



# Presented by EPIC and CVS Caremark

Sree Chaguturu, M.D.

Chief Medical Officer of CVS Caremark and SVP of CVS Health

**Bob Eisendrath** 

EPIC Pharmacy Practice

**Craig Schmidt** 

EPIC Wellness & Health Management Practice

# **OVERVIEW**



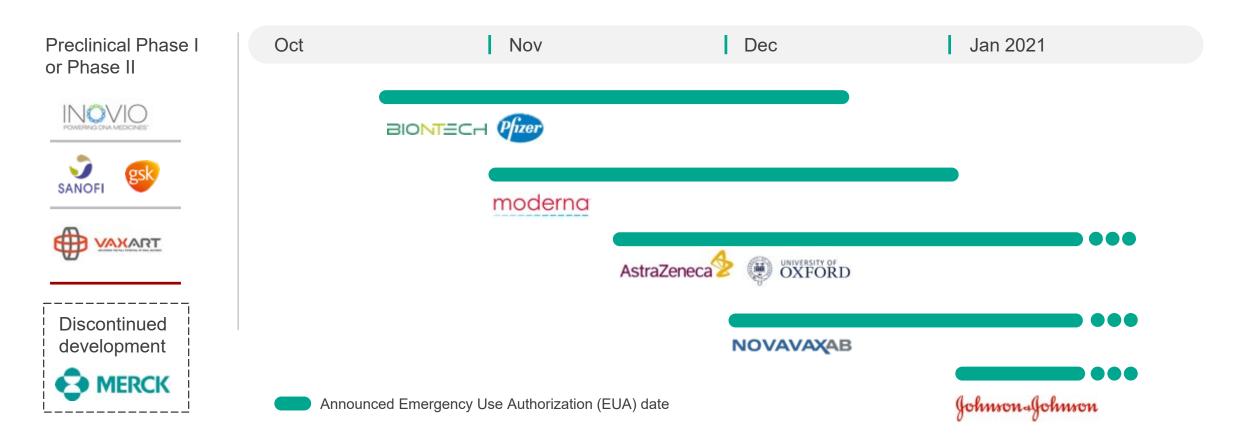
This is the second in a two part COVID-19 Vaccine Webinar Series

- Vaccine pipeline update, implications of variants and emerging efficacy data
- Frequently asked clinical questions
- Vaccine roll-outs
- CVS ready to help
- Key Workplace Initiatives



# We started 2021 with nine leading vaccine candidates

with the potential for emergency use authorization



Not comprehensive. Preliminary – Not meant to communicate clinical, legal, or regulatory advice. Sources: BioCentury; ClinicalTrials.gov; Milken Institute COVID-19 Treatment and Vaccine Tracker.



# Efficacy and safety of current FDAauthorized vaccines

### Pfizer/BioNTech vaccine

Final efficacy analysis demonstrated vaccine

# 95% effective

Efficacy in preventing moderate to severe symptomatic COVID-19

Efficacy evaluated 7 days after second dose

# **Overall safe profile**

Sources: https://www.nejm.org/doi/full/10.1056/NEJMoa2035389 https://www.nejm.org/doi/full/10.1056/NEJMoa2034577

#### Moderna vaccine

Full efficacy analysis demonstrated vaccine

# 94.1% effective

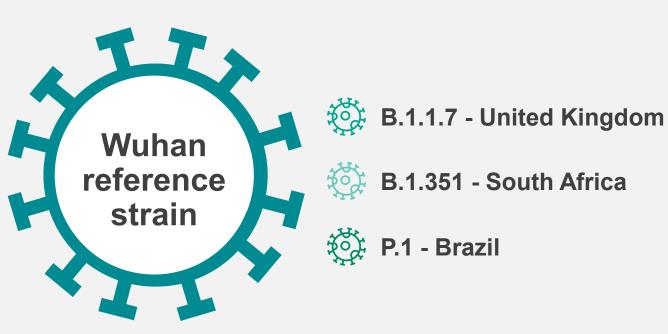
Efficacy in preventing moderate to severe symptomatic COVID-19

Efficacy evaluated 14 days after second dose

# **Overall safe profile**



# Information on new COVID-19 variants



All share the N501Y mutation in the spike protein

South African and Brazil strains share the E484K mutation in the same protein

Common mutations emerging in different parts of the world

All three are in the United States

Sources: https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e2.htm https://scdhec.gov/news-releases/south-carolina-public-health-officials-detect-nations-first-known-cases-covid-19 https://www.health.state.mn.us/news/pressrel/2021/covid012521.html



