population Fully Vaccinated (2 Doses)




**By Age Group**

| Age Group | Vaccines Reported | % of Vaccines Reported |
|---|---|---|
| 0-10 years | 56,125 | 21.97% |
| 11-20 years | 32,159 | 12.59% |
| 21-30 years | 17,755 | 6.95% |
| 31-40 years | 21,406 | 8.38% |
| 41-50 years | 23,589 | 9.23% |
| 51-60 years | 32,055 | 12.55% |
| 61-70 years | 38,015 | 14.88% |
| 71-80 years | 24,554 | 9.61% |
| 81+ years | 9,861 | 3.86% |

**By Patient Race**

| Patient Race | Vaccines Reported | % of Vaccines Reported |
|---|---|---|
| American Indian Or Alaska Native | 405 | 0.16% |
| Asian | 3,236 | 1.27% |
| Black Or African American | 25,043 | 9.80% |
| Native Hawaiian Or Other Pacific Islander | 260 | 0.10% |
| White | 157,292 | 61.56% |
| Other | 34,813 | 13.62% |
| Unknown | 34,470 | 13.49% |

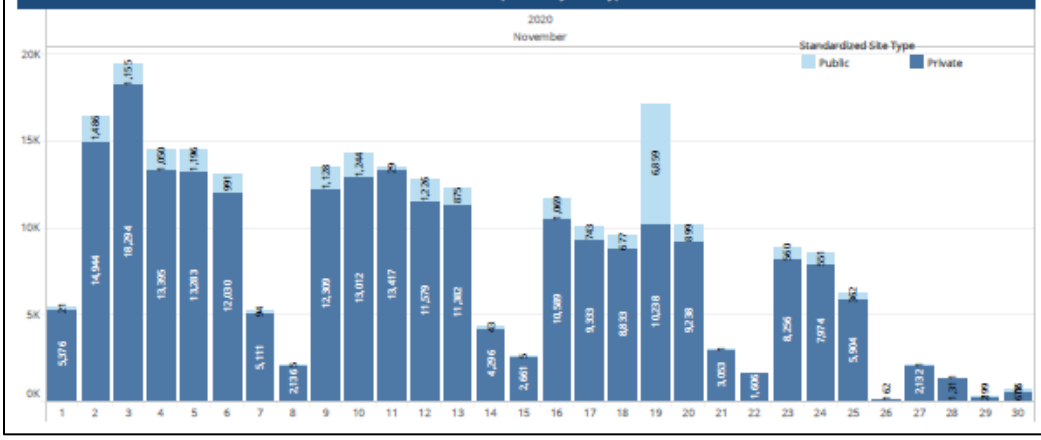
**By Patient Ethnicity**

| Patient Ethnicity | Vaccines Reported | % of Vaccines Reported |
|---|---|---|
| Hispanic Or Latino | 20,722 | 8.11% |
| Not Hispanic Or Latino | 190,438 | 74.53% |
| Unknown | 44,359 | 17.36% |

**By Patient Sex**

| Patient Sex | Vaccines Reported | % of Vaccines Reported |
|---|---|---|
| Female | 140,923 | 55.15% |
| Male | 114,531 | 44.82% |
| Other | 2 | 0.00% |
| Unknown | 63 | 0.02% |

### Vaccines Reported By Site Type



Possible daily county health department report:

| Patient County | Population 2019 | Vaccines Administered | Partially Immunized | % Partially Immunized | Fully Immunized | % Fully Immunized |
|---|---|---|---|---|---|---|
| ANDERSON | 76978 | 2,777 | 2,773 | 3.60 | 2 | 0.01 |
| BEDFORD | 49702 | 1,538 | 1,534 | 3.09 | 2 | 0.01 |
| BENTON | 16167 | 578 | 572 | 3.54 | 3 | 0.04 |
| BLEDSOE | 15062 | 559 | 555 | 3.68 | 2 | 0.03 |
| BLOUNT | 133084 | 4,578 | 4,570 | 3.43 | 4 | 0.01 |
| BRADLEY | 108116 | 3,472 | 3,460 | 3.20 | 6 | 0.01 |
| CAMPBELL | 39842 | 1,096 | 1,092 | 2.74 | 2 | 0.01 |
| CANNON | 14689 | 394 | 394 | 2.68 | 0 | 0.00 |
| CARROLL | 27761 | 946 | 938 | 3.38 | 4 | 0.03 |
| CARTER | 56390 | 1,631 | 1,623 | 2.88 | 4 | 0.01 |
| CHEATHAM | 40668 | 1,656 | 1,647 | 4.05 | 3 | 0.01 |
| CHESTER | 17304 | 361 | 361 | 2.09 | 0 | 0.00 |
| CLAIBORNE | 31959 | 884 | 884 | 2.77 | 0 | 0.00 |
| CLAY | 7622 | 310 | 300 | 3.94 | 5 | 0.13 |
| COCKE | 35998 | 1,561 | 1,553 | 4.31 | 4 | 0.02 |
| COFFEE | 56529 | 2,196 | 2,182 | 3.86 | 7 | 0.02 |
| CROCKETT | 14228 | 483 | 483 | 3.39 | 0 | 0.00 |
| CUMBERLAND | 60517 | 1,838 | 1,828 | 3.02 | 5 | 0.02 |
| DAVIDSON | 694150 | 28,148 | 27,979 | 4.03 | 83 | 0.02 |
| DECATUR | 11661 | 266 | 266 | 2.28 | 0 | 0.00 |
| DEKALB | 20490 | 822 | 820 | 4.00 | 1 | 0.01 |
| DICKSON | 53943 | 1,734 | 1,724 | 3.20 | 5 | 0.02 |
| DYER | 37158 | 664 | 664 | 1.79 | 0 | 0.00 |
| FAYETTE | 41129 | 1,287 | 1,277 | 3.10 | 5 | 0.02 |
| FENTRESS | 18512 | 379 | 377 | 2.04 | 1 | 0.01 |
| FRANKLIN | 42210 | 1,670 | 1,660 | 3.93 | 5 | 0.02 |
| GIBSON | 49138 | 1,811 | 1,805 | 3.67 | 3 | 0.01 |
| GILES | 29466 | 808 | 808 | 2.74 | 0 | 0.00 |
| GRAINGER | 23315 | 744 | 742 | 3.18 | 1 | 0.01 |
| GREENE | 69067 | 1,894 | 1,886 | 2.73 | 4 | 0.01 |

