



Covid-19 Update: The Final Push Vaccines, Boosters, Testing, Monoclonal Antibodies, and 5-11 Vaccines

**Maryland Department of Health
Maryland Primary Care Program
Program Management Office**

3 November 2021

We Can Win This Game With A Triple Play

❖ Push vaccines

- The last hesitant unvaccinated- accounting for deaths
- 5-12 year old
- Boosters for all
- Third doses for the immunocompromised

❖ Monoclonal antibodies

- All eligible positive cases
- All unimmunized contacts

❖ Testing

- Primary care offices
- Schools
- Businesses
- Home testing and more

Agenda

- ❖ Current Pandemic data
- ❖ Vaccine Updates
- ❖ Monoclonal antibodies
- ❖ Testing
- ❖ Third doses and boosters
- ❖ End game for the pandemic
- ❖ Guest Presentation: Alex Nowalk
- ❖ Guest Presentation: Dr. Monique Soileau-Burke
- ❖ Guest Demonstration: PROPs Team

Daily COVID-19 Report

Data reported as of 11/3/2021 for data through 11/2/2021

562,896

cases cumulative

14,188,340

tests cumulative

11.8

7-day avg. case rate

7,305

total hospital census

10,694

deaths cumulative

696

cases reported yesterday

27,605

tests reported yesterday

3.01%

7-day avg. positivity

359

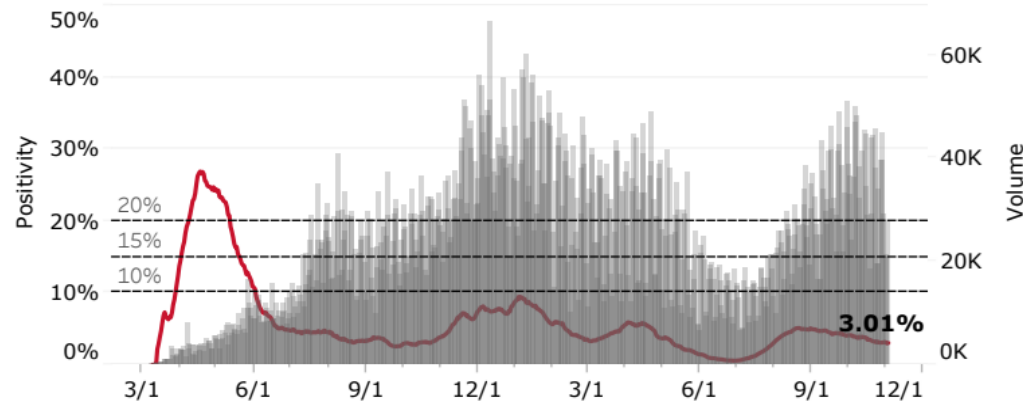
change in total hospital census

12

deaths reported yesterday

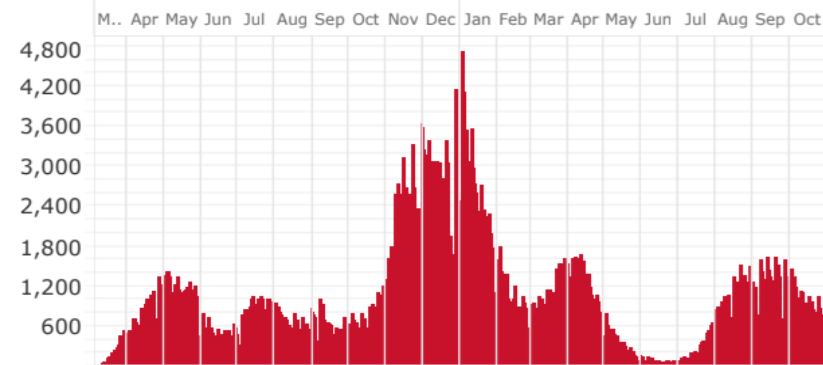
7-Day Avg. Percent Positivity and Total Testing Volume