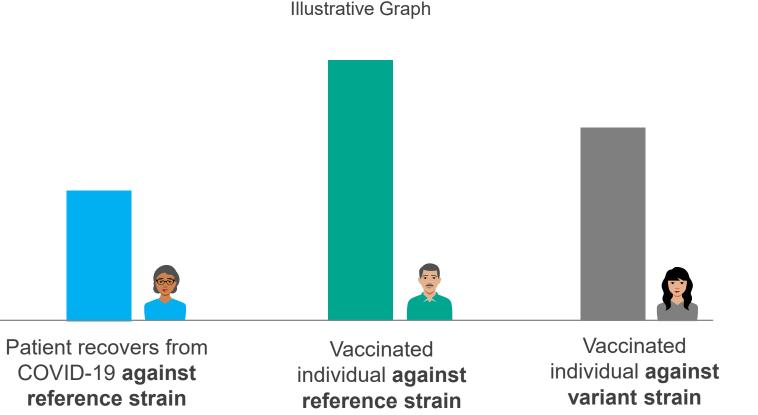
# **Questions about new COVID-19 variants**

Are they more transmissible?

Do people get sicker?

Will the FDA-authorized vaccines continue to work?

# Level of antibody response to COVID-19 appears to be different in various scenarios



Vaccines produce powerful levels of immune protection so they should be able to withstand some drop in potency while still protecting people



# FDA-authorized vaccine efficacy against new variants

### **Pfizer**

The vaccine appears to produce similar antibody response (neutralizing titers) against the B.1.1.7 UK variant

### Moderna

The vaccine appears to produce similar antibody response (neutralizing titers) against the B.1.1.7 UK variant

Six-fold reduction in antibody response against B.1.351 South Africa variant

- Antibody levels remain above levels expected to be protective (Cushion effect)
- May suggest potential risk of earlier waning of immunity to B.1.351 strains

#### Sources:

https://www.biorxiv.org/content/10.1101/2021.01.18.426984v1 https://www.biorxiv.org/content/10.1101/2021.01.07.425740v1

https://investors.modernatx.com/news-releases/news-release-details/moderna-covid-19-vaccine-retains-neutralizing-activity-against

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# **Implications**

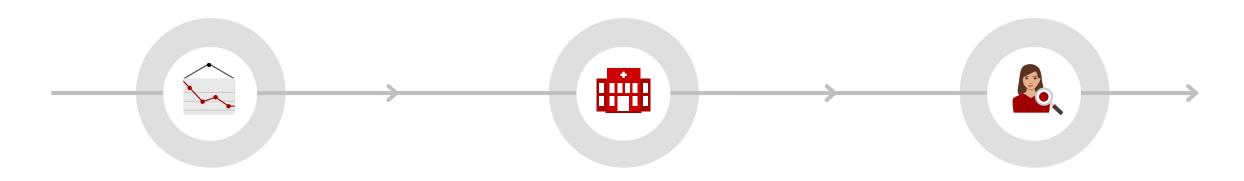
Both vaccines produce powerful levels of immune protection so they should be able to withstand some drop in potency while still protecting people

Laboratory data only – still need real-world efficacy

Vaccines can be updated as needed to confer the protection we see against the reference strain



# There are several ways to look at vaccine trial efficacy data



Overall efficacy preventing symptomatic COVID-19

Efficacy at reducing hospitalizations and severe COVID-19 Efficacy in sub-group analyses – e.g., variants, age (elderly vs. pediatrics)



### **Johnson & Johnson**

# Efficacy – interim analysis

Interim analysis demonstrated vaccine

# 66% effective

Efficacy in preventing moderate to severe symptomatic COVID-19

Efficacy evaluated 28 days after one dose

#### Sources:

https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial. https://www.nejm.org/doi/10.1056/NEJMoa2034201.

#### Phase III study in 43,783 participants aged 18 years and older

- 34% of participants over the age of 60
- 44% of participants from the U.S., 41% from Latin America, and 15% from South Africa

# Efficacy based upon 468 symptomatic cases of COVID-19 among trial participants

- Did not include mild COVID-19 cases in vaccine efficacy analysis
- Breakdown of cases observed in the placebo group vs. the vaccine group not yet released

# 85% efficacy in preventing severe disease across all regions studied

- No reported cases of COVID-19 related hospitalization and death (day 28 post-vaccination)
- Vaccine efficacy by region: **72%** in the U.S., **66%** in Latin America, and **57%** in South Africa

Overall fever rates: 9%, Grade 3 fever: 0.2%

Overall serious adverse events reported were higher in participants who received placebo as compared to the active vaccine candidate

No anaphylaxis observed

#### **Positive Notes**

- 100% efficacy in preventing hospitalizations and deaths
- One dose
- Easier cold chain shipping and storage requirements



#### Novavax

# Efficacy – interim analysis

Interim analysis demonstrated vaccine

89.3% effective

Efficacy in preventing moderate to severe symptomatic COVID-19

Efficacy evaluated 7 days or more days after second dose

<u>Source: https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-ukphase-3.</u>

