

Updates from the CMO

Shannon Dowler, MD December 2020

Top Priorities: Clinical, Quality, Pop Health

Non-Managed Care

- Evaluate telehealth use & Finalize permanent changes(post PHE)
- Annual Quality Report
- Health Equity scrub on CCP
- National Speaking on Telehealth
- Electronic Visit Verification
- Develop Physician Leadership
- Listening Sessions Future of Value Based Care
- BCCCP qualification change
- Family Planning modernization
- Creation of Easy Button for Clinical Policy coverage
- LTC and Vaccine COVID Response
- Launch time-limited payments:
 - Social Determinants screening and diagnosis
 - Loolth Coulty

Managed Care

- Engagement: Fireside Chats & AMH Webinars
- Operationalize AMH changes
- Socialize:
 - Attestation Process for Clinical Policy
 - PCP Attribution
 - AMH Glidepath Requirements
- Partner with Specialty Societies
- Design Thinking: Oversight
- CMARC/CMHARP Transition
- Engage Providers: timely contracting, accuracy of practice information, establishing AMH level, PCP assignment accuracy, understanding attribution,
- maintaining continuity of care

What do you need in May to feel confident we are on a path to success for a July launch?

Two Questions

How will you know in mid-July the transition to Managed Care was successful?

APPENDIX

REFRESHER: Advanced Medical Homes

Goal: provide a pathway for practices to have a larger role in managing the health outcomes and cost for their patient populations

Guiding principles

- 1. Preserve broad access to primary care services for enrollees
- 2. Strengthen the role of primary care in care management, care coordination, and quality improvement
- 3. Provide clear incentives for practices to become more focused on cost and quality outcomes, increasing accountability over time

Expectations are high:

- Penetration rates are much higher than current
- Location of care is designed to be highly community-based
- Need to address the continuum of care needs from **rising risk** to **high risk** to **unmet social needs**

AMH program represents an opportunity for providers to fund population health investments critical to a VBP environment!



NEW Program Incentives and Supports

The Department considered the best ways to help AMH Tier 3 practices prepare for launch.

Changes will:

Add new payment stream for practices in the run-up to launch

Emphasize importance of data exchange to support AMH Tier 3

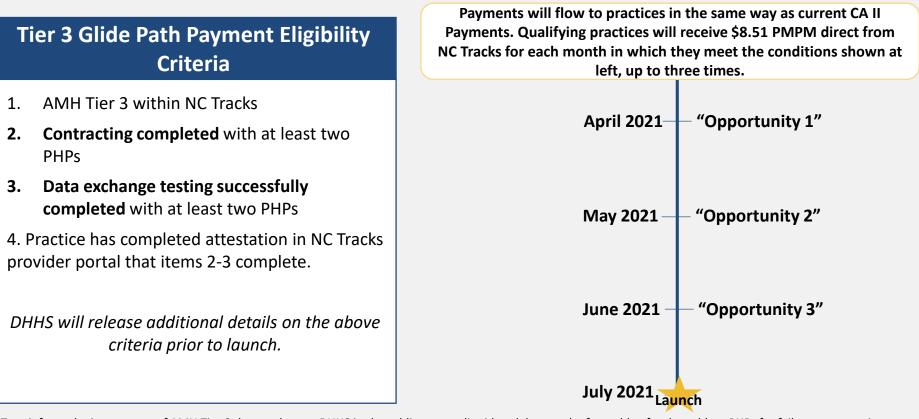
Provide options for practice supports prior to launch

Standardize quality measures and reporting

Protect Care Management Rates

AMH Tier 3 Glide Path Payments

DHHS will implement a new \$8.51 PMPM payment stream to AMH Tier 3 practices <u>90 days</u> prior to the launch of Managed Care to assist with and incent Tier 3 preparation



To reinforce the importance of AMH Tier 3 data exchange, DHHS is also adding a new liquidated damage (enforceable after launch) on PHPs for failure to transmit a beneficiary assignment file or claims to an AMH Tier 3 practice (or CIN/Other Partner) within the Department's published data specifications

	Incentives and		AMH Quality	
	Practice Supports	Assignment	Measure Set	

Support for AMH Practices through AHEC

NC AHEC will offer practice support and education aligned with the AMH program.