Since 3/1/20

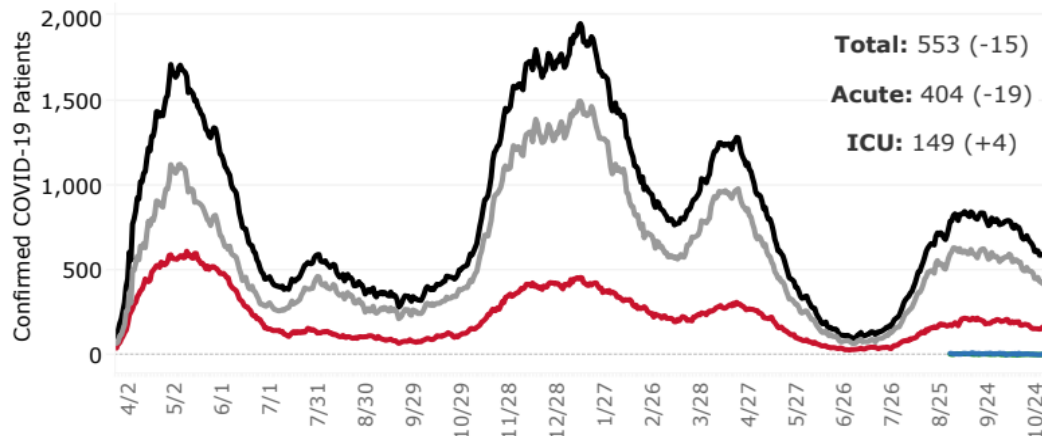


Daily New Cases

by Specimen Collection Date



Statewide Acute/ICU Beds Occupied by COVID Patients

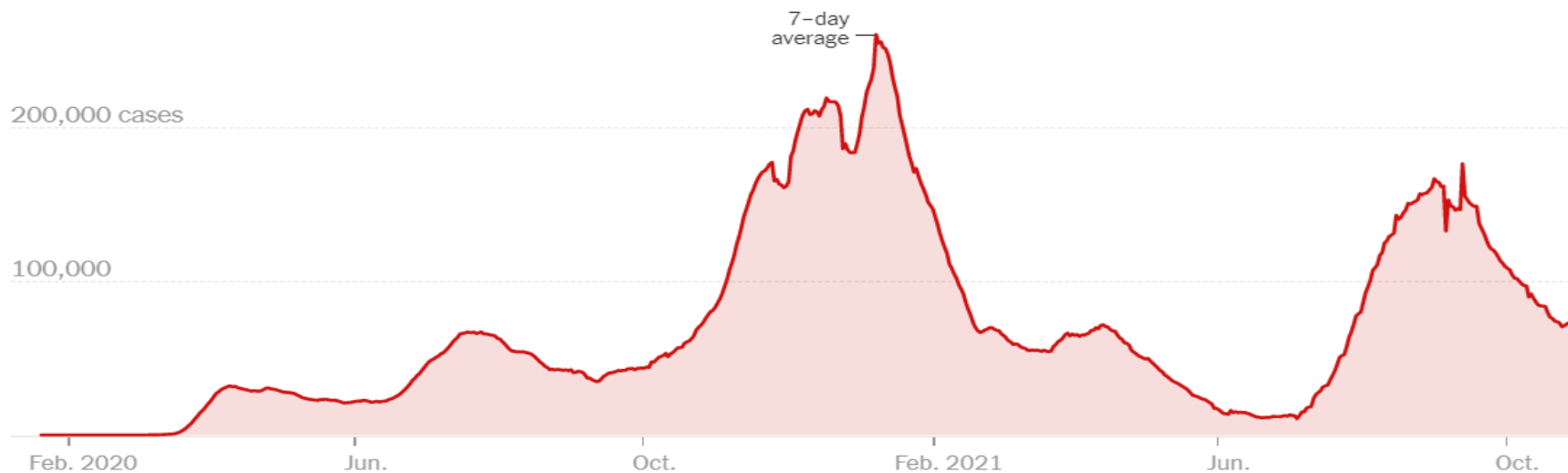


Overview of Current Pandemic Trends in the United States

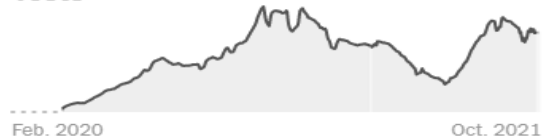
New reported cases

All time

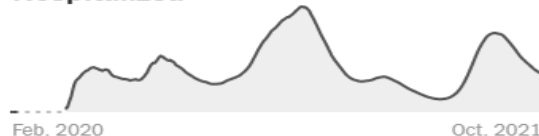
Last 90 days



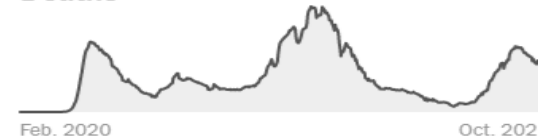
Tests



Hospitalized



Deaths



DAILY AVG. ON OCT. 31

14-DAY CHANGE

TOTAL REPORTED

Cases

72,961

-13%

45,934,095

Tests

1,440,565

+10%

Hospitalized

50,126

-17%

Deaths

1,346

-12%

745,535

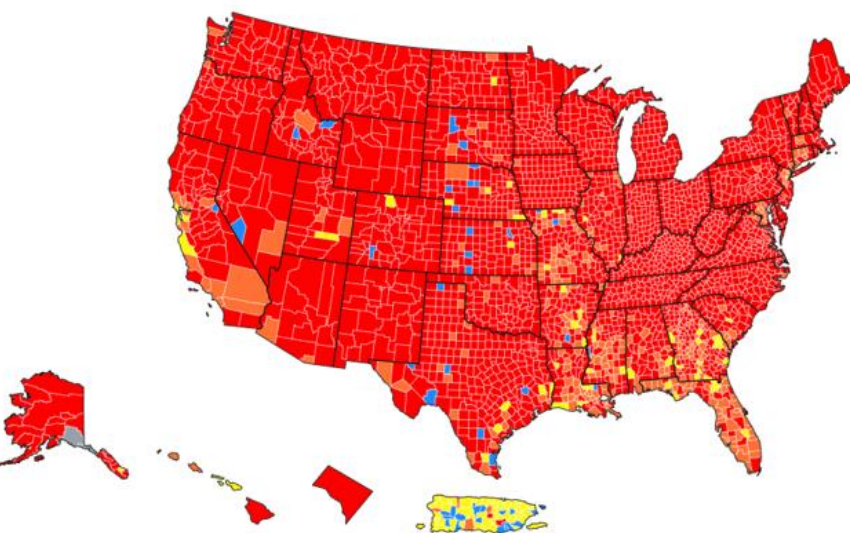
[About this data](#)

Source: [New York Times](#)

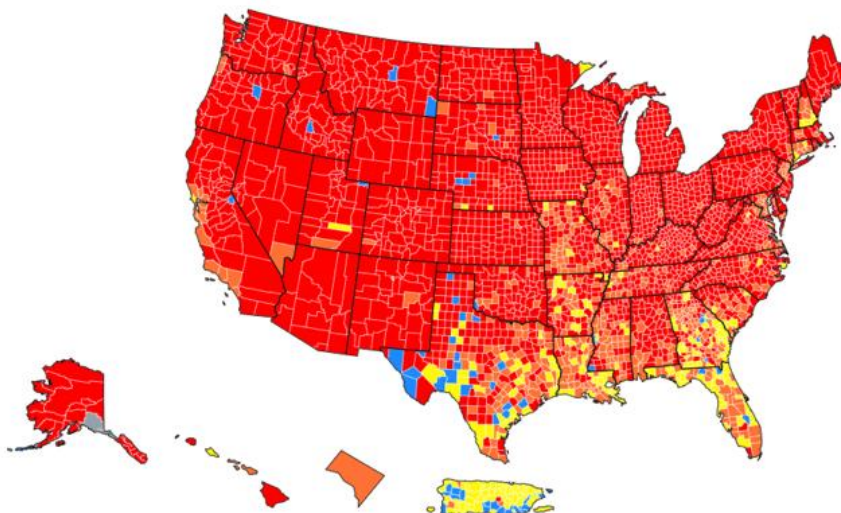
Data Updated 11/1/2021

US Community Transmission

Community Transmission in the United States,
October 12 – October 18



Community Transmission in the United States,
October 24 – October 30



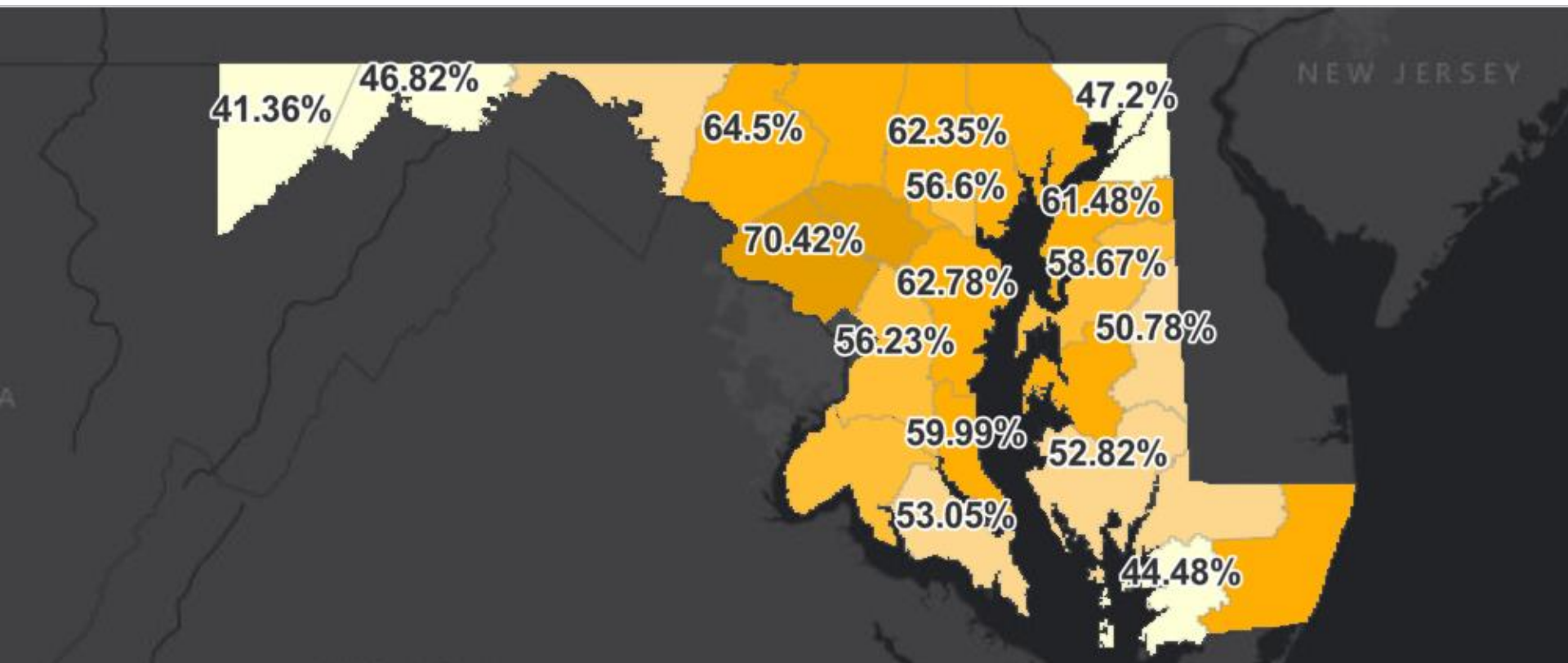
Community Transmission in

	Total	%	% Change
High	2733	84.82%	-4.41%
Substantial	319	9.9%	3.29%
Moderate	122	3.79%	1.02%
Low	43	1.33%	0.06%

First Play: Vaccines

- ❖ The first and most important out in the triple play
- ❖ Primary Care Providers are the key players in completing this part of the play

Proportion Vaccinated by County



Pregnant Individuals

- ❖ [CDC issued an urgent health advisory](#) encouraging pregnant individuals to obtain a Covid vaccine
 - Only 34.6% of pregnant individuals are vaccinated
 - As of 11/1, there have been over 134,000 confirmed Covid cases among pregnant individuals
 - Pregnant individuals with Covid have an increased risk of:
 - ✓ Hospitalization
 - ✓ Death from Covid
 - ✓ Adverse pregnancy outcomes
- ❖ GoVAX Fast Facts brochure

Primary Care and Vaccines

Cumulative Doses Administered

226,294

Primary care providers are one of the most influential people in patients' lives and with increasing cases, we are inviting all providers to join the vaccination efforts

- ❖ 86.5% of Marylanders 18+ have received at least one vaccine dose
- ❖ 456 primary care practices are involved in the Primary Care Vaccine Program

We are excited to acknowledge the top 5 MDPCP practices and CTOs for Covid-19 vaccination efforts!