#### UK Phase III study in >15,000 participants aged 18-84 years

- 27% of participants over the age of 65 years

#### Interim analysis demonstrated overall vaccine efficacy of 89.3%

- **56** cases in the placebo group and 6 cases observed in the vaccine group
- 1 severe case in the placebo group and 0 in the vaccine group
- 95.6% efficacy against original COVID-19 strain
- 85.6% efficacy against UK variant B 1.1.7

# South African Phase IIb study demonstrated vaccine efficacy of 49.4%

- 60% efficacy observed in the 94% of the study population that was HIV-negative

Severe, serious, and medically attended adverse events occurred at low levels, balanced between vaccine and placebo groups

U.S. phase III trial will complete enrollment in February; interim data may be available in March-April 2021

#### **Positive Notes**

- 100% efficacy in preventing hospitalizations and deaths
- Easier cold chain shipping and storage requirements



# Key takeaways on vaccine pipeline



We have two new promising candidates nearing authorization

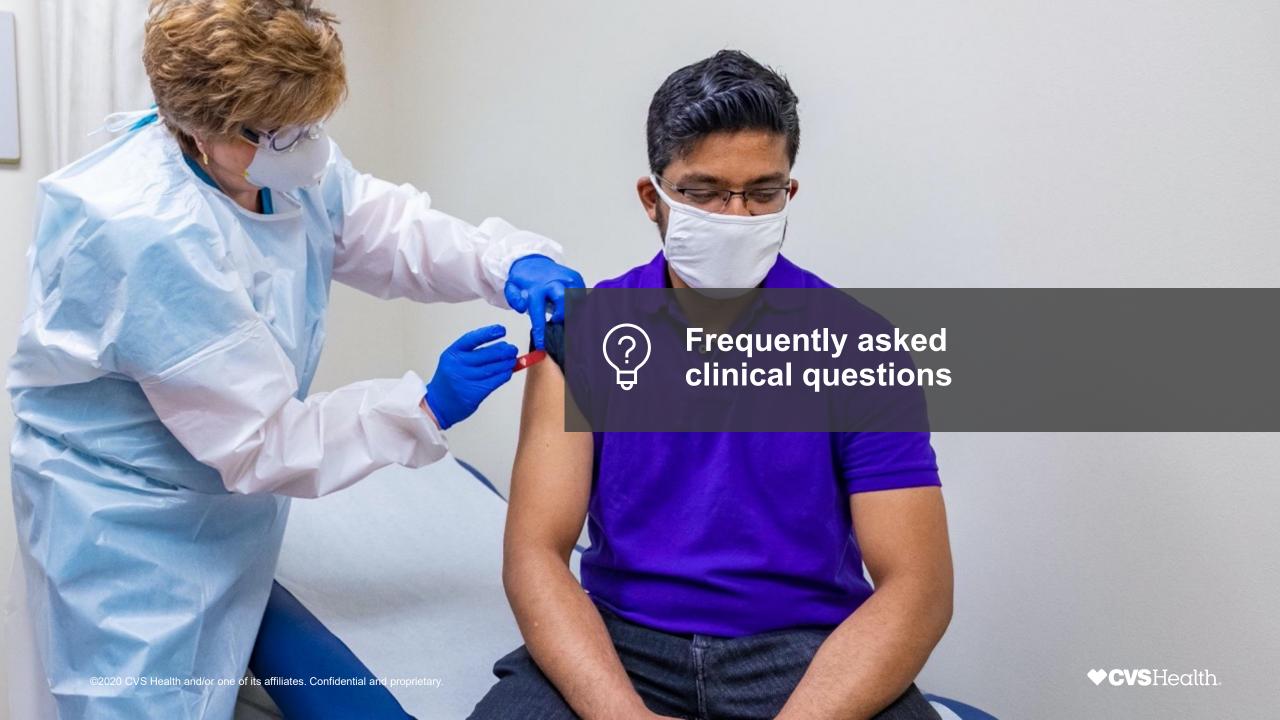
All vaccines authorized or nearing authorization appear to have high efficacy in preventing hospitalizations and deaths from COVID-19

As the virus continues to spread, the higher likelihood that even fitter variants will emerge

More people vaccinated means less chance for COVID-19 to continue mutating

Reinforces need to vaccinate faster







#### Are the vaccines safe?

Yes. Each of the vaccines undergo rigorous, placebo-controlled, randomized clinical trials. The data are reviewed and analyzed by an independent committee of experts for recommendations on authorization to the U.S. Food and Drug Administration (FDA). This process was carefully followed for both the Moderna and the Pfizer vaccines, and will be for the remaining vaccines candidates.

### Are the two current FDA-authorized vaccines equally effective?

Studies show both the Moderna and Pfizer vaccines appear to be equally beneficial.

#### What kind of side effects should I expect?

Mild to moderate side effects include injection site pain, tiredness, headache, muscle pain, chills, joint pain, and fever. Long-term side effects are unlikely, but still being studied.



# ...I have underlying health conditions or if I'm immunocompromised?

People with underlying health conditions or who are immunocompromised are encouraged to get vaccinated. You should always consult with your doctor first.