***(note: numbers listed in sample report are for illustration only and do not reflect COVID-19 vaccination data)***

Below are proposed uses for COVID-19 vaccination coverage reports:

- Ensure COVID-19 vaccine providers are administering allocated vaccine and follow-up with providers via email if they have not submitted vaccine administration data into TennIIS within a certain number of days
- Verify COVID-19 vaccinating providers are submitting data into TennIIS within 24-hours of vaccine administration
- Track vaccine wastage via vaccine administration; data may be triangulated with vaccine ordering
- Ensure vaccines are coded appropriately into TennIIS as administered vs. historical doses
- Encourage vaccinating providers to submit patient phone and address data
- Determine gaps in vaccine administration across geographic or demographic populations to inform targeted outreach efforts.

## Section 10: COVID-19 Vaccination Second-Dose Reminders

**A.** ***Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.***

**Method 1:** TDH/VPDIP encourages all COVID-19 vaccinating providers to give out a paper copy of proof of vaccination to every individual that receives their first dose of COVID-19 vaccine. Vaccine recipients are encouraged to take a picture of their paper record immediately. This paper copy will also indicate the date when the individual is due for their second dose of COVID-19 vaccine, if applicable. The paper copy may be a COVID-19 vaccination record card provided as part of vaccine ancillary kits by CDC, a vaccination record card provided by the Tennessee Department of Health (TDH), or a printed copy of proof of vaccination from the provider's EHR and/or the Tennessee Immunization Information System (TennIIS). This record may include the following information: patient first and last name, patient date of birth, date of first COVID-19 vaccine dose administration and date for subsequent dose (if indicated), facility name where patient received first COVID-19 vaccine dose, vaccine manufacturer, and vaccine lot number. TDH/VPDIP encourages providers that have the capability to schedule second dose appointments when the individual receives their first dose.

**Method 2:** TDH/VPDIP will leverage TennIIS to send reminder/recall (R/R) text messages to individuals who require a second dose of COVID-19 vaccine. During Phase 1 of limited vaccine availability, VPDIP will pull data from TennIIS to generate a list of individuals who received their first dose and are coming due for their second dose. Reminder text messages will be sent to individuals reminding them that they are due for their second dose of COVID-19 vaccine in five days. Recall text messages will be sent to individuals who are past-due, encouraging them to get their second dose as soon as possible. Reminder/recall text messages will be sent at least once per week and as needed. To comply with HIPAA regulations, text messages will not include private information but will send the recipient to the TDH/COVID-19 vaccine website that will display a general message about the importance of receiving the second dose of COVID-19 vaccine. This message will appear in multiple languages and include information about how to find COVID-19 vaccinating providers in TN. During Phase 2 of general vaccine availability, TDH/VPDIP will continue to send R/R text messages, but R/R may also be conducted by vaccinating facilities using the TennIIS Reminder/Recall functionality.

**Method 3:** TDH/VPDIP encourages all COVID-19 vaccinating providers to send out reminder/recall notice(s) to every individual to whom they administered a COVID-19 vaccine that requires a second dose. TDH/VPDIP also provides training materials on how providers may use the Reminder/Recall functionality in TennIIS to generate a list of patients who are due to receive the second dose within the next 5-7 days, and/or those who are overdue for their second dose.

On November 1, 2020, VPDIP began requiring phone numbers to be entered when manually creating or updating patient records in TennIIS. The importance of entering a patient's phone number into TennIIS has been communicated across all COVID-19 vaccinating providers. This will assist with the response rate of R/R activities conducted via text messages and/or phone calls.

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## Section 11: COVID-19 Requirements for IISs or Other External Systems

**A.** ***Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.***

a. The temporary and high-volume vaccination clinics use TennIIS' Mass Immunization Module to document COVID-19 vaccine administration at the time of the mass vaccination event. The TennIIS Mass Immunization Module is an integral part of, and is built into, the IIS, eliminating the need to build an interface.