AHEC practice supports will include:

AMH Practice Coaching

- Starting in January, AHEC coaches will work with individual practices to accelerate adoption of Tier 3 standards and facilitate transition, starting with a standardized assessment tool
- Available to primary care practices who are in network with at least one Standard Plan
- PHPs may refer practices that need assistance meeting AMH standards

Education

- AHEC will offer webinars, tip sheets, bulletins and other mass communications on the AMH program
- Education will be geared toward all interested Medicaid practices

First webinar: December 10, 2020. Registration information will be posted <u>here</u>.

	Incentives and	Accignment	AMH Quality	Contracting
	Practice Supports	Assignment	Measure Set	Contracting

AMH Quality Measures

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DHHS has streamlined the AMH Measure Set to simplify AMH quality reporting and performance incentive payment arrangements. <u>PHPs will be required to use only these</u> <u>measures</u> to develop AMH performance incentive payments.

Updated AMH Measure SetAdolescent Well-Care VisitChildhood Immunization Status (Combination 10)Immunization for Adolescents (Combination 2)Screening for Depression and Follow-up PlanWell-Child Visits in the First 15 Months of LifeCervical Cancer ScreeningChlamydia Screening in WomenComprehensive Diabetes Care: HbA1c Poor Control (>9.0%)Controlling High Blood PressurePlan All Cause Readmission-Observed to Expected Ratio

Other Measures

PHPs will also be required to share total cost of care information with AMH practices. DHHS will publish additional guidance on sharing total cost of care information with practices at a later date.

		Incentives and Practice Supports			Payment	
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AMH Tier 3 Payments

The Department has finalized several policies regarding Year 1 AMH Tier 3 payments:

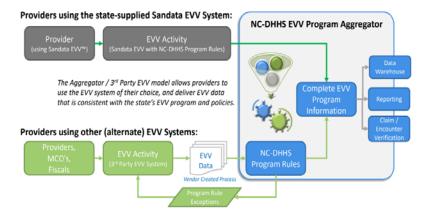
Guaranteed care management fees—PHPs may not place Tier 3 practices' care management fees at risk based on AMH performance or any other metrics. PHPs must pay the full negotiated care management fee amount to all contracted Tier 3 practices.

Use of AMH Measure Set for Tier 3 Performance Incentives—PHPs must offer performance incentive payments in all Tier 3 contracts. These payments <u>must be based</u> <u>only on the AMH measure set</u>, and may not factor in performance on measures beyond those included in the AMH measure set..

NC Electronic Verification Visit (EVV) Implementation Update

- What is it:
 - method used to verify visit activity statewide for services delivered as part of home- and community-based service programs.
 - EVV offers a measure of accountability to help ensure that individuals who are authorized to receive services in fact receive them.
- NC DHHS awarded a contract to Sandata Technologies, LLC on Sept. 24, 2020 and will begin on statewide on Jan. 1, 2021.
- The system is an Open Model which means, State Plan PCS, CAP/DA, and CAP/C Providers can use the Sandata EVV System free of charge or elect to use a system they have chosen. LME/MCOs and PHPs will select an EVV vendor and submit encounter/claims for aggregation.
- NC Medicaid provided an initial training on November 12, for providers on the Alt EVV process and will continue to work closely with providers though the pre-launch and post launch phases.
- Provider Training for Regular EVV began November 30 and will continue through post launch Phase.
- NC will go-live with PCS services in Medicaid Direct (FFS) and CAP C and CAP D/A waiver programs January 1, 2021
- NC will go-live with all MC programs (LME/MCOs and PHPs) July 1, 2021.