### ...I'm pregnant, trying to conceive, or breastfeeding?

Women who are pregnant, breastfeeding, or trying to conceive are encouraged to get vaccinated, but should consult with their doctor first.

#### ...I'm currently positive for COVID-19?

If you currently have COVID-19, or COVID-19 like symptoms, you should wait to receive a vaccine until after you recover.

#### ...I have recovered from COVID-19?

Yes. Even if you have already had COVID-19 you can still benefit from the vaccine. You may contract the infection again and spread it to others, so it's important you get vaccinated to protect your family and your community.



# Will I still be protected from the virus if I'm late getting the second vaccine dose? What if I don't get the second dose at all?

Receiving the second dose late should not diminish the effectiveness of the vaccine. Although you gain some protection after the first dose, both manufacturers recommend two doses for strong and enduring protection.

# After I get the second dose, how long before the vaccine takes effect?

In general, it takes 1-2 weeks for immunity to develop following vaccination.

# If I am vaccinated against COVID-19, can I spread the virus to others?

Studies are underway to determine if a vaccinated person can spread the virus. Even after getting vaccinated, you should continue mask wearing, hand washing, and social distancing.

### How often will I need to get the COVID-19 vaccination?

It is unclear at this time, but current information suggests that the COVID-19 vaccine will be like the flu vaccine, requiring annual dosing.



# State governments will determine who gets the vaccine and when, guided by the following ACIP recommendations to the CDC:





Health care workers

Long-term care residents



Phase 1b

Front-line essential workers

People ages 75+



Phase 1c

People ages 65–74

People with high-risk medical conditions, ages 16–64

Other essential workers



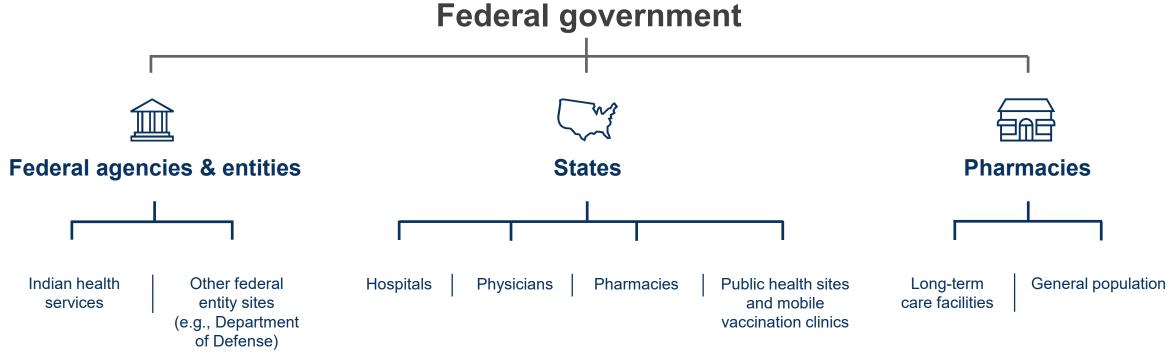
Phase 2

General population, ages 16+



# Distribution in the U.S. – how it works





**EXAMPLES OF ADMINISTRATION SITES** 



# The Biden Administration's key vaccine initiatives

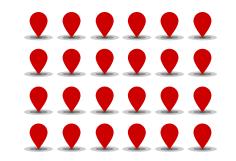
# More people

need to get the vaccine



# More locations

to administer vaccinations



# More supplies

of vaccines and ancillaries available



# **More** immunizers

to get vaccines in arms



# More consumer education

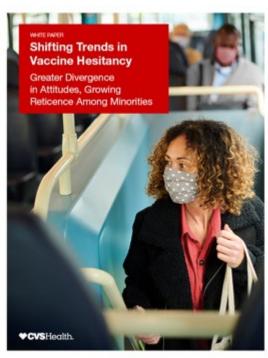
to address vaccine hesitancy





#### CVS Health survey early January 2021 findings on vaccine hesitancy

# Some hopeful signs, some concerning trends



Hyperlink to the white paper

38% were interested in a vaccine as soon as it is available

28% in November 2020

21% would wait until others had been vaccinated

35% in November

17% were uncertain about receiving a vaccination

20% in November

24% did not plan on being vaccinated

17% in November 2020

☐ 35% Black respondents
26% in November

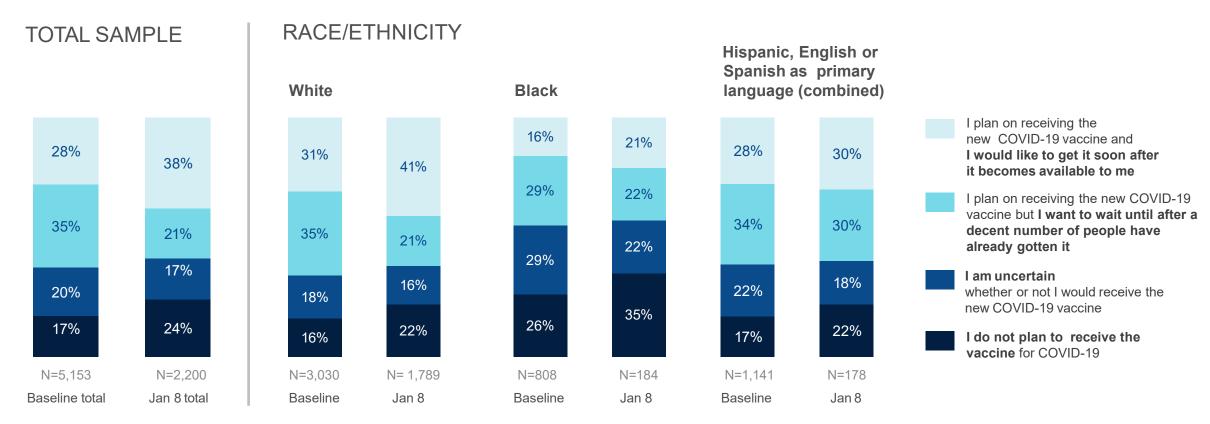
22% Hispanic respondents17% in November

Findings from survey conducted January 8-11, 2021 compared to baseline findings from November 10-15, 2021.

Survey methodology: This survey was initiated on January 8, two days after Congress certified the results of the November 3, 2020 Presidential Election. The survey ran nationwide from January 8–11 among a national sample of 2,200 adults. The interviews were conducted online, and the data were weighted to approximate a target sample of adults based on age, educational attainment, gender, race, and region. Results from the full survey have a margin of error of plus or minus 2 percentage points. We constructed our total sample to be representative of the U.S. population as described by the U.S. Census Bureau. Participants represent the general population and were not screened as customers of CVS Health. We ascribed weights based on gender, age, race/ethnicity, and region of residence. Participants had the option of choosing more than one race/ethnicity.



# Survey results show vaccine hesitancy continues to be an issue



Findings from survey conducted January 8-11, 2021 compared to baseline findings from November 10-15, 2021.

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Since December, through February 8, CVS Health has administered over 3 million doses,

that's like giving one COVID-19 vaccine every 1.3 seconds.

# Our ongoing partnership with the federal government

# The long-term care pharmacy partnership program

Patient eligibility dictated by the state

Timing and scope of activation dictated by the state

Supply allocated to pharmacies dictated by the CDC

First: vaccination of nursing home residents and staff

**Second:** vaccination of assisted living and other facilities enrolled in the program

Most states chose to prioritize skilled nursing facilities and did not activate the assisted living and other facilities portion of the program until well into January.





# Vaccinating long-term care residents and staff

~8K

Nursing homes

partnered with CVS

Health

100%
First dose clinics completed\*

86%
Second dose clinics completed

1.8M+
Total
vaccines
administered in skilled
nursing facilities

38K

Assisted living and other facilities partnered with CVS Health

82%

First dose clinics completed

21%

Second dose clinics completed

1.2M+

Total vaccines administered in assisted living and other facilities

**CVS**Health.

CVS Health data as of February 8, 2021. Excludes 0.3% of skilled nursing facilities that 1) requested a later date due to a COVID-19 outbreak or other reason, 2) were rescheduled due to lack of responsiveness, or 3) requested to be added to the program after the start date or did not meet original program criteria regarding distance from CVS Health locations, but that CVS Health has opted to support.

# Broader allocation of COVID-19 vaccines opening up to retail pharmacies over coming weeks





Federal allocations to pharmacies only available for LTCF program.
All other allocations going to states for targeted distribution and some states have partnered with pharmacies as part of their vaccination programs.

Mid-Dec through Mid-Jan



## **State transfer program**

States given mechanism to transfer allocations to Federal Retail Pharmacy partners to broaden access