The Mass Immunization Module allows for faster data entry during mass vaccination events as Lot Number Defaults are added prior to conducting these events. Setting the default lot number(s) results in the lot number being automatically populated in the patient's TennIIS record. When the administered vaccine and lot number are added to the patient record, the vaccine dose is subtracted from the TennIIS inventory, maintaining vaccine dose accountability and accurate inventory management.

All Public Health clinic users have been trained on TennIIS' Mass Immunization Module and used this module during last fall's Fight Flu TN mass vaccination events. Any non-public health site that will be hosting a mass vaccination event can access the Mass Immunization Module Quick Reference Guide and reach out to TennIIS.Training@tn.gov when in need of additional assistance.

As TennIIS is a web-based system, outages are uncommon. Federal funding is being used to purchase remote internet hot spots that will allow for data entry at sites without internet access. In the event that TennIIS is unavailable, vaccine administration information will be recorded on paper logs or in Excel spreadsheets that will be transcribed into TennIIS when access returns.

b. Planned contingencies for network outages or other access issues.

The planned contingencies for network outages or other access issues is ensuring that blank vaccine administration sheets are available in hard copy (paper copies) and in soft copy on the mass vaccination user desktops/laptops (i.e., Excel spreadsheets).

On December 25, 2020, downtown Nashville was the target of a suicide bombing that resulted in disruption of AT&T telecommunication and internet services, including services to TDH and TennIIS was down till 5 pm CT. This resulted in the activation of this contingency plan, as well as the need to temporarily relocate TDH Incident Command to another site.

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**B.** ***List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.***

The following is the list of the required and optional data elements that CDC is proposing IISs report, and the ability of these data elements to be captured in TennIIS iWeb (manual data entry via TennIIS web portal), TennIIS Mass Immunization Module (manual data entry via TennIIS Mass Immunization web portal) and TennIIS PHC Hub (HL7 electronic exchange):

| **Data elements required for IIS to report** | **Can be captured in TennIIS iWeb portal?** | **Can be captured in TennIIS Mass IMM module?** | **Can be captured in TennIIS PHC Hub (HL7 Electronic Data Exchange)?** |
|---|---|---|---|
| Administered at location: facility name/ID | Yes | Yes | Yes (RXA 11) |
| Administered at location: type | Yes | Yes | No |
| Administration address (including county) | Yes | Yes | Yes (RXA 11.9-11.15) |
| Administration date | Yes | Yes | Yes (RXA 3) |
| CVX (Product) | Yes | Yes | Yes- or NDC (RXA 5) |
| Dose number | Yes | Yes | No |
| IIS Recipient I | Yes | Yes | Yes (PID 3 as SR) |
| IIS vaccination event ID | No | No | No |
| Lot Number: Unit of Use and/or Unit of Sale | Yes | Yes | Yes (RXA 15) |
| MVX (Manufacturer) | Yes | Yes | Yes (RXA 17) |
| Recipient address | Yes | Yes | Yes (PID 11) |
| Recipient date of birth | Yes | Yes | Yes (PID 7) |
| Recipient name | Yes | Yes | Yes (PID 5) |
| Recipient sex | Yes | Yes | Yes (PID 8) |
| Sending organization | Yes | Yes | Yes (MSH 4) |
| Vaccine administering provider suffix | Yes | Yes | No |
| Vaccine administering site (on the body) | Yes | Yes | Yes (RXR 2) |
| Vaccine expiration date | No | No | Yes(RXA 16) |
| | | | |
| **Data elements required for IIS to report** | **Can be captured in TennIIS iWeb portal?** | **Can be captured in TennIIS Mass IMM module?** | **Can be captured in TennIIS PHC Hub (HL7 Electronic Data Exchange)?** |
| Vaccine route of administration | Yes | Yes | Yes(RXR 1) |
| Vaccination series complete | No | No | No |

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| | | | |
|---|---|---|---|
| Comorbidity status (Y/N) | No | No | No |
| Mass Vaccination | No | No | No |
| Recipient ethnicity | Yes | Yes | Yes(PID 22) |
| Recipient race | Yes | Yes | Yes (PID 10) |
| Recipient missed vaccination appointment (Y/N) | No | No | No |
| Vaccination Refusal (Y/N) | No | No | Yes (RXA 3, RXA 18) |
| **Other Data elements** | **Captured and Required in TennIIS iWeb portal?** | **Captured and Required in TennIIS Mass IMM module?** | **Captured and Required via HL7 Electronic Data Exchange?** |
| Chronic Medical Conditions | No | * No | No |
| Occupation | No | * No | No |
| Membership in Other Critical Population Groups | No | * No | No |

(*) Populations may be able to be defined as "tiers" in the mass immunization module, allowing for tracking of these groups.