Practices

1. Charlestown Medical Center - **92.92%**
2. Dr. Luis A. Casas, M.D. - **92.64%**
3. Linda M. Lang, M.D., LLC - **92.59%**
4. Doctors Saba, Koltz and Walters - **92.45%**
5. Dorchester Family Medicine - **92.27%**

CTOs

1. Holy Cross Health, Inc. - **88.75%**
2. PHS Doctors CTO - **86.31%**
3. Ascension Saint Agnes Community Health Partners - **85.40%**
4. Greater Baltimore Health Alliance Physicians, LLC - **85.38%**
5. University of Maryland Care Transformation Organization, LLC - **84.43%**

Note: percentages represent percent of MDPCP beneficiaries fully vaccinated

We are excited to acknowledge the top 5 MDPCP practices and CTOs for accomplishing the biggest improvement in vaccinating their unvaccinated patients in the last week!

Practices

1. Riderwood Village Medical Center - **3.73%**
2. Opal Medical Group, PA - **2.44%**
3. Allegheny Medical - **2.01%**
4. Physicians Inpatient Care Specialists at Rehabilitative Services, LLC - **1.98%**
5. Syed A. Sadiq, M.D. - **1.65%**

CTOs

1. Maryland Collaborative Care Transformation Organization - **0.37%**
2. MedChi Practice Transformation - **0.36%**
3. Management Solutions, LLC - **0.29%**
4. Aledade Accountable Care 30, LLC - **0.26%**
5. University of Maryland Upper Chesapeake Health System, Inc. - **0.24%**



Note: percentages represent percent increase of MDPCP beneficiaries fully vaccinated

Boosters - Pfizer



- ❖ At least six months after 2nd dose
- ❖ Eligible populations:
 - 65 years and older
 - Age 18+ who live in [long-term care settings](#)
 - Age 18+ who have [underlying medical conditions](#)
 - Age 18+ who work in [high-risk settings](#)
 - Age 18+ who live in [high-risk settings](#)


Boosters - Moderna

- ❖ At least six months after 2nd dose
- ❖ Eligible populations:
 - 65 years and older
 - Age 18+ who live in [long-term care settings](#)
 - Age 18+ who have [underlying medical conditions](#)
 - Age 18+ who work in [high-risk settings](#)
 - Age 18+ who live in [high-risk settings](#)
- ❖ Note: Moderna booster dose is a **half dose**
 - *Third doses for immunocompromised individuals are **full doses***

Boosters - J&J

- ❖ At least two months after initial dose
- ❖ Everyone who obtained J&J for the initial dose is now eligible for a booster dose
- ❖ [COVID-19 Vaccine Booster Guide for PCPs](#)





COVID-19 Vaccine Booster Guide for PCPs

Last Updated 10/27/2021


This guide is designed to assist you with identifying eligible populations for COVID-19 vaccine boosters, timing of eligibility, and how to provide eligible patients with booster doses.


Quick Links:
[CDC Media Announcement on Booster Recommendations \(10/21/2021\)](#)
[FDA Recommendations on COVID-19 Vaccine Boosters \(10/20/2021\)](#)

PFIZER

The CDC now recommends a booster injection for the following populations that have previously obtained the Pfizer COVID-19 primary series:

- 65 years and older
- Age 18+ who live in [long-term care settings](#)
- Age 18+ who have [underlying medical conditions](#)
- Age 18+ who work or live in [high-risk settings](#)

 These populations are eligible for a booster injection [six months](#) after completing the primary series

 [Pfizer Storage and Handling Guide Link](#)

Pfizer CPT Codes

- 0001A for the first dose of Pfizer
- 0002A for the second dose of Pfizer
- 0003A for the third dose of Pfizer (immunocompromised)
- **0004A for the booster dose of Pfizer**

Page 1

Heterologous Dosing - Mixing and Matching

- ❖ The CDC has now advised that booster doses can be a different vaccine type than the primary series
 - Ex: An individual that originally obtained Moderna for doses 1 and 2, can now obtain Moderna, Pfizer, or J&J for a booster if they are eligible for a booster dose
- ❖ All Moderna booster doses are a **half dose**, regardless of the individual's primary vaccine type

Second Play: Monoclonal Antibody Therapy

- ❖ Second out in the triple play
- ❖ Primary Care Providers are on second base
- ❖ Prevent deaths, prevents hospitalizations
- ❖ Sadly, many are hospitalized and die without benefit of this therapy

Monoclonal Antibodies Updates

The Only Outpatient Covid-19 Therapy

- ❖ Currently available from USG by allocation to each state (125,000 doses national/week)
 - Maryland receiving 1484 doses this week
- ❖ Subcutaneous administration available for Regeneron
 - Post Exposure Prophylaxis for unvaccinated , high risk
 - Expanded patient qualifications – clinical judgment
 - Bam-Etes and Regeneron for PEP
 - HHS Protect registration and reporting required

Patient Facing Resources

❖ Website

- [Landing page](#)-- general page highlighted at Governor's 9/30 press conference
- [FAQ](#)-- detailed information about mAb

❖ Contact tracing

- Direct text message to all contacts and people with positive tests (ages 18+) linking to Landing Page (Eng. & Sp.)
- mAb information sent to Interviewed Cases & Exposed Contacts at conclusion of contact tracing interview

❖ Site Access and PEP status

- Flyer with treatment location list, PEP information, and self-referral information

Self-Referral Options for Patients

- ❖ Patients should coordinate with their respective physician or care provider before contacting a location to schedule an appointment.
- ❖ Patients without a healthcare provider, contact [eVisit](#) to schedule a virtual appointment or complete a [self-referral form](#).
 - Eligible patient(s) will be referred to an infusion site for treatment.
- ❖ For those without internet access or a healthcare provider, they may contact the **MDH-supported monoclonal antibody call center** at **410-649-6122** (Monday – Friday from 8 a.m. to 5 p.m) and speak to a clinician to review eligibility.
 - *Odenton VFD, City of Praise Ministries, and [MDmAbs](#) also accept direct patient contact to determine eligibility and/or schedule treatment

Provider-Facing Resources

- ❖ Webinars- over 100
- ❖ Clinician Letters
 - “Checklist” to assist providers in determining patient eligibility for mAbs.
- ❖ Ease in making referral
 - Option 1: [CRISP eREFERRAL for Monoclonal Antibody Infusion](#)
 - Option 2: [Maryland Referral Form for Monoclonal Antibody Infusion Treatment](#) (Updating to include sites where PEP is available)
 - Some sites allow patients to self-refer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

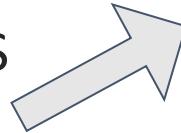
The Maryland Department of Health (MDH) provides this clinical criteria checklist as a resource for referring or administering monoclonal antibodies (mAb). There are currently three products authorized under Emergency Use Authorization (EUA): [Bamlanivimab and Etesimab](#), [REGN-3031](#), and [Sotrovimab](#).¹ Monoclonal antibodies are currently indicated for two purposes: certain individuals with active COVID-19 and as a post-exposure prophylaxis in vulnerable persons (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

Determine Eligibility for Monoclonal Antibody Treatment for Patients	
Track 1 - Active COVID-19 Infection	Track 2 - Post-Exposure Prophylaxis
1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.	1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO , STOP ; YES , proceed to number 2.
2. Does the patient have a positive COVID-19 PCR or antigen test result? If NO , STOP ; YES , proceed to number 3.	2. Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance? ² If NO , Proceed to Number 3 ; YES , proceed to number 4.
3. Does the COVID-19 positive patient have mild to moderate COVID-19 symptoms such as fever, cough, shortness of breath, loss of taste/smell, fatigue, nausea, vomiting, diarrhea, throat pain, congestion, myalgia, or headache? If NO , STOP ; YES , proceed to number 4.	3. Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If NO , STOP ; YES , proceed to number 4.
4. Has it been less than 10 days since symptom onset and positive COVID-19 test result? If NO , STOP ; YES , proceed to number 5.	4. Is the individual NOT fully vaccinated? ³ If NO (individual is fully vaccinated), Proceed to Number 5 ; YES (individual is not fully vaccinated), proceed to number 6.
5. Is the COVID-19 positive patient at high risk ⁴ for progression to severe COVID-19, including hospitalization or death? If NO , STOP ; YES , proceed to number 6.	5. Is the individual anticipated to NOT mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If NO , STOP ; YES , proceed to number 6.
6. If any of the following apply, STOP ; the patient is not eligible for treatment. Otherwise, proceed to number 7. <ul style="list-style-type: none">• Patient hospitalized for COVID-19• Patient requires oxygen therapy due to COVID-19• Patient requires require an increase in baseline oxygen flow rate due to COVID-19• Patient is in imminent need of hospitalization due to COVID-19	6. If exposure occurred within the past 96 hours, patient meets eligibility criteria; proceed with administration or referral. Patients who meet eligibility criteria can be referred to facilities geographically spread across Maryland for equitable access. To refer a patient, please use the CRISP platform eReferral Tool or the Maryland Department of Health (MDH) Maryland Referral Form .
7. Patient meets eligibility criteria; proceed with administration or referral. For referral resources see Track 2 No. 6.	