Mid-Jan through Early/Mid-Feb



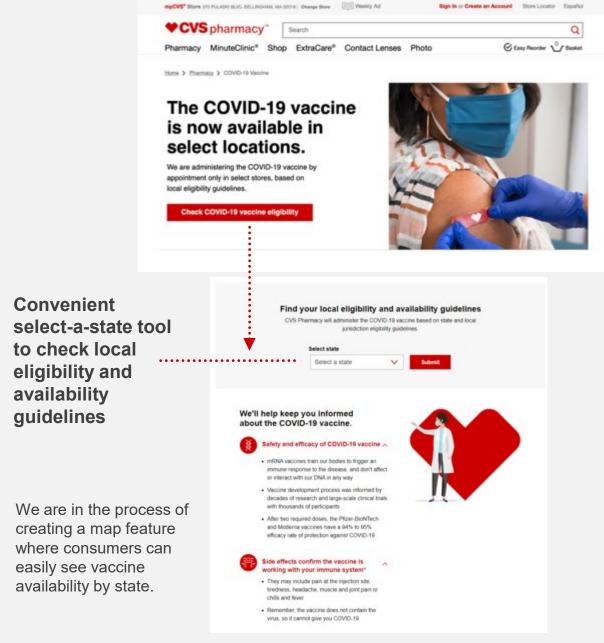
# Full federal / pharmacy partnership

Pharmacies given direct allocations above and beyond state allocations

Early/Mid-Feb

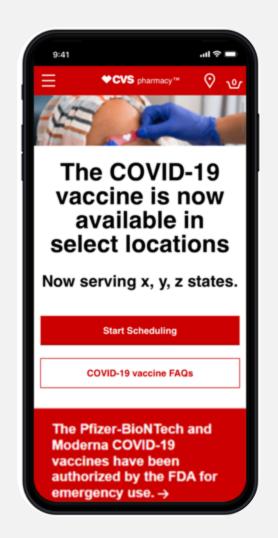


# Clarity on COVID-19 vaccine eligibility and availability at CVS.com





First, we screen out patients with symptoms, then we check if they need both doses or just the second dose

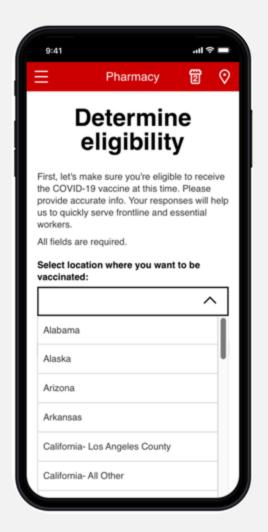


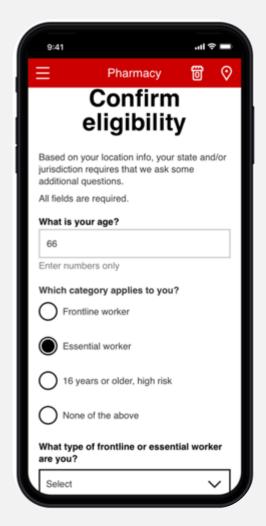


Scheduling tool subject to change as we learn and refine the patient experience



Our configurable eligibility screener accommodates state and jurisdiction-level eligibility differences

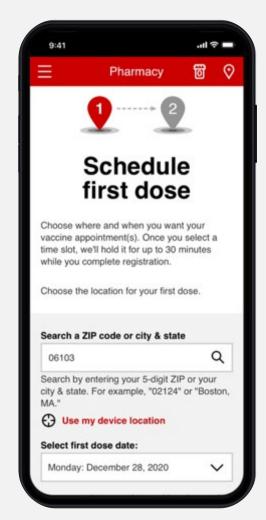


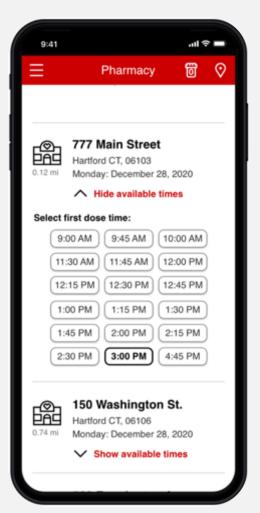




We make sure eligible consumers understand the two-dose regimen, and then allow them to schedule their first dose

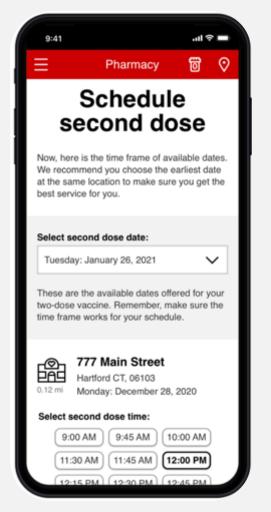


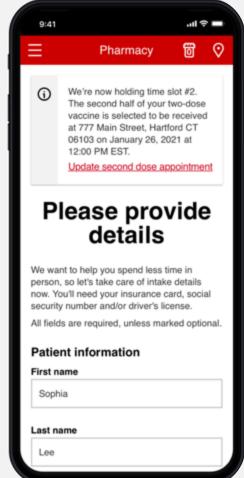


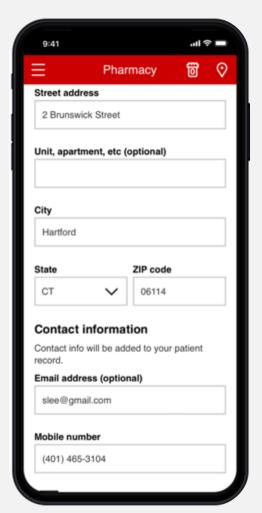




Consumers then move to the next screen to book their second dose appointment





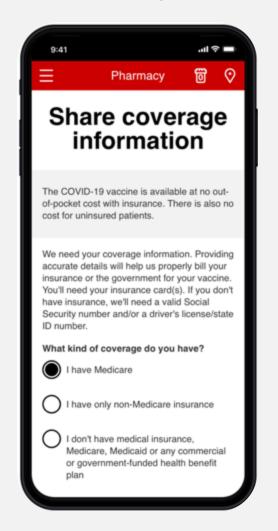




We capture insurance information to get reimbursed from the insurance provider for vaccine administration.