**C.** ***Describe your jurisdiction's current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program. Current numbers (patients, vaccinations, providers). Efforts to improve capacity:***

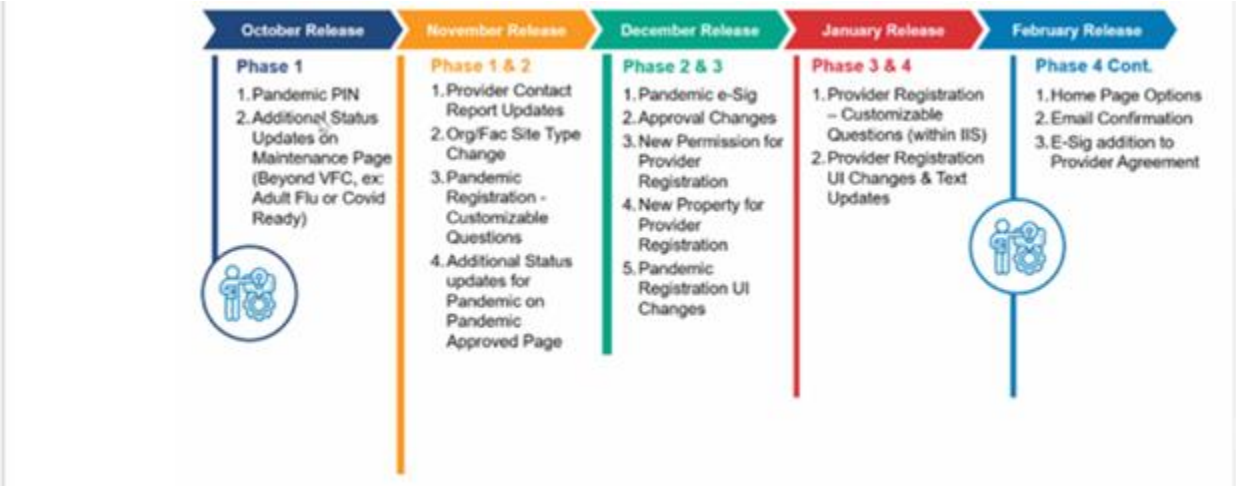
TennIIS is a Software as a Service (SAAS) platform that is maintained by STChealth. STChealth maintains TennIIS on Amazon Web Services (AWS) and provides the patches and fixes to the STChealth proprietary code. The VPDIP program manages TennIIS and supports its users. As of October 2020, TennIIS holds +8.2 million patients and +78 million vaccinations. TennIIS has +13,500 users across +5,700 facilities. Of these 5,700 facilities, 44% report data to TennIIS via direct data entry using the TennIIS iWeb web portal, 35% report data electronically sending HL7 messages via a batch process, and 21% report data via real-time HL7 messaging.

The TennIIS and VPDIP epidemiologists use SAS and Tableau to analyze and visualize TennIIS data.

VPDIP recently moved the TennIIS servers in the cloud from Windows to Linux. This move to Linux has been completed for all three TennIIS environments (test, staging and production). Having TennIIS reside on Linux servers addresses a number of security vulnerabilities and improves TennIIS performance.

On Sept. 1, 2020, TDH signed an emergency contract with STC. Through this contract, STC is developing and implementing functionality that will facilitate rapid and streamlined

(pandemic) registration at the organization, facility and user levels. This includes streamlining provider site types for TennIIS organizations and facilities, adding a flag to indicate which providers are pandemic vaccine providers, adding a Pandemic PIN, and adding a self-service workflow for all aspects of registration that will allow TennIIS staff to quickly make changes to registration forms/requirements and independently respond to current needs without involving the TennIIS vendor. An expedited user level request form will reduce the burden on TennIIS staff. Delivery of this functionality began with an October 2020 software release and will finish with the February 2021 release.




The VPDIP team is finalizing a new contract between the State of Tennessee and STC. The start date of this new IIS contract is Feb 23, 2021. The execution of this contract will provide uninterrupted TennIIS availability through the current vendor. Included in the scope of this contract is a secondary TennIIS iWeb, PHC-Hub and VOMS read database that syncs with the TennIIS production databases so that data can be pulled and analyzed without impacting the TennIIS production.

**D.** ***Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.***

Tennessee's first priority is to onboard hospitals and pharmacies that can administer vaccines to healthcare personnel. The vast majority of the Tennessee hospitals and all major pharmacy chains report immunizations to TennIIS via an electronic interface between their EHR systems and TennIIS. If the connection between the EHR and TennIIS is currently not a real-time, bi-directional interface, we have been working with these entities and their EHR vendors to try to upgrade their interface.

All public health users have been trained on TennIIS iWeb and TennIIS Mass Immunization Module. Tennessee's public health patient management system, PTBMIS, has a real-time bi-directional interface with TennIIS.

Those providers that do not already have an electronic interface between their EHR and TennIIS, or aren't already registered in TennIIS, will be registered by the TennIIS registration team and will receive TennIIS iWeb and TennIIS Mass Immunization module training.

**E.** ***Describe your jurisdiction's current status and plans to onboard to the IZ Gateway Connect and Share components.***

The following agreements are in place:

1. Data use agreement (DUA) between the Tennessee Department of Health (TDH) and the Association of Public Health Laboratories (APHL) to participate in the IZ Gateway.
2. Business Associates Agreement between TDH and APHL.
3. Memorandum of Understanding between TDH and AIRA to share data with other jurisdictions via the IZ Gateway Share component.
4. DUA between TDH and CDC for sending COVID-19 vaccine administration data to the CDC IZ Data Clearinghouse

**F.** ***Describe planned backup solutions for offline use if internet connectivity is lost or not possible.***

The planned back-up solution for offline use of the IZ Gateway Connect component is compiling a CSV file of the data elements and sending the data to the CDC via a transfer SFTP site.