¹ Sotrovimab is not authorized for post-exposure prophylactic administration and is only commercially available at this time.
² Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (coughing or sneezing, for example). See this website for additional details: <https://www.cdc.gov/coronavirus/2019-ncov/faq-what-constitutes-close-contact.html>
³ Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as the Johnson & Johnson/Janssen vaccine). See this website for more details: <https://www.cdc.gov/vaccines/imz/faq.html>
⁴ For further information as to what qualifies an individual as high risk please see slide 39 of the Monoclonal Antibody Clinical Implementation Guide available at: <https://www.dhs.gov/eo-sav/2020/05/COVID-19/monoclonal-antibody-clinical-implementation-guide>

Practice mAb Referral Workflow

- 1) Daily, go into the CRISP ENS PROMPT to [view new positive Covid-19 test results](#) for your patients
- 2) For Covid-positive patients, assess every patient for [mAb eligibility](#)
- 3) For eligible patients, call the patient to recommend mAb treatment
 - a) See this [patient-facing website](#)
- 4) Refer the patient to mAb treatment through [CRISP](#) or [externally](#)



HOME CALIPR PATIENT SNAPSHOT **ENS PROMPT** HEALTH RECORDS

COVID-19 RESULTS VIEWER REFERRAL PORTAL 2021 ECQMS SBIRT

Filter by Name or MRN CRISP DEMO

All Not started In progress Completed

Notifications count: 75
last updated: 15:54 10/19/21

COCONUT DEMO1 (180034567)

MD NEDSS
10/12/2021 09:05 AM
OP Test Result
COVID-19 Tested negative for COVID-19

Monoclonal Antibody Treatment: Post-exposure Prophylaxis

- ❖ Who is eligible for post-exposure prophylaxis?
 - Individuals with significant medical condition(s) who have no Covid-19 symptoms, but have been exposed in the past four days to a known or suspected case of COVID-19 and are in one of the following categories:
 - ✓ Are not fully vaccinated
 - ✓ Are vaccinated but not expected to have an adequate immune response to the vaccine
 - ✓ Are in a congregate living situation such as a nursing home or prison

Merck Oral Covid Medication

- ❖ Molnupiravir - Merck and Ridgeback Biotherapeutics' oral antiviral treatment
 - Phase 3 trial indicates a reduction in risk of hospitalization or death by around 50% in high risk unvaccinated Covid patients
- ❖ Plans for next steps
 - Merck to seek emergency use authorization in U.S. and submit marketing applications to other global drug regulators
 - If authorized, could be first oral antiviral medicine for Covid
- ❖ Study data
 - 7.3% of patients treated were hospitalized within 29 days
 - 14.1% of placebo patients were hospitalized or died by day 29
 - 0 deaths among treated patients and 8 deaths among placebo patients by day 29

Third Play: Testing

- ❖ The final out and the game winner to restore normality and a robust economy
- ❖ Primary Care Providers close the deal with onsite testing and making sure the ball isn't dropped for all other results

Why Testing is Important

- ❖ Identify those that can spread Covid-19
- ❖ Return to work
- ❖ Return to school
- ❖ Contact tracing
- ❖ This information will facilitate the containment of spread and the opening of the economy
- ❖ Identify those eligible for monoclonal therapy

Primary Care POC testing

- ❖ MDH is expanding the use of point-of-care testing
- ❖ [MDH guidance](#) for point-of care testing
 - Rapid point-of-care testing [toolkit](#)
 - Point-of-care testing through MDPCP [request form](#)
 - Abbott BinaxNOW [getting started guide](#)

Flu Season Is Here

- ❖ Timeline
 - Occurs in the fall and winter
 - Most of the time the flu peaks in between December and February
- ❖ Flu vaccines recommended for all individuals that are 6 months old and older
- ❖ [Patients who visit medical offices](#) after patients with influenza-like illnesses are more likely to show signs of influenza-like illness within the following two weeks than non-exposed patients
- ❖ CDC FAQs for the 2021 – 2022 season are [here](#)

Will it ever be truly “over”

❖ End games - and Herd Immunity

- Eradication- smallpox- none now
- Elimination- measles- near complete vaccine herd immunity
- Containment- flu- natural immunity plus vaccine



“Everything will be okay in the end. If it’s not okay, it’s not the end.”

- John Lennon

CME Accreditation and Designation

- ❖ This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of MedChi, The Maryland State Medical Society, and The Maryland Department of Health. MedChi is accredited by the ACCME to provide continuing medical education for physicians.
- ❖ MedChi designates this live webinar educational activity for a maximum of 1 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Contact Frank Berry at fberry@medchi.org

CME Disclosures and Evaluation

- ❖ Presenters and Planners: Howard Haft, MD, has reported no relevant financial relationships to disclose.
- ❖ MedChi CME Reviewers: The reviewers from the MedChi Committee On Scientific Activities (COSA) for this activity have reported no relevant financial relationships to disclose.
- ❖ *Attendees can receive CME credit by completing [this evaluation](#) after each webinar. MedChi will then be in contact with the certificate*

Announcements

Thank you to all of our providers and their staff who have been true healthcare heroes throughout the pandemic!

Our next Covid-19 Update Webinar has been rescheduled for:

❖ **RESCHEDULED:** Thursday, November 18, 2021 (5:00 pm - 6:00 pm)

➤ Registration link:

<https://attendee.gotowebinar.com/register/2698793490339203339>

Open enrollment is live for Maryland Health Connection - Additional information is in the Appendix of this slide deck

Guest Speaker

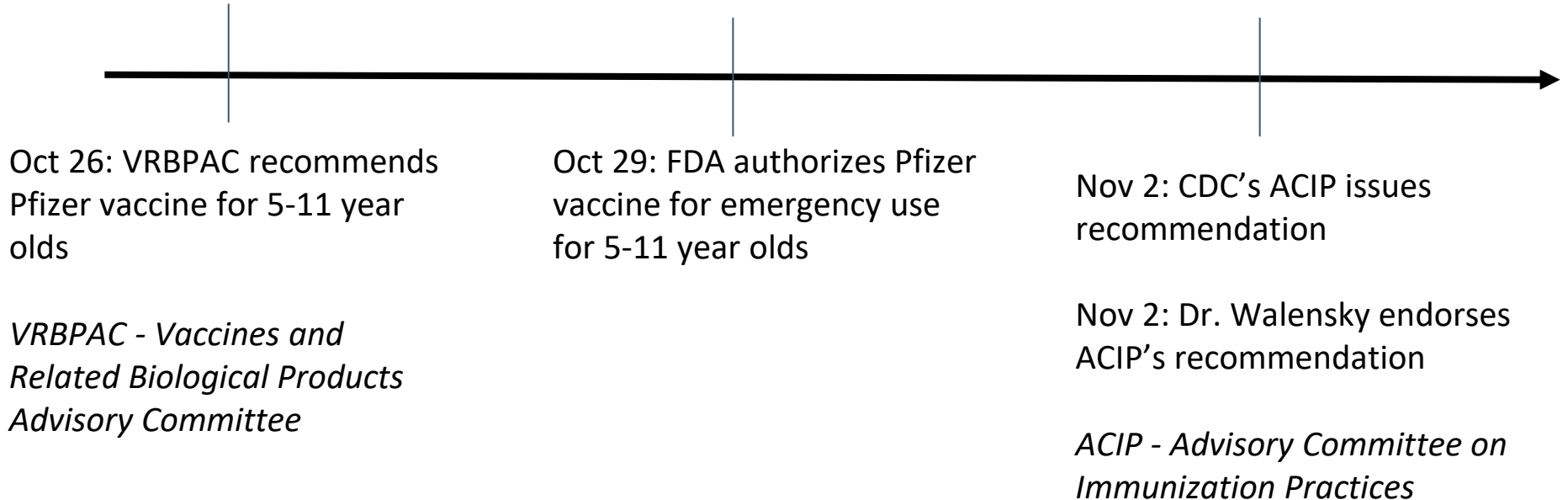
Alex Nowalk, Member of the Maryland
Department of Health Pediatric
Vaccine Team

COVID-19 Vaccination Planning Update

Pfizer Vaccine: 5-11 years






Pfizer Review Process



Pfizer Storage and Usage

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL

	 Purple Cap	 Gray Cap	 Orange Cap
Age	12+	12+	5 - <12
Formulation	PBS / Sucrose	Tris / Sucrose*	Tris / Sucrose*
Diluent Required	YES (1.8mL)	NO (DO NOT DILUTE)	YES (1.3 mL)
Dosage	30 mcg	30 mcg	10 mcg
Doses per Vial	6 doses	6 doses	10 doses
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Storage in ULT Freezer (-90°C to -60°C)	Up to 9 months	Up to 6 months*	Up to 6 months*
Storage in Refrigerator (2°C to 8°C)	Up to one month	Up to 10 weeks*	Up to 10 weeks*
Storage in Freezer (-25°C to -15°C)	Up to 2 weeks	N/A	N/A
Status	ON MARKET	NOT YET APPROVED	NOT YET APPROVED

5-11 Pfizer Vaccine: Packaging and Handling

- Will have an **orange** lid and **orange** border around the label.
 - Ages will be marked in **red** on label.