Anyone without insurance will be covered by the HRSA uninsured program.

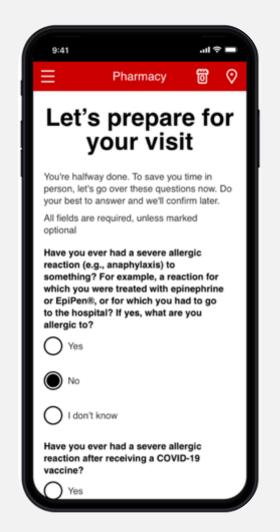
Consumers will not be charged for the vaccine or its administration, even if they don't have insurance.

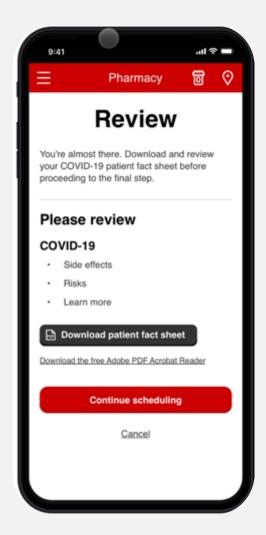






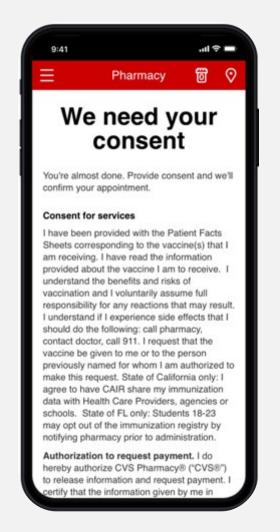
Consumers
can save time
by answering
clinical questions
before their visit

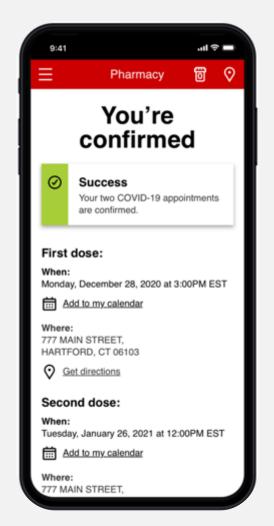






We capture consent and confirm both appointments, followed by a series of email and text message reminders



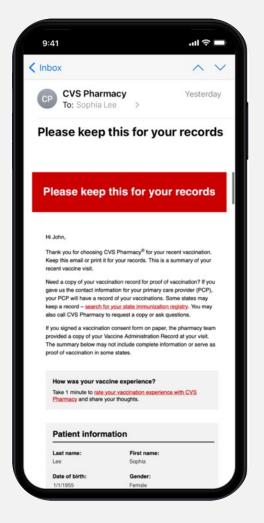




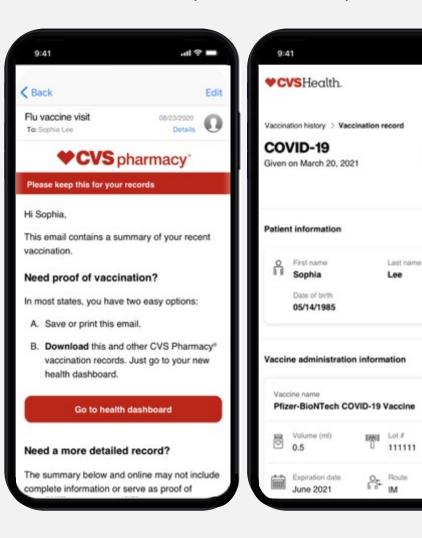
# All patients who opt in will receive an electronic vaccine record.

We're also working to make it even easier for patients to access and share their vaccine record securely.