In the event of a loss of connectivity with the IZ Gateway Share component, STC will queue outgoing messages from Tennessee to be backloaded to IZ Gateway Share upon return of TennIIS connectivity.

**G.** ***Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique***

A team of TennIIS epidemiologists uses SAS 9.4 to extract data from the Provider Enrollment REDCap project and the TennIIS database and compile bi-weekly reports for submission to CDC. Provider Enrollment data is deduplicated as data are collected to the REDCap project. All members of this team have access to upload Tennessee reports into Secure Access Management Services (SAMS); this redundancy ensures reports are submitted in a consistent and timely manner.

## Section 12: COVID-19 Vaccination Program Communication

**A.** ***Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.***

a. *Healthcare Associations*—TDH has engaged state healthcare associations and professional societies in the creation of Tennessee's plan and will have ongoing scheduled meetings within and external to the larger Stakeholder Group. These associations assist with the recruiting of pandemic providers and the relaying of messages to their constituents.

b. *Pandemic Vaccine Planning Stakeholder Meeting*—TDH convenes a bi-weekly Planning Stakeholder Meeting that currently includes representatives of approximately 30 partnering agencies and offices. This group was instrumental in the vetting of the initial plans for the phased roll-out of vaccine to priority populations and will continue to provide expertise and feedback to the Program for as long as necessary. This group is able to disseminate communications to a vast network of stakeholders and constituents, which is critical to earning the trust of the public and ensuring a transparent and equitable allocation and distribution process.
c. *TNHAN direct to providers*—TNHAN announcements will be used to communicate critical information surrounding vaccine allocation, distribution, administration, and reporting, as needed, throughout the implementation of this plan.
d. *Additional media campaigns*—Proactively messaging the safety, efficacy and continued monitoring of vaccines is critical to obtaining adequate public vaccination rates to achieve herd immunity. The creation, timing, and utilization of COVID-19-related media campaigns is at the discretion of the Governor's office.
e. *TDH Pandemic Vaccine website*—The Program has drafted two pandemic vaccine-related web pages—one where the public may find information around developments in pandemic vaccine and its distribution, and the second to provide onboarding information to possible pandemic vaccine providers. Each of these sites is accessed through TDH's existing COVID-19 resources website.
f. *CDC Vaccine finder website*—The CDC Vaccine Finder website link will be placed on the vaccine information webpage and pandemic providers will be asked to participate.
g. *Proactive communications with elected officials*—the State is providing pro-active messaging to local, state, and federal government officials to keep them updated as to the vaccination efforts and provide them with messaging for dissemination to their constituents.
h. *Tennessee State Microsite*—the State has contracted with a third-party vendor to host the Tennessee COVID-19 Information Hub (tn.gov). This site is a public-facing website that provides information on all aspects of Tennessee's COVID-19 pandemic response and now includes vaccine-related information.

**B. *Describe your jurisdiction's expedited procedures for risk/crisis/emergency communication, including timely message development as well as delivery methods as new information becomes available.***

TDH, TEMA and the Governor's Office have participated in weekly tabletop exercises to identify gaps in internal and external communications. The Governor's communications team has been drafting media releases to communicate the arrival and initial administration of COVID-19 vaccines in Tennessee, priority populations and structure of phased allocation, and crisis response such as vaccine recall. Additionally, communication chains have been defined to ensure timely communication between the State's agencies, as well as rapid review and approval of crisis/emergency communications. Proactive messaging that provides transparency of the vaccine allocation and distribution process, sets expectations,

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provides education and clearly communicates critical points of emphasis will assist in reducing the need for crisis communications.

## Section 13: Regulatory Considerations for COVID-19 Vaccination

**A.** ***Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.***

Emergency Use Authorization fact sheets are given to the providers in their training materials and discussed during training webinars and communications. The federal requirement to distribute these materials, along with any applicable VISs, are communicated to all vaccine providers.

**B.** ***Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.***

Providers receive an electronic educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents include the product-specific EUA fact sheets for COVID-19 vaccination providers and the EUA fact sheets for vaccine recipients. Providers are instructed to read the EUA fact sheets and reach out to the Program with any questions prior to beginning administration of COVID-19 vaccine. Providers are informed through the educational packet of the federal requirement to provide the recipient fact sheet or VIS to each patient prior to vaccine administration. The fact sheets and VISs are linked on TDH's COVID-19 website, located where other relevant information for providers is housed. Updates to EUAs or VISs will be distributed via a Listserv or a COVID-19 provider distribution email group and posted to the COVID-19 website. Information about EUA face sheets and VISs has also been included in tabletop exercises conducted across the state.

## Section 14: COVID-19 Vaccine Safety Monitoring

**A.** ***Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).***

Providers receive an electronic educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents include information on required reporting of vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS). Use of the online reporting tool is demonstrated during training webinars and tabletop exercises, and the link to the VAERS site is posted on TDH's COVID-19 website, located where other relevant information for providers is housed. Reports made to VAERS are reviewed by the Medical Director of the Vaccine-Preventable Diseases and Immunization Program.