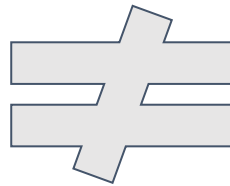
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5-11 Pfizer Vaccine: Packaging and Handling

- **Different** product from 12+
 - New NDC code
 - **Cannot** use 12+ interchangeably - **do not stockpile current Pfizer for 5-11**
 - $\frac{1}{3}$ dose of 12+ (10 mcg)
 - Based on **age**, not weight (even if age changes between shots)
 - 21 days between 1st and 2nd dose

5-11 Pfizer Vaccine: Packaging and Handling

Drawing 10 mcg dose
of adult/adolescent
Pfizer vaccine



Drawing 10 mcg dose
of pediatric Pfizer
vaccine

- Some inactive ingredients in the pediatric Pfizer vaccine are different from the adult/adolescent Pfizer vaccine
- Therefore, drawing up an 10 mcg dose of adult/adolescent Pfizer vaccine is not the same as drawing a 10 mcg dose of pediatric Pfizer vaccine

Vaccine Expiration Dates

- Pfizer does not have an expiration date look-up tool
- The QR code on the label is a link to the EUA factsheet - not an expiration date look-up
- Peds (5-11) has a 6-month expiration if held frozen at ULT
 - To calculate: manufacture date + 6 months = expiration date
 - This includes the month of manufacture
 - A vial marked “8/2021” expires at the end of January 2022

Tris-Sucrose* Formulation Overview

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL

Vial	10-Pack, 25-Pack	Thermal Shipper
 <p>Pfizer-BioNTech Multi-dose vial</p>	<p>10-Pack ●●</p> <p>Single carton holds 10 vials</p>  <hr/> <p>25-Pack ●●</p> <p>Single carton holds 25 vials</p> <p><i>Phasing out product configuration end of 2021</i></p> 	<p>Single-Use Shipper</p> <ul style="list-style-type: none">• Real-time data monitoring• 10-packs and 25-packs• Return the logger, but not the box 

NOTE: The vaccine cap color, carton, and artwork will differ based on the manufacturing location, supplier, and/or indication. The images above are illustrative and shows the carton for the New COVID-19 Vaccine Ages 12+ Presentation for Q4 2021/2022. The estimated size of the plastic boxes are subject to change based on plant of manufacture.

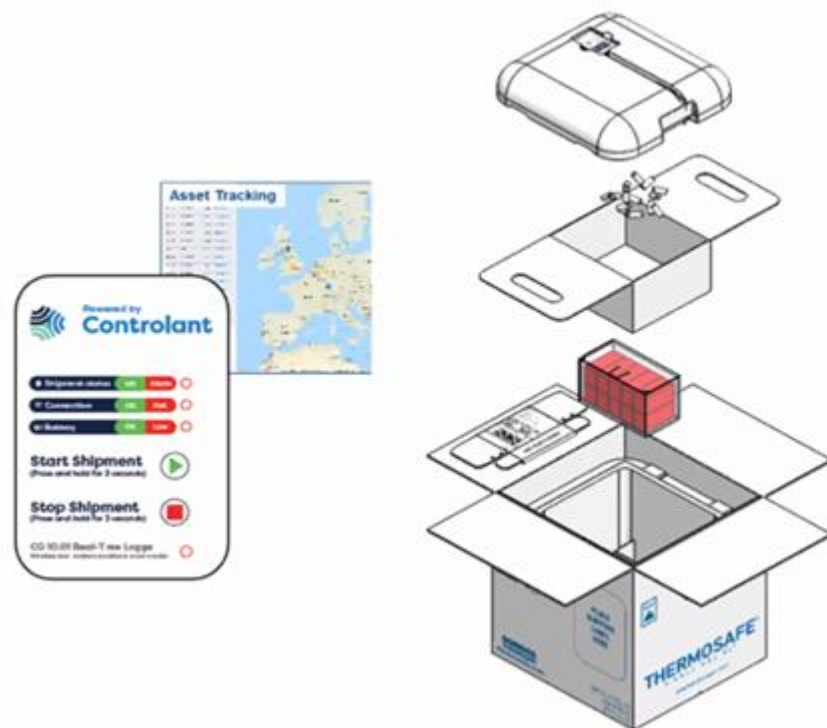
New Single-Use Shipper

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL

SINGLE-USE SHIPPER

Key Considerations*

Controlant Logger/ Monitoring	Real-time Data Monitoring
Pack Options	10-pack
Shipper Duration	3 Days
External Dimensions	410 X 412 X 477mm
Shipper Return	Not Applicable – Destroyed per procedure
Controlant Logger Return	Returned without Shipper in provided return envelope
Thermal System	Dry Ice – 10kg
POU Considerations	<ul style="list-style-type: none"> • Lightweight • Not reusable • Not designed for on-site storage • Vials must be transferred to ULT or refrigerator upon receipt • Differentiated from Medium ULT through nomenclature & Pfizer Global Supply brochure



*Pfizer does not recommend storing pediatric Pfizer doses in the medium ULT

New Single-Use Shipper

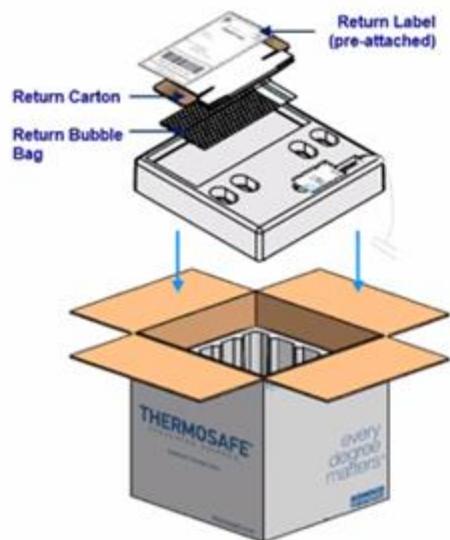
PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL



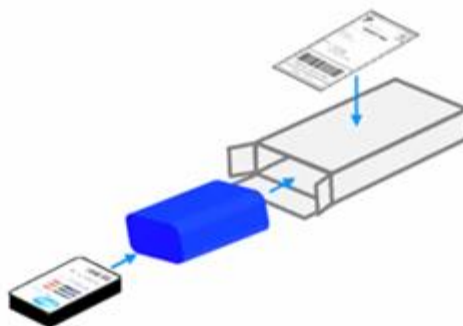
New Single-Use Shipper

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL

- 1** POU will receive vaccines in Single-Use Shipper with Logger Return Kit embedded within lid of shipper



- 2**
- POU removes Logger from thermal shipper and places it inside of Bubble Bag
 - POU places Bubble Bag into Return Carton
 - Return Label applied to Return Carton (or may come pre-attached)



**Single-Use Thermal Shipper will not be returned, solely the Logger*

- 3** Logger Return Carton collected at POU or dropped off for return to Controlant Service Center



Partners Include:

- FedEx
- UPS
- U.S. Postal Service

*Single-Use Thermal Shipper will not be returned, solely the Logger.

New Single-Use Shipper

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL

Turn off the temperature monitor upon receipt and return it in the box provided.