EVV Data Flow- Providers to Aggregator



5 Sandata

Timeline	Phase	Milestones
Oct - Dec 2020	Pre- Launch	Initial provider training and credentialing, SIT, UAT testing, Provider Survey and Registration
		Vendor Outreach, Creation of Vendor Interface, Sandata Vendor Support, Vendor Credentialing and testing, EVV Data Deliveries
Jan- Mar 2021	Launch	EVV System Go-live ; On-going Training; Evaluation (first KPI report)
Apr-Jun 2021	Post Launch	System implemented with full functionality for FFS
April 2021	MC Launch	PHPs and LME/MCOs go-live

NC DHHS COVID-19 Vaccination Briefing

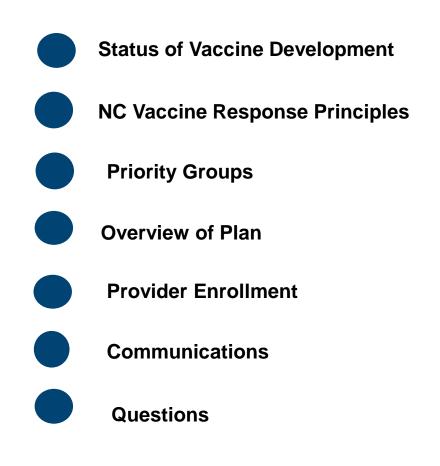
December 9, 2020





NC DHHS COVID – 19 Response

Agenda



Developing, Manufacturing and Distributing a COVID-19 Vaccine

Multiple COVID-19 vaccines are being developed. Thousands of people have volunteered as part of research trials to see if a vaccine prevents COVID illness and to learn more about its safety in these overlapping steps. Promising vaccines are being manufactured at the same time they are being tested, so there will be an initial supply ready to go right away when the science shows which vaccines are found to be safe and effective. Once we have a vaccine or vaccines, it will still be some time before it is widely available to everyone. States will receive limited supplies at the start. North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine distribution plan.

PHASE 1 & 2: Safety & Dosing

10s-100s of healthy volunteers

- Are there any side effects? How many volunteers experience side effects?
- What is the best vaccine dose to create an immune response with the fewest tolerable side effects?

PHASE 2 & 3: Safety & Efficacy

>30,000 of volunteers

- Does the vaccine prevent COVID-19 infection?
- What are the most common side effects?
- Do the benefits of the vaccine outweigh the risks?

Approval & Distribution

- FDA reviews the safety and efficacy data to determine if benefits are greater than risks
- An independent, non-FDA scientific committee reviews findings
- Vaccine is authorized and recommended for use (may only be for certain populations)
- Vaccine is labeled for use, benefits, side effects

Manufacturing

Preparation: Manufacturing development, scaling up, quality-control testing

Large-Scale Manufacturing: Making millions of vaccine doses for nationwide distribution, continued quality-control testing of vaccine batches and manufacturing facilities, FDA and CDC continually monitor vaccinated patients for safety

Availability: Limited availability in the beginning. More widely available over time.

https://files.nc.gov/covid/documents/Vaccine-Timeline.pdf

Two Leading COVID-19 Vaccine Candidates

		Pfizer Vaccine		Moderna Vaccine	
Preliminary Efficacy Data	• • •	Nov 18 Press Release data analysis reported 95% effectiveness in preventing illness. 162/170 cases were in placebo group 9/10 severe cases were in placebo group Phase 3 trial included over 43,000 participants, 42% with diverse backgrounds.	•	November 30 Press Release data analysis 94.1% effectiveness in preventing illness. 185/196 cases were in placebo group 30/30 severe cases were in placebo group Phase 3 trial included 30,000 adult participants, 37% with diverse backgrounds.	
Timing of EUA	•	Applied for EUA 11/20/20 FDA Review Dec 8-10	•	Applied for EUA 11/30 FDA Review Dec 17 th	
Temperature and Storage	•	Requires ultra-cold storage (-75 degrees Celsius). Lasts up to 5 days at refrigerated temperatures.	•	Requires storage at -20 degrees Celsius (similar to the chickenpox vaccine). Lasts up to 30 days at refrigerated temperatures.	
Dosing	•	2-dose schedule Administered 21 days apart.	•	2-dose schedule Administered 28 days apart.	
Type of Vaccine	•	Both vaccines use mRNA technology from the coronavirus's own genes to have people's cells make viral proteins to trigger immune system to produce antibodies against the COVID virus. mRNA vaccines can be made faster than older vaccines and require frozen storage to remain stable			
Safety	•	No reports of serious safety concerns in either variable reactions (e.g., fever, soreness at site of injection			