Additionally, all providers of pandemic vaccine receive training on the VSafe Program and are asked to promote its use among those who receive vaccine.

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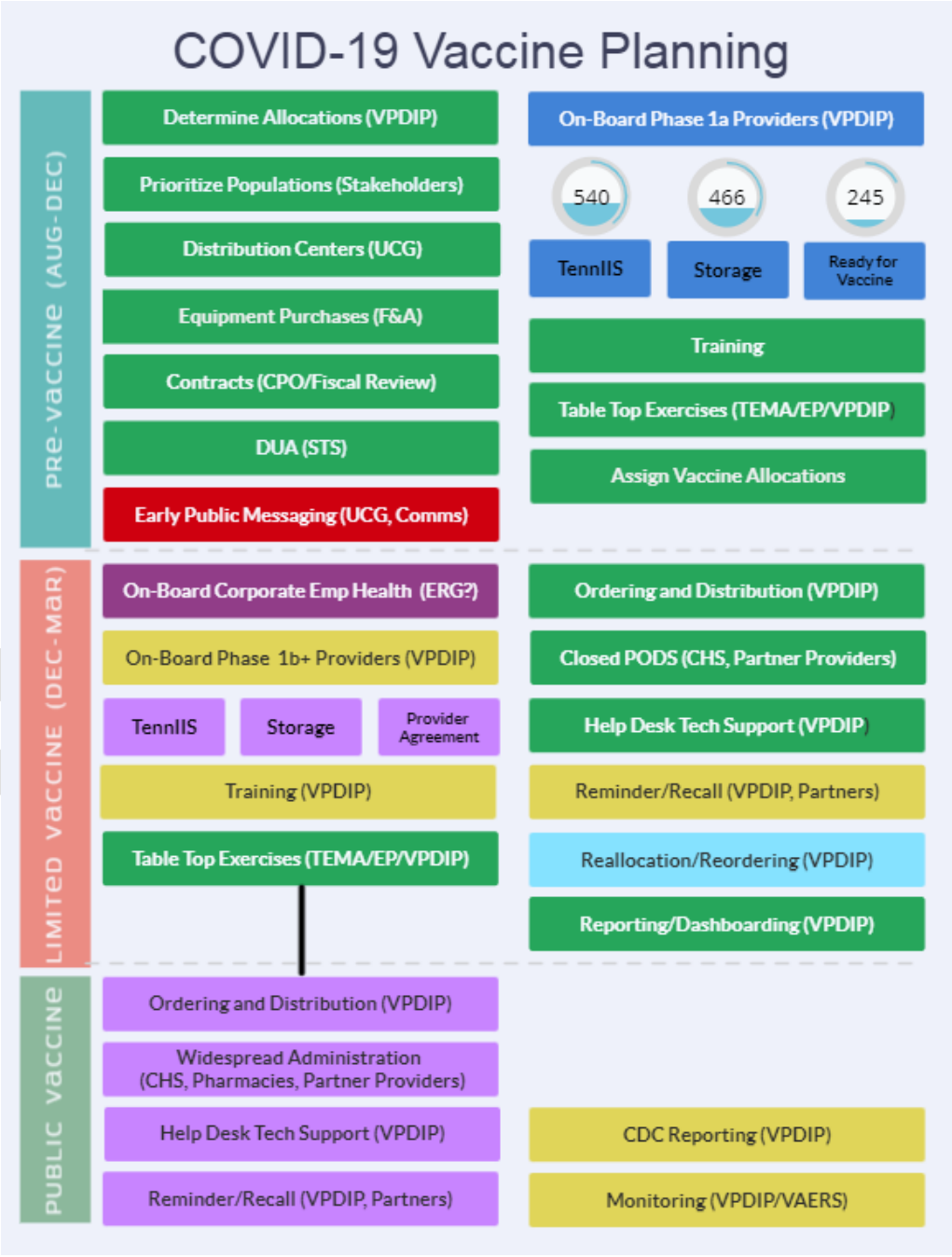
## Section 15: COVID-19 Vaccination Program Monitoring

**A.** ***Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation.***

The following is a visual representation of high-level progress through the planning and implementation process. Completed tasks are in green. This graphic is used to provide weekly updates to the UCG, and includes progress with onboarding, tasks to be completed, and assignments.



a. Provider enrollment

Provider enrollment is monitored through a REDCap project that tracks progress through the three stages of onboarding: TennIIS enrollment, storage and handling capabilities, and submission of the completed CDC Provider Agreement and Profile. The location of providers is also mapped via GIS so that geographic coverage of providers may be monitored and providers recruited in areas where there are gaps.