5-11 Pfizer Vaccine: Packaging and Handling

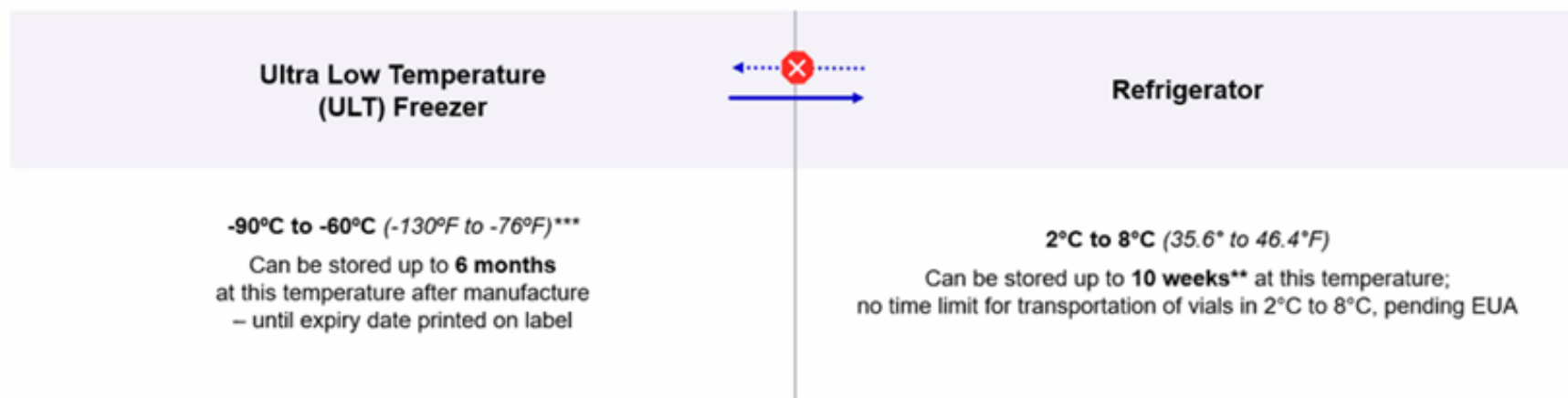
- **Will** require reconstitution.
 - Diluent and mixing syringes will be included in ancillary kit
 - While these vials appear to contain sufficient diluent for multiple vials, they **must only be used once**.
- Storage
 - Ultracold until expiration
 - Refrigerator for **10 weeks**
 - All storage time falls within 6 month timeframe (ULT *and* fridge)
 - May **NOT** be stored in regular freezer
 - Will still be delivered on dry ice
- Ancillary kits includes needles, syringes, diluent alcohol swabs, limited PPE, shot cards; ship at the same time as vaccine

Can COVID-19 vaccine be co-administered?

Yes, the COVID-19 vaccine for 5-11 year olds can be co-administered with other vaccines, including flu vaccine.

NEW Formulation Pfizer 5-11yo Vaccine, **ORANGE** Cap

PRELIMINARY - SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION APPROVAL



NOTE: Once the vaccine has been thawed, it should not be re-frozen (*i.e., if vial cartons are delivered at 2°C to 8°C, vaccine needs to stay at 2°C to 8°C*). All thaw times for Tris/Sucrose are still under review pending results from stability studies.
Tris/Sucrose vials cannot be stored in freezers at -25°C to -15°C.

COVID-19 Vaccination Planning Update

Pfizer Vaccine: 5-11 years
Ordering/Allocations



5-11 Pfizer Vaccine: Ordering and Allocation

- ~515,000 Maryland children ages 5-11
- Maryland receiving initial 180,000 Pfizer doses
- Working in partnership with pediatricians, pharmacies, school systems, local health departments, and the Vaccine Equity Task Force
- Every jurisdiction will receive doses
 - Wave 1: Shipments have occurred (cannot administer until ACIP recommendation)
 - Wave 2: Delivered 2-7 days after EUA approval
 - Wave 3: Delivered 3-9 days after EUA approval

5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

- Receive confirmation of order AFTER the EUA authorization
- 100 doses minimum order Week 1 and thereafter
- Allocation survey to be sent Wednesday, Nov 3 and due Friday, Nov 5
- Providers will need to manage 2nd dose appointments through supply provided; **no separate allocation for 2nd doses**

5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

- Reallocation
 - From Pfizer: no limit on number of transfers as long as cold chain is maintained
 - New redistribution/transfer guidance will be released
 - Pfizer is offering training to providers

5-11 Pfizer Vaccine: Ordering & Allocation (cont'd)

- Pharmacies participating in the federal retail program will be able to order vaccine to select pharmacy locations
 - The pharmacy allocation will be much smaller than the state's
 - PREP act allows pharmacists to administer vaccine to children as young as 3 years old
 - Anticipated ordering in Wave 2
- Small quantities allocated for other federal entities as part of Wave 2

COVID-19 Vaccination Planning Update

5-11 Pfizer Vaccine: Training

Thursday 11/4/2021

Pfizer Manufacturer Series

Time: 12:00 PM ET

Platform: WebEx

[Attendee link – November 4 – 12 PM ET](#)

Password: Y4ZkXdh2bz7

Friday 11/5/2021

Pfizer Manufacturer Series

Time: 12:00 PM ET

Platform: WebEx

[Attendee link – November 5 – 12 PM ET](#)

Password: rJSpNPts332

Additional Notes

- Providers receiving doses in Week 1 should be prepared to provide “shots in arms” immediately upon ACIP recommendation
- Vaccines that are pre-positioned may not be administered until ACIP recommendation
- After Week 1, allocations will continue until further notice through a routine survey
- Plan to use shipment for both 1st *and* 2nd doses

COVID-19 Vaccination Planning Update

Pfizer Vaccine: 12+



12+ Pfizer Vaccine: Packaging and Handling Updates

- Current 1170 packaging and storage will remain in effect until further notice
 - **New packaging will not begin shipping until the 1170 vaccine stock has been depleted, expected mid-Nov**
 - **NOTE:** 1170 will be paused 10/29-11/4 to focus on 5-11
- New packaging will have a **grey** lid and the label will have a **grey** border (current packaging - **purple** lid)
 - Ages will be marked in **red** on label
- **New 12+ doses will not require reconstitution**
 - No diluent will be included in the ancillary kit

12+ Pfizer Vaccine: Packaging & Handling Update (cont'd)

- Storage
 - Ultracold until expiration
 - Refrigerator for 10 weeks
 - All storage time falls within 6 month timeframe (ULT *and* fridge)
 - May **NOT** be stored in regular freezer
 - Will still be delivered on dry ice
- Packaging size - 2 options
 - 10 Pack - 60 doses
 - 25 pack - 150 doses - phased out
- Still have 6-hour limit once punctured.
 - Pfizer has submitted data to FDA for a 12-hour limit

***Additional
information in
appendix***

Guest Speaker: Dr. Monique Soileau-Burke

- ❖ Vice President of the Maryland Chapter of the American Academy of Pediatrics
- ❖ Practicing Pediatrician at The Pediatric Center, LLC
- ❖ Commissioner on the State Commission for Vaccinations
- ❖ Member of the Maryland Department of Health Pediatric Vaccine work group

Guest Speaker

PROPs Portal Demonstration

*Demonstration provided by Michael Shalosky,
Morgan Burke, Romae Atkinson, and Gregory
Williams*

Question and Answer Session

Appendix

Additional Pediatrics Information

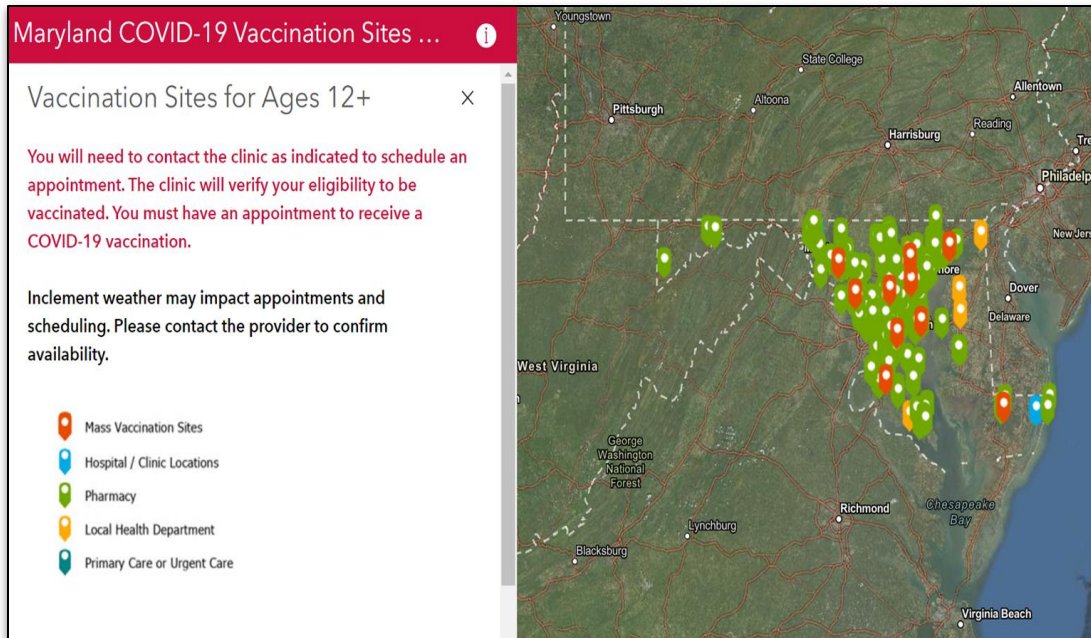
COVID-19 Vaccination Planning Update

Resources



How to Find Vaccine for 5-11 year olds

- Current covidLINK vaccination site finder:
<https://coronavirus.maryland.gov/pages/vaccine>
- Tool will be updated to include providers administering to children 5-11