#### Email available today

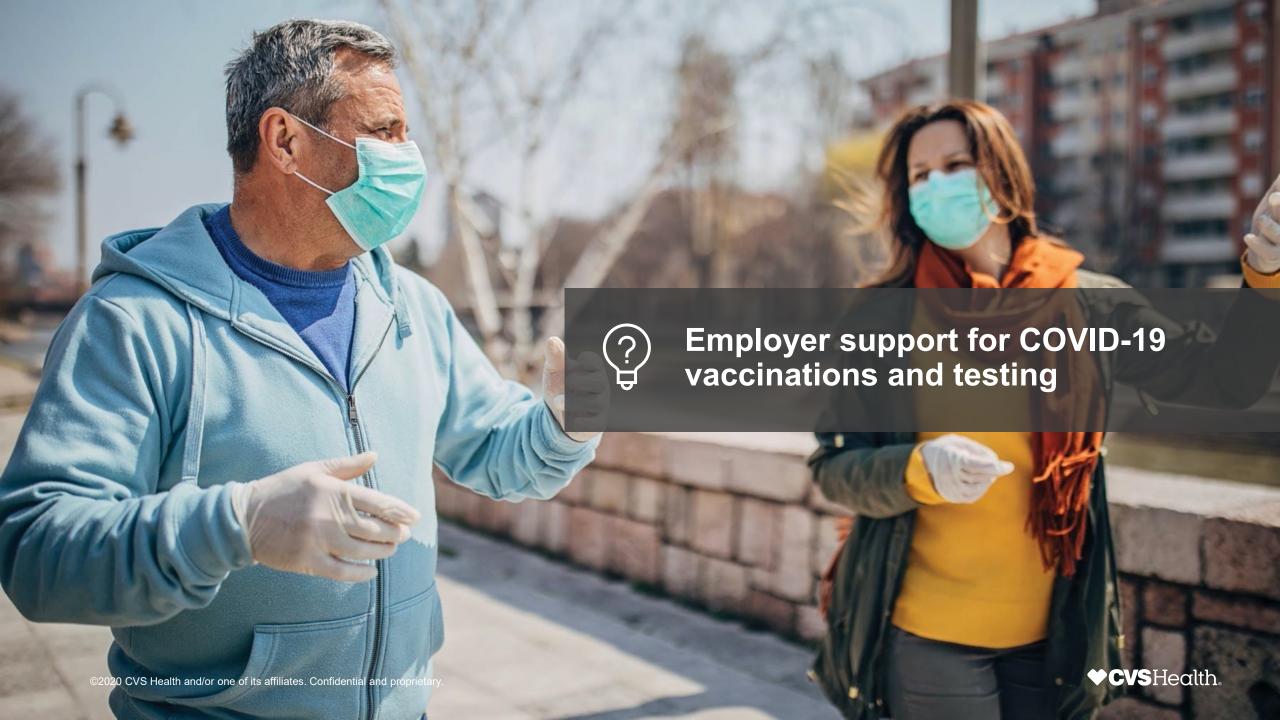


#### Enhanced experience in development





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# Onsite COVID-19 vaccination clinics – **bring the vaccine to your employees**

#### **Current requirements for onsite clinics**

Employers has secured a dedicated vaccine allocation for their employees/essential workers from the state

Employer has more than 1,000 eligible essential workers that can be vaccinated at a single location

Contract required

When COVID-19 vaccine supply expands, requirements for onsite clinics may change and more employers may be eligible to contract for dedicated vaccination clinics.







# Key Workplace Initiatives

# WORKPLACE COVID-19 INITIATIVES

### Pre-vaccine

Communication is key (CDC.gov toolkits)

Limit number of employees in and around workplace

Monitor employees for symptoms

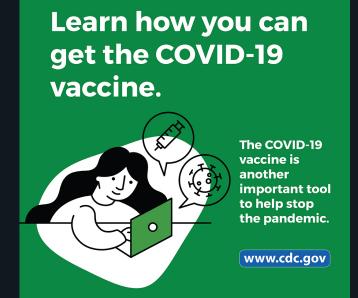
Monitor employees for contact tracing

Individual employees may be eligible before total workforce

Don't forget about the flu, encourage employees to get the flu vaccine







# **WORKPLACE COVID-19 INITIATIVES**



## When your organization is eligible for vaccines

- Stay in contact with your local public health department
- Build COVID-19 vaccine confidence at your workplace
  - Encourage leaders in your family, community, or organizations to be vaccine champions.
  - Have discussions about COVID-19 vaccines where people can openly discuss their views and ask questions.
  - Share key messages through multiple channels that people trust and that promote action.
  - Help educate people about <u>COVID-19 vaccines</u>, how they are developed and monitored for safety, and how
    individuals can talk to others about the vaccines.
  - Learn more about <u>finding credible vaccine information</u>. When you come across COVID-19 information, cross-check with CDC.gov and learn how to respond to misinformation you encounter.
  - When vaccine is offered to you, make <u>visible</u> your decision to get vaccinated and celebrate it!
- Survey employees on who wants a vaccine
- Company stance: strongly recommending, incentivizing or mandating employee vaccines

# **WORKPLACE COVID-19 INITIATIVES**



## **Post-vaccine**

- Continue to monitor employees for symptoms and contract tracing
- Do not rush to go back to normal working conditions, continue worksite safety precautions
- Continue with masks and social distancing policies
- Vaccines are up to 95% effective, not 100%
- Not all employees will get COVID-19 vaccine
- Not all employee family members will be eligible for COVID-19 vaccines

E P I C

Wrap-Up

# **EPIC COVID-19 VACCINE WEBINAR – PART 2**



Materials will be sent to all attendees and available on our **EPIC Brokers** site.



# Thanks for attending!