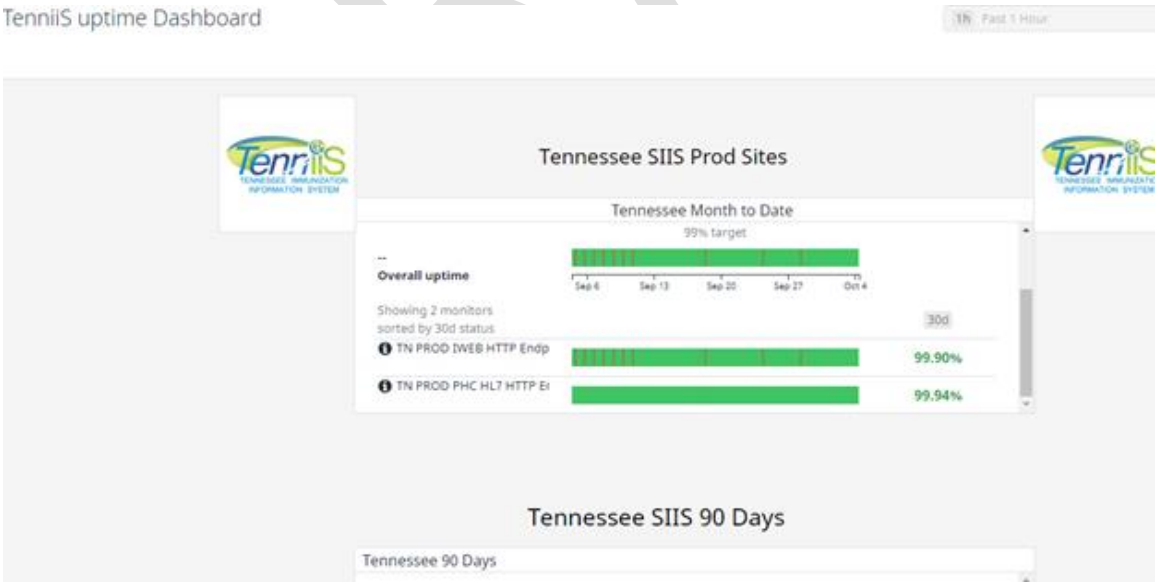
b. Access to COVID-19 vaccination services by population in all phases of implementation

Some functionality exists in the Tiberius platform that is capable of assisting with the monitoring of vaccines administered to specific populations. Tennessee is also able to capture data through the mass immunizations module by setting "tiers" that indicate population groups. GIS mapping of provider locations will also assist in ensuring that locations with high-risk populations have sufficient access to vaccinating providers, and vaccination strike teams and the recording of other closed POD events will also provide details to specific populations that are provided vaccine.

c. IIS or other designated system performance

STC provides 24/7 monitoring of the TennIIS production instance which includes memory, disk, processing and network loads. STC is automatically notified when instance issues arise and will attempt to remediate the issue without impacting TennIIS users. If the steps required to remediate the issue do result in a client-facing impact, STC's Operations team coordinates with the TennIIS Director or Deputy Director via the support team to outline the issue, steps to remediate, and gain approval to execute the remediation plan.

The TennIIS team also has access to the following TennIIS uptime dashboard:




On the Cloverleaf engine side, the Cloverleaf administrators check uptime and processes. Alerts are set up on every Cloverleaf thread for every trading partner. If a thread goes down, an alert is sent to the Cloverleaf administrators.

The Cloverleaf administrators also receive autogenerated reports that come from the Cloverleaf server. These reports show the files that are in the queue and/or any locked jobs (jobs get locked when a trading partners MSH 4 value doesn't match the value in the Cloverleaf database tables or when a file has a bad format). Reports are generated every 30 minutes.

d. Data reporting to CDC

VPDIP reports bi-weekly to CDC via CSV file upload of CDC Provider Agreements and Profiles.

COVID-19 vaccine information is collected through TennIIS. Every day, VPDIP reports Administered Vaccine data to the CDC via an upload to the CDC IZ Data Clearinghouse.

Vaccine inventory information at the provider level is collected through VOMS/TennIIS. Every day, VPDIP reports Vaccine Inventory via an upload to CDC's Vaccine Finder.

e. Provider-level data reporting

The TennIIS epidemiologists create reports that evaluate timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility levels. This report includes flags for follow-up that are based on the percentage of errors and delays in reporting. There is a flag when a vaccine is submitted >72 hours after the administration date and a flag for when a provider has not reported vaccine administration in more than 48 hours.

The TennIIS Registration (if direct data entry COVID-19 providers) and Electronic Data Exchange (if electronic data exchange COVID-19 providers) teams review this report on a daily basis.

f. Vaccine ordering and distribution

Enrollment into the COVID-19 Vaccination Program is monitored using data from VPDIP's provider tracking REDCap and data visualization software (Tableau). VPDIP epidemiologists utilize data exports from REDCap and SAS code to generate a weekly update to a Tableau dashboard. This allows metrics such as the number of providers with VPDIP-approved storage and handling, the number of COVID-19 vaccination providers onboarded into the IIS, and the number of providers with a complete COVID-19 Provider Agreement to be visualized. This data is used to inform how many providers have been onboarded into the COVID-19 Vaccination Program and are therefore eligible to begin receiving vaccine allocations or be approved for ordering.