How MDH Can Support You

MDH can support providers' vaccination efforts by:

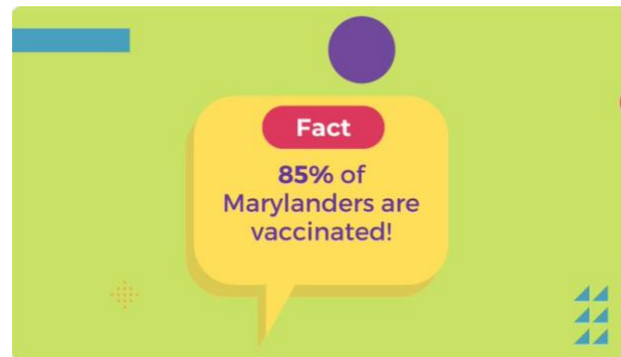
- Assisting with **ImmuNet** registration;
- Providing **materials** and **strategies** for vaccine outreach;
- **Connecting** providers with local health departments and other stakeholders;
- Coordinating with MCOs to fill **resource gaps**;
- Distributing **vaccine supply** and resources; and
- Executing, reporting, and monitoring vaccine **administration**.

Key Messaging

Vaccines are safe and effective

Vaccines offer the best protection against hospitalization and serious illness

Vaccines offer the best chance at keeping kids in school and ending the pandemic



Maryland Vaccine Resources

- covidLINK: <https://covidlink.maryland.gov/>
- General Resources - <https://covidlink.maryland.gov/content/vaccine/resources/>
- Provider Resources - <https://health.maryland.gov/mdpcp/Pages/Coronavirus.aspx>
- Pediatric Vax FAQ - https://health.maryland.gov/mdpcp/Documents/Peds_Vaccine_FAQs.pdf
- COVID-19 Vaccine Locator - <https://maryland.maps.arcgis.com/apps/instant/nearby/index.html?appid=0dbfb100676346ed9758be319ab3f40c&sliderDistance=15>
- GoVAX Toolkit (Password = Vaccine2021) - https://www.gkvclients.com/public/folder/Y1Av-UXmGkOHS_4avnEmbA/GoVAX_Assets

Appendix

Maryland's Official Health Insurance Marketplace: Open Enrollment Information

What's New with Maryland Health Connection

November 2021



Maryland's Official Health Insurance Marketplace

Open Enrollment
November 1, 2021

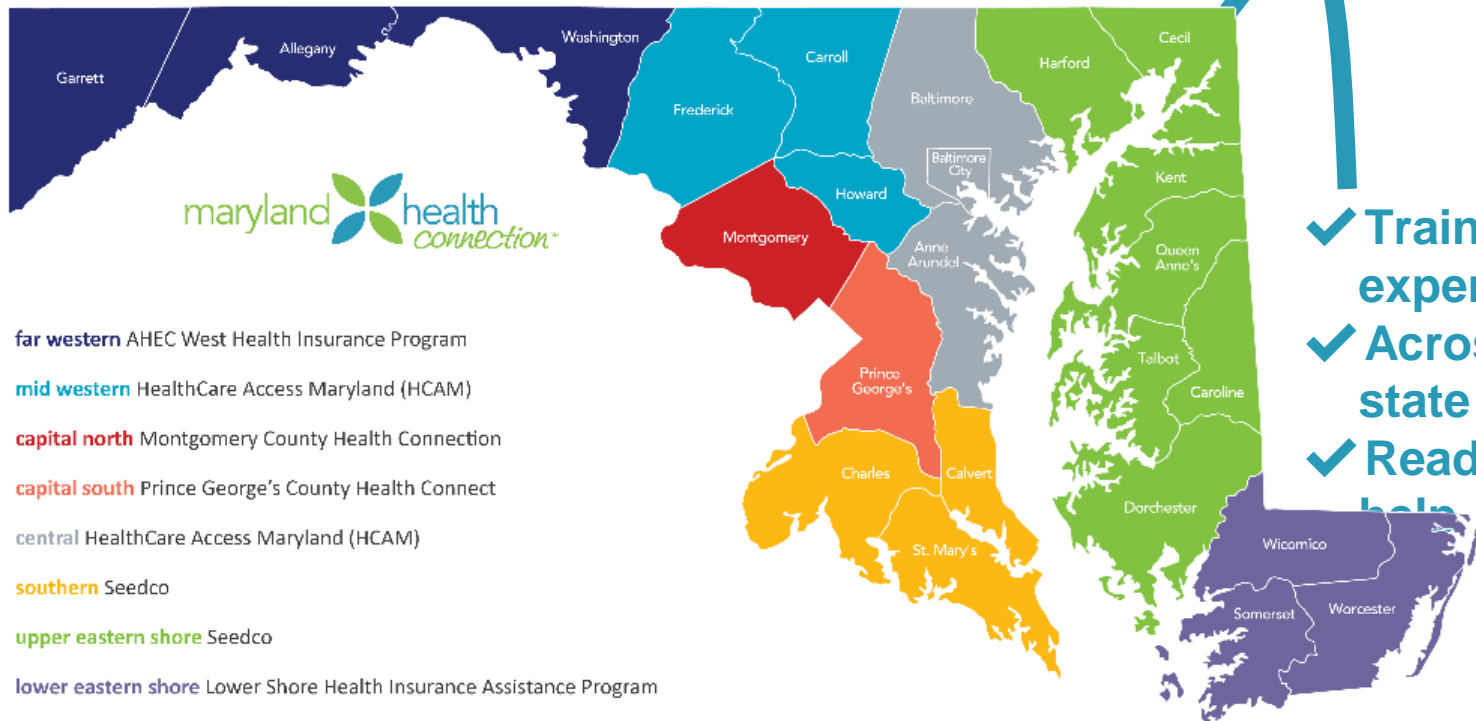
January 15, 2022,
to be covered for
2022



www.MarylandHealthConnection.gov

www.MarylandHealthConnection.gov/es

Where to Find Help



- ✓ Trained experts
- ✓ Across the state
- ✓ Ready to help

The Only Place to Get Financial Help

Maryland Health Connection is the only place Marylanders can get financial help to pay for their health plan. In fact, **9 out of 10 who enroll get savings.**



More Savings for More Marylanders

Did you know the **American Rescue Plan** includes big savings for health insurance?

- For the **uninsured**, it's worth checking out the 2022 health plan options – there are now new, bigger savings.
- If someone **didn't qualify for savings before** they should take another look because, for the first time, there are savings available for Marylanders with higher incomes.

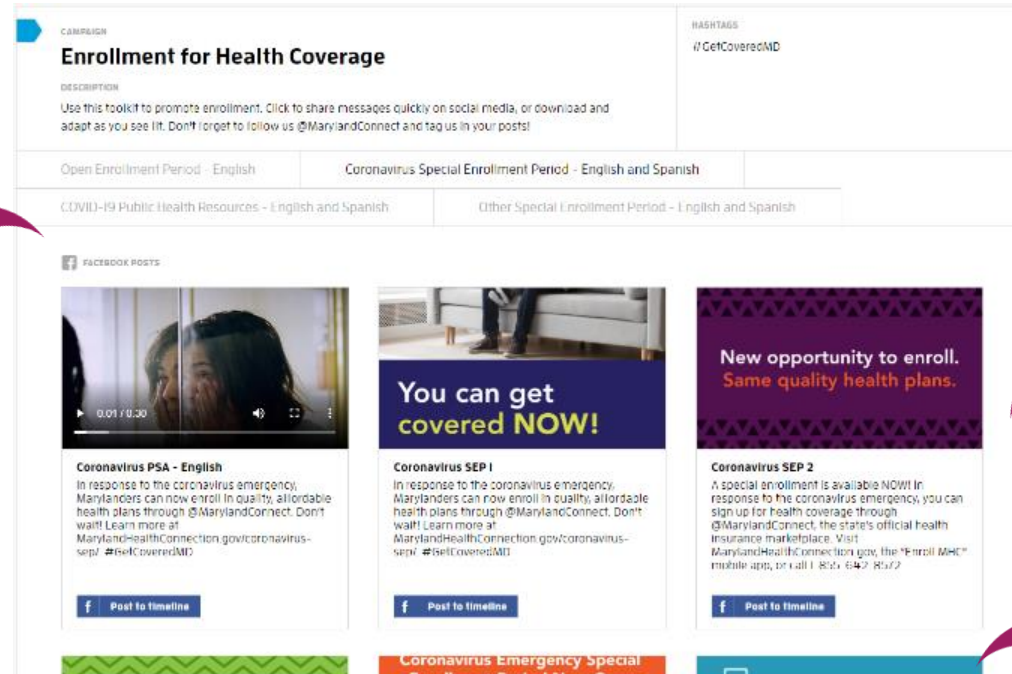
Did you know Maryland has **new discounts for young adults** ages 19-34? They're new for 2022 health plans!