	AstraZeneca	Johnson Johnson janssen	SANOFI gsk	Creating Temporov's Vaccime Techy
Туре	Non-replicating viral vector	Non-replicating viral vector	Protein Subunit	Protein Subunit
Phase	Phase II/III	Phase III	Phase I/II	Phase II/III
Estimated Availability	Est: Early 2021	Est: Early 2021	Est: First half 2021	Est: Early 2021
Doses Required	Doses: 2 (testing half- dose: full-dose regimen v. two full doses) First interim analysis 90% effective with first half- dose	Doses: 1 or 2 (<i>testing</i> both)	Doses: 1 or 2 (testing both)	Doses: 1
Transport Temp	36°F - 46°F	36°F - 46°F	36°F - 46°F	36°F - 46°F
Storage Temp	36°F - 46°F	36°F - 46°F	36°F - 46°F	36°F - 46°F
Target Supply	3B	1B in 2021	1B by mid 2021	2B+ in 2021
At Risk US Government Purchase	400M	100M	100M	100M

Sources: BioPharma Dive, NIH, ClinicalTrials.gov, Johnson & Johnson News, Sanofi News

Provider agreement language updated to reflect that the vaccine must be provided at no cost to recipient;

Vaccine cost covered by federal government; administrative costs covered by Medicare, Medicaid, and commercial insurance; HRSA will reimburse providers for COVID-19 vaccines administered to uninsured individuals.

Medicaid

 As long as a state is claiming enhanced Medicaid match as part of the Public Health Emergency, the state must cover, without cost sharing, "any testing services and treatments for COVID-19, including vaccines;" this extends to vaccines authorized via EUA.

Medicare

The CARES Act mandated that Medicare Part B cover a COVID-19 vaccine without any cost sharing in cases where "such vaccine is licensed under section 351 of the Public Health Service Act"; a vaccine authorized by an EUA would not meet this standard.

 To address this gap, CMS <u>announced</u> a new rule on October 28th guaranteeing Medicare coverage for a vaccine approved via EUA; this guarantee applies to beneficiaries enrolled in both traditional Medicare and Medicare Advantage.

Uninsured

- HRSA will reimburse providers for COVID-19 vaccines administered to uninsured individuals, once a COVID-19 vaccine receives either an EUA or full licensure from the FDA.Provider Relief Fund (https://www.hrsa.gov/CovidU ninsuredClaim)
- Consistent with HRSA's prior guidance regarding treatment services, an individual with public or private health coverage will be <u>deemed</u> "uninsured" for purposes of the HRSA Program if the individual has a form of health coverage that excludes vaccines (e.g., individuals enrolled in a limited Medicaid family planning program).

Commercial

 Current law and regulations require vaccines recommended by ACIP to be covered as an Essential Health Benefit without cost sharing.

COVID-19 Vaccine Toolkit

NC COVID-19 Vaccination Plan: Vision of Success



Immunize every person living in North Carolina who is eligible and wants to receive a COVID-19 vaccine

GUIDING PRINCIPLES



All North Carolinians have equitable access to vaccines



Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations



Transparent, accurate, and frequent public communications is essential to building trust



Data is used to promote equity, track progress and guide decision-making



Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation

COVID-19 Vaccine Advisory Committee

- **Purpose**: Provide updates from industry and stakeholders to ensure alignment
- Group of >60 stakeholders
- Historically Marginalized Populations Advisory Group
 - **Purpose:** Identify and address issues related to HMP in the COVID pandemic response
 - Vaccine team presents regularly to HMP Advisory Group for input and partnership opportunities
 - Group of >80 internal and external stakeholders
- COVID-19 Vaccine Communications Advisory Group
 - **Purpose**: Enhance the development of North Carolina's COVID-19 Vaccine Communications Plan and to serve as dissemination partners to extend the reach of the communications efforts, especially to prioritized, critical, and historically marginalized populations

COVID-19 Vaccinations: Those most at risk get it first.