Vaccine distribution is monitored by leveraging TN's existing influenza allocation summary SAS code or data available through the Tiberius platform. Allocation code is updated to include base metrics for the amount of vaccine to be allocated, including the number of patients, number of staff, capacity, county, etc., as identified in sections 3 and 4 of this document. Each time TN receives a vaccine allocation from CDC, the amount distributed to a provider will be determined by these metrics. The code will output a summary that is

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updated after each allocation to track the number of vaccines distributed to each location by NDC code/presentation and will be marked complete when the base metrics are met.

Vaccine ordering will be monitored using SAS-generated reports created by VPDIP epidemiologists. VPDIP will leverage existing SAS code used to monitor VFC Provider ordering and inventory management practices and evaluate adherence to COVID-19 vaccine reconciliation and inventory requirements. If an order is not accepted into a provider's inventory within four business days, the provider will receive an auto-generated email asking them to accept their vaccine order. The VOMS epidemiologist will run a daily report using IIS data to generate a list of providers who have not accepted an order into their VOMS inventory within seven business days. This report will be sent to the VOMS team for immediate follow-up with the provider. The VOMS epidemiologist will generate a monthly report utilizing IIS data to identify providers that are not reconciling their inventory every 30 days. These reports will be sent to the VOMS team for immediate provider follow-up.

g. 1- and 2-dose COVID-19 vaccination coverage

Every day, Monday through Friday, an internal report will be generated from TennIIS. This report will detail both 1- and 2-dose COVID-19 vaccination administration data compared to county and/or region census data for coverage and geographic estimates.

**B.** ***Describe your jurisdiction's methods and procedures for monitoring resources, including:***

*a.* ***Budget—***The senior leadership team meets with the program Fiscal Administrator each month to review the budget and verify that funds are being spent appropriately and on track to be fully expended by the end of the budget period.

*b.* ***Staffing—***The senior leadership team meets weekly to discuss staffing needs, discuss capacity, anticipate demands, and redirect resources, as needed.

*c.* ***Supplies—***The VPDIP Operations and Administration Director works with the Emergency Preparedness Program to ensure that supplies are ordered and delivered on-time and that future needs are anticipated.

**C.** ***Describe your jurisdiction's methods and procedures for monitoring communication, including:***

***a.*** ***Message delivery—***The Program will ensure that provider training documents are received and reviewed by requiring acknowledgement of receipt and attestation of review. Pandemic-related communications that are critical to the health care workforce will be shared via the Tennessee Health Alert Network. Public communications may be monitored through social media site metrics and views. Answers to questions are provided in real-time via weekly webinars with pandemic providers and FAQs are posted to the website for viewing on demand.

b. ***Reception of communication messages and materials among target audiences throughout jurisdiction—***The Pandemic Vaccine Planning Stakeholder Group is a conduit through which feedback from constituents may be shared with the State, including the reception of messages by target audiences. Additionally, the Group is

used to vet messaging prior to its dissemination to ensure messages are crafted in a way that resonates with those audiences.

**D.** ***Describe your jurisdiction's methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).***

Eighty-nine of Tennessee's 95 counties are under the jurisdiction of TDH and supervised centrally. This results in the ability to communicate quickly and effectively with these local jurisdictions. Additionally, TDH has close relationships with the health departments that are located in Tennessee's six metropolitan jurisdictions and communications channels are well-established. The Pandemic Vaccine Planning Stakeholder Group involves representatives of approximately 30 different offices and organizations, both within and outside of state and local government. Each of these representatives is able to communicate messaging back to their constituents, as well as relay information to TDH, to ensure there is local-level situational awareness of TDH activities and statewide progress, as well as awareness of local activities at the state level. Additionally, the Governor's office and the Unified Command Group are regularly updated as to progress and are able to send public messaging, when appropriate.

Public-facing information will be posted to the State's COVID-19 website as well as the TDH COVID-19 website as described below.

**E.** ***Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.***

Publicly-reported vaccination program metrics mimic the current format used to report COVID-19 metrics on the THD public website (https://www.tn.gov/health/cedep/ncov/data.html). Vaccination program metrics are pulled from TennIIS and visualized using SAS and Tableau software. Vaccine metrics are limited by TennIIS' data availability and data quality. The publicly-facing dashboard is posted to the State's COVID-19 information site on Tuesdays and Fridays and may be found here: Vaccine.pdf (tn.gov)

Below are the initial COVID-19 Vaccination Program metrics, which may be expanded upon as needed, throughout vaccine distribution roll-out.

1. Number of COVID vaccine doses administered (total)
    a. # vaccines administered by organization site type (e.g., PUB, PRIV, OTH/PRIV, etc.)
    b. # vaccines administered within the last XX number of days (e.g., 1 day, 7 days, etc.)
    c. # vaccines administered, disaggregated by age group, sex, race, ethnicity (see example below)

   d. # vaccines administered, disaggregated by region and/or county
   e. % of county population partially and fully vaccinated
2. Number of individuals who are partially vaccinated
   a. Disaggregated by age group, sex, race, ethnicity
   b. By region and/or county
3. Number of individuals who are fully vaccinated
   a. Disaggregated by age group, sex, race, ethnicity
   b. By region and/or county
4. Examples of maps
   a. rate of vaccines administered by county of residence

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## Appendix

***Instructions:*** *Jurisdictions may choose to include additional information as appendices to their COVID-19 Vaccination Plan.*

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