TheSocialPressKit.com/MarylandConnect

Visit our **Social Press Kit** for ready-to-post graphics to share on your social media channels, messaging to share with your community, and more.

Variety of
messages
and
languages



Easy to
post
videos
and
graphics
Already
written
text (you
can adapt)

A large, stylized green leaf graphic composed of several overlapping leaf shapes, positioned on the left side of the slide.

Enrollment ends
January 15.

#GetCoveredMD



@MarylandConnec

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Appendix

Resources and Links

General Vaccine Resources

- ❖ [CDC Covid-19 Vaccination Communication Toolkit](#) - ready made materials, how to build vaccine confidence, social media messages
- ❖ [New York Times Vaccine Tracker](#) - information on every Covid vaccine in development
- ❖ [New York Times Vaccine Distribution Tracker](#) – information on the distribution of Covid vaccines in the United States
- ❖ [MDH Covidlink Vaccine Page](#) - information on vaccine priority groups in Maryland
- ❖ [CDC Vaccine Storage and Handling Toolkit](#)
- ❖ [Project ECHO Webinar](#) - webinar on vaccines and Long Term Care Facilities, relevant for primary care
- ❖ CDC [Moderna vaccine storage](#)

Covid-19 mAb Treatment Criteria

❖ Patient Criteria

- Use clinical judgment
- Have BMI ≥ 35
- Have chronic kidney disease
- Have diabetes
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years old
- Are ≥ 55 years old and have
 - ✓ Cardiovascular disease, or
 - ✓ Hypertension, or
 - ✓ Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 – 17 years old AND have
 - ✓ BMI $\geq 85^{\text{th}}$ percentile for their age and gender based on CDC growth charts, or
 - ✓ Sickle cell disease, or
 - ✓ Congenital or acquired heart disease, or
 - ✓ Neurodevelopmental disorders, or
 - ✓ A medical-related technological dependence, or
 - ✓ Asthma

Scheduling In-Office Appointments

- ❖ Patient calls in for an appointment
 - Reception screens patient on the phone using the [pre-visit screening template](#)
 - Schedule in-office visits for different groups: At-risk and vulnerable patients on certain days, healthier patients on other days
 - Schedule telehealth and non-office-based care for other patients including follow-ups and patients uncomfortable with office visits
- ❖ Check In
 - Practice remote check in and limited front-desk contact
 - Consider using a triage zone outside of office or main area;
 - Or use a barrier at the front desk
 - Design your office to accommodate patients who come in specifically for Covid testing and triage, separate from patients who arrive for non-Covid related and elective procedures
 - ✓ Ensure patients and staff do not cross between Covid and non-Covid areas
 - ✓ Set aside a specific area for patients who come in for testing to wait and be triaged

Scheduling In-Office Appointments

- ❖ Checking out
 - Practice remote check out, limit front desk exposure;
 - Or use a barrier at the front desk
- ❖ If patient is paying co-pays, etc., set up credit card reader outside of the barrier
- ❖ Other workflow resources
 - [Care management workflows](#)
 - [BMJ telemedicine workflow graphics](#)
 - [CDC flowchart to identify and assess 2019 novel Coronavirus](#)
 - [CDC telephone evaluation flow chart for flu](#)
 - [CDC guidance for potential Covid-19 exposure associated with international or domestic travel](#)

CDC Guidelines for Covid Patient Management

- ❖ Healthy people can be monitored, self-isolated at home
- ❖ People at higher risk should contact healthcare providers early, even if illness is mild
- ❖ Older adults and people with severe underlying chronic medical conditions are at higher risk, need closer contact
- ❖ Emergency Department and hospitals only when needed - not for screening or low risk/minimal disease
- ❖ **Guidelines are important and powerful tools, but remember providers' clinical experience and judgment are key to care**

Personal Protective Equipment (PPE) Sources and Requests

- ❖ Practices should initially request PPE through their usual vendors
- ❖ Practices should make their PPE requests through their local health departments
- ❖ Maryland PPE Manufacturers List – next slide
- ❖ [National and international PPE supplier list](#)
- ❖ [PPE request form](#)

Personal Protective Equipment (PPE) Sources and Requests

- ❖ Increasing Maryland's supply of PPE – one of the 4 building blocks on the Road to Recovery
- ❖ Maryland has launched the [Maryland Manufacturing Network Supplier Portal](#), an online platform that helps connect Maryland suppliers with buyers in need of critical resources
- ❖ For additional business resources during Covid-19, visit businessexpress.maryland.gov/coronavirus
- ❖ Providers may also request PPE from the non-profit [‘Get Us PPE’](#)

Provider/Patient Mental Health Resources

❖ Providers

- “Helping the Helpers and Those They Serve,” a [webinar series](#) from the Maryland Department of Health Behavioral Health Administration and MedChi
- [Heroes Health Initiative](#)

❖ Patients

- [Ask Suicide-Screening Questions toolkit](#)
- CDC [list of resources](#) for coping with stress

Health Equity Resources

- ❖ [Maryland Department of Health Office of Minority Health and Health Disparities](#) (MHHD)
- ❖ Maryland Department of Health Minority Outreach and Technical Assistance Program [overview](#)
- ❖ MHHD fiscal year 2020 minority outreach and technical assistance [program information](#)
- ❖ [Description](#) of the term “health disparity”
- ❖ [Implicit bias test](#)
- ❖ “Hundreds of Days of Action as a Start to Address Hundreds of Years of Inequality” – New England Journal of Medicine [article](#) by Maulik Joshi, DrPH
- ❖ “Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine” – [discussion draft](#) for public comment by Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, The National Academies of Science, Engineering, Medicine

Telehealth Resources

- ❖ [Maryland Health Care Commission Telehealth](#)
- ❖ [Maryland Health Care Commission Telehealth Readiness Assessment Tool](#)
- ❖ [U.S. Department of Health and Human Services Health Insurance Portability and Accountability Act \(HIPAA\) for Professionals](#)
- ❖ [American Telehealth Association](#)
- ❖ [Maryland Telehealth Alliance](#)
- ❖ [National Consortium of Telehealth Resource Centers](#)

Support for Patients at Home

❖ Food

- Meals on Wheels

❖ Caregivers

- Visiting nurses and caregivers

❖ Emotional support

- Support from family
- Phone calls and videochat to fight loneliness
- MD Department of Aging [Senior Call Check Program](#)

Food Resources

❖ Nutrition: Inform patients that children can receive three free meals/day at sites listed on:

➤ [Maryland Summer Meals](#)

➤ [Montgomery County](#)

➤ [Prince Georges County](#)

➤ [Charles County](#)

➤ [Frederick County](#)

[Howard County](#)

[Anne Arundel County](#)

[St. Mary's County](#)

[Harford County](#)

[Calvert County](#)

❖ Free meals available from 42 rec centers in Baltimore

➤ Call 311 for locations and to schedule pickup time

Resources for Specific Groups

- ❖ Community- and Faith-Based Organizations
(<https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-community-faith-organizations.html>)
- ❖ Mass Gatherings and Large Community Events
(<https://www.cdc.gov/coronavirus/2019-ncov/community/mass-gatherings-ready-for-covid-19.html>)
- ❖ Non-Pharmaceutical Interventions for Specific Groups
(<https://www.cdc.gov/nonpharmaceutical-interventions/index.html>)

Resources and References

- ❖ Maryland Department of Health Coronavirus Website (<https://coronavirus.maryland.gov>)
- ❖ CDC Coronavirus Website (<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>)
- ❖ CDC National data on Covid-19 infection and mortality (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>)
- ❖ CDC Interim Guidance for Homes and Communities (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>)
- ❖ CDC Interim Guidance for Businesses (<https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-business-response.html>)
- ❖ CDC Interim Guidance for Childcare and Schools (<https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-for-schools.html>)
- ❖ CDC Travel Website (<https://wwwnc.cdc.gov/travel/>)