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. Independent state and federal public health advisory committees have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, reaching more people as the vaccine supply increases from January to June. Keep practicing the 3W's—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to vaccinate.

Health care 1 workers fighting COVID-19 & Long-Term Care	Adults at highest 2 risk of severe illness and those at highest risk for exposure	Adults at high risk for exposure and at increased risk of severe illness	Students and 4 critical industry workers	Everyone who wants a safe and effective COVID-19 vaccination
Every health care worker at high risk for exposure to COVID-19—doctors, nurses, and all who interact and care for patients with COVID-19, including those who clean areas used by patients, and those giving vaccines to these workers. Long-Term Care staff and residents—people in skilled nursing facilities and in adult, family and group homes.	Adults with two or more chronic conditions that put them at risk of severe illness as defined by the CDC, including conditions like cancer, COPD, serious heart conditions, sickle cell disease and Type 2 diabetes, among others. Adults at high risk of exposure including essential frontline workers (police, food processing, teachers), health care workers, and those living in prisons, homeless shelters, migrant and fishery housing with 2+ chronic conditions. Those working in prisons, jails and homeless shelters (no chronic conditions requirement).	Essential frontline workers, health care workers, and those living in prisons, homeless shelters or migrant and fishery housing. Adults 65+ Adults under 65 with one chronic condition that puts them at risk of severe illness as defined by the CDC.	College and university students. K-12 students when there is an approved vaccine for children. Those employed in jobs that are critical to society and at lower risk of exposure.	

VACCINE DISTRIBUTION PRIORITIZATION FRAMEWORK

Risk-based prioritization based on National Academy of Medicine Framework for Equitable Allocation of COVID-19 and CDC Advisory Committee Immunization Practice. Refined by input by North Carolina Institute of Medicine Vaccine Advisory Committee. May be revised based on Phase III clinical trial safety and efficacy data and further federal guidance

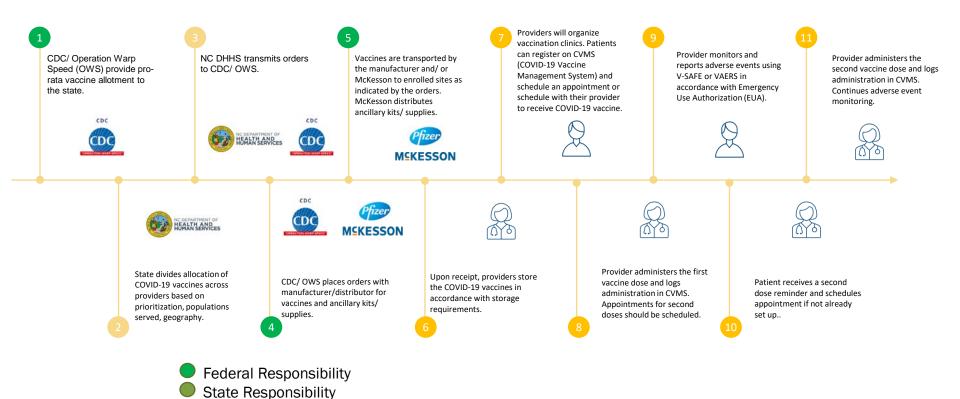
Phase 1	Phase 2	Phase 3	Phase 4
 Phase 1a: Health care workers at high risk for COVID-19 exposure based on work duties or vital to the initial COVID vaccine response High risk of exposure is defined as those caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, performing procedures at high risk of aerosolization (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR), handling decedents with COVID. administering vaccine in initial closed or targeted vaccination clinics. Population includes: nurses, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental services staff, EMT/paramedics, home health workers, personal care aides, community health workers, health care trainees(e.g., medical students, pharmacy students, nursing students, etc.), morticians/funeral home staff, pharmacists, public health nurses, public health and emergency preparedness workers who meet the above definition of "high risk of exposure." Long Term Care staff and Residents (e.g., Skilled Nursing Facilities, adult care homes, family care homes, and group homes; individuals with intellectual and developmental disabilities who receive home and community-based services and the workers directly providing those services) Phase Ib: Adults with high risk of complications per CDC and staff of congregate living settings Operationally prioritize settings based on risk of exposure (s.g., firefighters, police, workers in meat packing plants, seafood and poultry not in congregate housing, food processing, preparation workers and servers, manufacturing, construction, funeral attendants and undertakers not included in Phase 1A with 2+ Chronic Conditions* Frontline workers with 2+ Chronic Conditions at high risk of exposure (e.g., firefighters, police, workers in meat packing plants, seafood and poultry not in congregate housing, food processing, preparation workers and servers, manufacturing, const	 Migrant Farm/fishery workers in congregate living without 2+ Chronic Conditions Incarcerated individuals without 2+ Chronic Conditions Homeless shelter residents without 2+ Chronic Conditions Frontline workers at high or moderate risk of exposure without 2+ Chronic Conditions All other Health Care Workers not included in Phase 1A or 1B Education staff (Child Care, K- 12, IHE) without 2+ Chronic Conditions Other adults age 18-64 with one chronic condition* 65+ year olds with one or no chronic conditions* 	 Workers in industries critical to the functioning of society and at increased risk of exposure who are not included in Phase 1 or Phase 2 K-12 students (if data from clinical trials), college students 	Remaining population

NC COVID-19 Vaccine Operational Plan: Overview

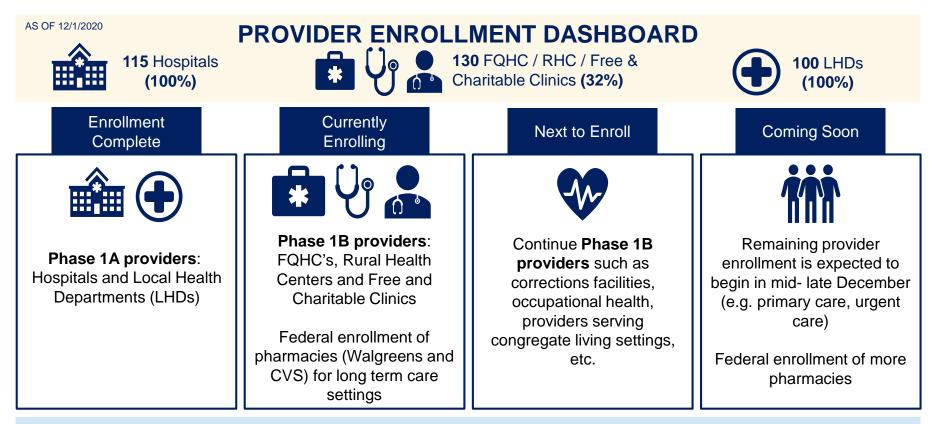
	Planning	Implementation	Adjustment	Transition
	Before vaccine is available	Begins when first vaccine doses are allocated to states	Large number of vaccine doses available	Sufficient supply of vaccine doses for entire population
Populations	 Establish priority groups 	 Phase 1 populations Stabilize health care delivery system and protect individuals at highest risk 	Continue to move through phased populations as vaccine supply allows	 Offer vaccination to all populations through Phases 3 and 4
Vaccination Channels	• N/A	Through local health departments and on-site vaccination clinics (in closed settings)	 Require more points of access, mass vaccination clinics, and broad vaccination sites 	 Vaccination in established channels Fewer mass, mobile, or community-based clinics
Enrollment/ Ordering/ Allotment	 Identify/enroll providers Expect CDC centralized distribution to 	 Continue to enroll providers Allocations to state, allotted to enrolled providers 	Transition to provider ordering vaccines based on need for population and local demand	Ordering similar to annual seasonal flu vaccine campaign
Shipment	 None shipped Expect vaccine and anc. supplies procured and distributed by fed gov't 	 Shipment in increments of 1,000 for some May require ultra-cold storage & 2-dose series 	Shipment minimum of 100 for most vaccines	 Move to high supply/lower demand
Data	 Confirm capability for required functionality, data collection, and reporting 	Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements	 Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements 	 Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements

Vaccine Journey

Provider Level



Vaccine: Provider enrollment



NC's provider enrollment strategy is based upon the prioritization strategy

Vaccine: Federal long-term care pharmacy program

LTC ENROLLMENT DASHBOARD

~498 Adult	427 Skilled Nursing
Care Homes	Facilities
(84%%)	(100%)

★ 12/21 ★ 12/21 ★ 12/28 Communication s to LTC facilities Start pulling vaccines from allocation banks Start administering vaccines

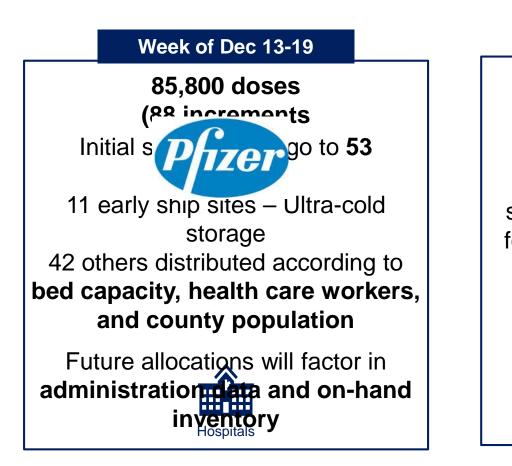
KEY PROGRAM DATES

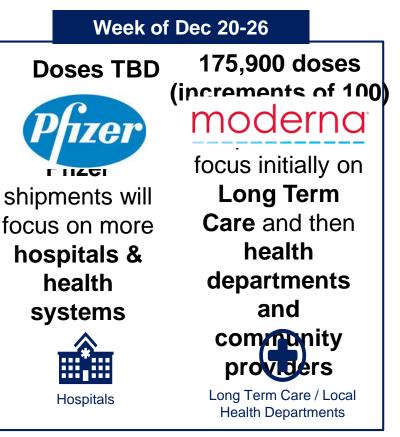
The federal government – in coordination with the CDC – has created the Pharmacy Partnership for Long-term Care (LTC) Program in partnership with CVS and Walgreens to vaccinate those in LTC settings

As part of this program, pharmacies will:

- Schedule and coordinate clinic dates with each facility
- Order vaccines and associated supplies
- Ensure cold chain management for vaccine
- Provide on-site administration of vaccine including patient information and consents as needed
- Report required vaccination data to local, state/territorial, and federal jurisdictions within 72 hours
 of administration

Allocation will come from state allocation starting with NC's week 2 allocation





Vaccine: COVID -19 Vaccine Management System (CVMS)

dosages

 ★ 11/23 ★ 11/30 ★ 12/8 ★ 12/10 ★ 12/17 CVMS Provider Enrollment CVMS Priority CVMS MVP Soft CVMS MVP Go-Live CVMS MVP R2 CVMS R 	★ TBD R3+ Go-Live
CVMS Provider Enrollment CVMS Priority CVMS MVP Soft CVMS MVP Go-Live CVMS MVP R2 CVMS R	R3+ Go-Live
Soft Launch invitation to:Access PreviewLaunch forAnd available toGo-LiveFuture f• Goshen Community Healthattended by 120+subset of PhasePhase 1a and PhaseAdditional featuresend	features and nhancements railable within CVMS
What is CVMS? CVMS is a secure, cloud-based vaccine Who will use CVMS?	use CVMS?
 management solution for COVID-19 that enables vaccine management and data sharing across providers, hospitals, State officials will enroll providers and verify provider eligibility along with verifying site readiness Pharmacies, such as CV Walgreens, will not use administer and manage verifying site readiness 	CVMS to
 agencies, and local, state, and federal governments on one common platform Providers will verify patient eligibility, log dosage administration, and track frequency and timing of additional Pharmacies will to use th systems 	

When the CVMS is launched on 12/10, providers will be able to:

- Enroll in the COVID-19 Vaccine
 Program
- Employees can register for vaccination
- Manage vaccine inventory
- Track vaccine administration data

Training for Phase 1 providers started week of 11/30
CVMS will be available to select

- CVMS will be available to select providers for a soft launch on 12/8 and the remaining providers will have access to the system on 12/10
- Building capability to ingest vaccine data files from pharmacies into CVMS

COVID Vaccine Communications: North Carolina's Commitment

Provide early, transparent, consistent, and frequent communications so that North Carolinians:



Trust the information that they receive from NC DHHS and local health departments about COVID-19 vaccinations



Understand the benefits and risks of COVID-19 vaccinations



Make informed decisions about COVID-19 vaccinations



Know how and where to get a COVID-19 vaccination



One in three North Carolinians say they will definitely get a COVID 19 vaccine once approved by the FDA and offered for free. Another one in four say they will probably get the vaccine.

Less likely to say they will get vaccine

- Blacks/African Americans
- Females
- High school or some college only
- Lower income groups
- Under age 35

More likely to say they will get vaccine

- Hispanic, Latinx
- Asians
- White Non-Hispanics
- Males
- College or higher educated
- Higher income residents
- Ages 65 and older

Most common reasons for vaccine avoidance:

- Concerned about side-effects
- Feel it hasn't been tested enough
- Don't want to be first to take the vaccine

Core COVID-19 Vaccine Messages

🖗 PROCESS

Great care has been taken to make sure COVID-19 vaccines are safe and effective.

- Scientists had a head start. Although the vaccines were developed quickly, they were built upon years of work in developing vaccines for similar viruses. Development time was cut without cutting corners.
- **Testing was thorough and successful.** More than 70,000 people participated in clinical trials for two leading vaccines to see if they are safe and effective. To date, the vaccines are nearly 95% effective in preventing COVID-19 with no safety concerns

WEXPECTATIO

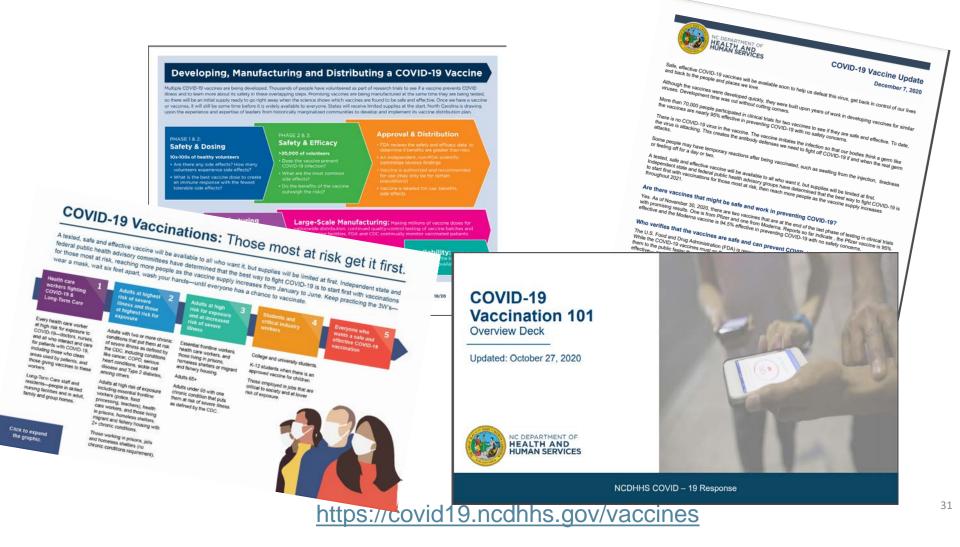
NS effective vaccine will be available to all who want it, but supplies will be limited at TIFST. The pest way to fight COVID-19 is to start first with vaccinations for those most at risk, then reach more people as the vaccine supply increases throughout 2021

NCLUSIVITY

North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine plan

Communication Tools https://covid19.ncdhhs.gov/vaccines

COVID-19 Communication Tools



Questions?