Clinician Letter: On Wednesday, December 16th, the Maryland Department of Health issued a clinician letter and a form regarding the referral process and available Maryland infusion sites for the two FDA-EUA-approved monoclonal antibody (mAb) treatments for COVID-19: bamlanivimab (Eli Lilly) and the antibody combination, casirivimab/imdevimab (Regeneron)."

Bulletins from the Maryland Insurance Administration:

- COVID-19 Vaccinations: The Maryland Insurance Commissioner issued an advisory reminding Marylanders that they cannot be billed for COVID-19 vaccinations. Providers may bill a patient's health plan for the cost of the administration and if the patient is uninsured, the provider may seek payment from the Provider Relief Fund established by HHS pursuant to the federal CARES Act. Read the advisory here.

- Billing for PPE: The Maryland Insurance Commissioner issued Bulletin 20-43 This bulletin states the Commissioner's position that "a health care provider participating in the carrier's network may not charge an additional fee to the patient for PPE or other infection control measures" and explains the enforcement provisions.

Population Health Update: The Secretary's Vision Group met to discuss year-end issues. With the naming of Dennis Schrader as Acting Secretary of Health, he led the meeting. Attached is the presentations discussed during the meeting. The main emphasis of the meeting was to discuss the Statewide Integrated Health Improvement Strategy (SIHIS). The SIHIS is designed to engage State agencies and the private sector in enhancing hospital quality, fostering care transformation, and improving population health in Maryland. The Maryland Department of Health submitted the proposal to CMI on December 14th. CMI has 90 days to respond. There are three main domains within the SIHIS: Domain 1 – Reduce avoidable admissions; improve readmission rates by reducing within hospital disparities. Domain 2 – Increase the amount of Medicare TCOC or Medicare beneficiaries under Care Transformation Initiatives, redesign programs or successor payment models; improve care coordination for patients with chronic conditions. Domain 3 – This domain focuses on diabetes, opioids and maternal child health. Under these categories, the goals are to reduce mean BMI for adults; improve overdose mortality; reduce severe maternal morbidity rate; decrease asthma-related ED visit rates for ages 2-17. The presentation contains specifics for each of these categories as well as presentations from Medicaid and the Maryland Primary Care Program on how policies will align with these goals.

Please see the attachments below.

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Statewide Integrated Health Improvement Strategy

Presentation to the Secretary's Vision Group

October 16, 2020

Agenda

- Statewide Integrated Health Improvement Strategy (SIHIS) Overview
- Population Health Domains
  - Opioids
  - Diabetes Prevention
  - Maternal and Child Health
- Program Alignment
  - Medicaid
  - Maryland Primary Care Program

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maryland
health services
cost review commission

Statewide Integrated Health Improvement Strategy

Update for the Secretary's Vision Group

December 2020

Tequila Terry
Principal Deputy Director
Health Services Cost Review Commission

Why does the Statewide Integrated Health Improvement Strategy Matter?

- The Maryland Total Cost of Care (TCOC) Model State Agreement indicates:

"Under this Model, CMS and the State will test whether statewide healthcare delivery transformation, in conjunction with Population-Based Payments, **improves population health and care outcomes for individuals**, while controlling the growth of Medicare Total Cost of Care."

TCOC Model Objective

- The TCOC Model aims to improve quality and population health while containing cost growth.

Policy Solution

- SIHIS is designed to engage State agencies and private-sector partners in enhancing hospital quality, fostering care transformation, and improving population health for Marylanders.

Implications

- SIHIS results will be used to demonstrate Maryland's ability to improve population health under the TCOC Model.
- Maryland's SIHIS performance will be an important consideration in CMMI's decision on the future of the Maryland Model.

What is the status on the SIHIS Proposal?

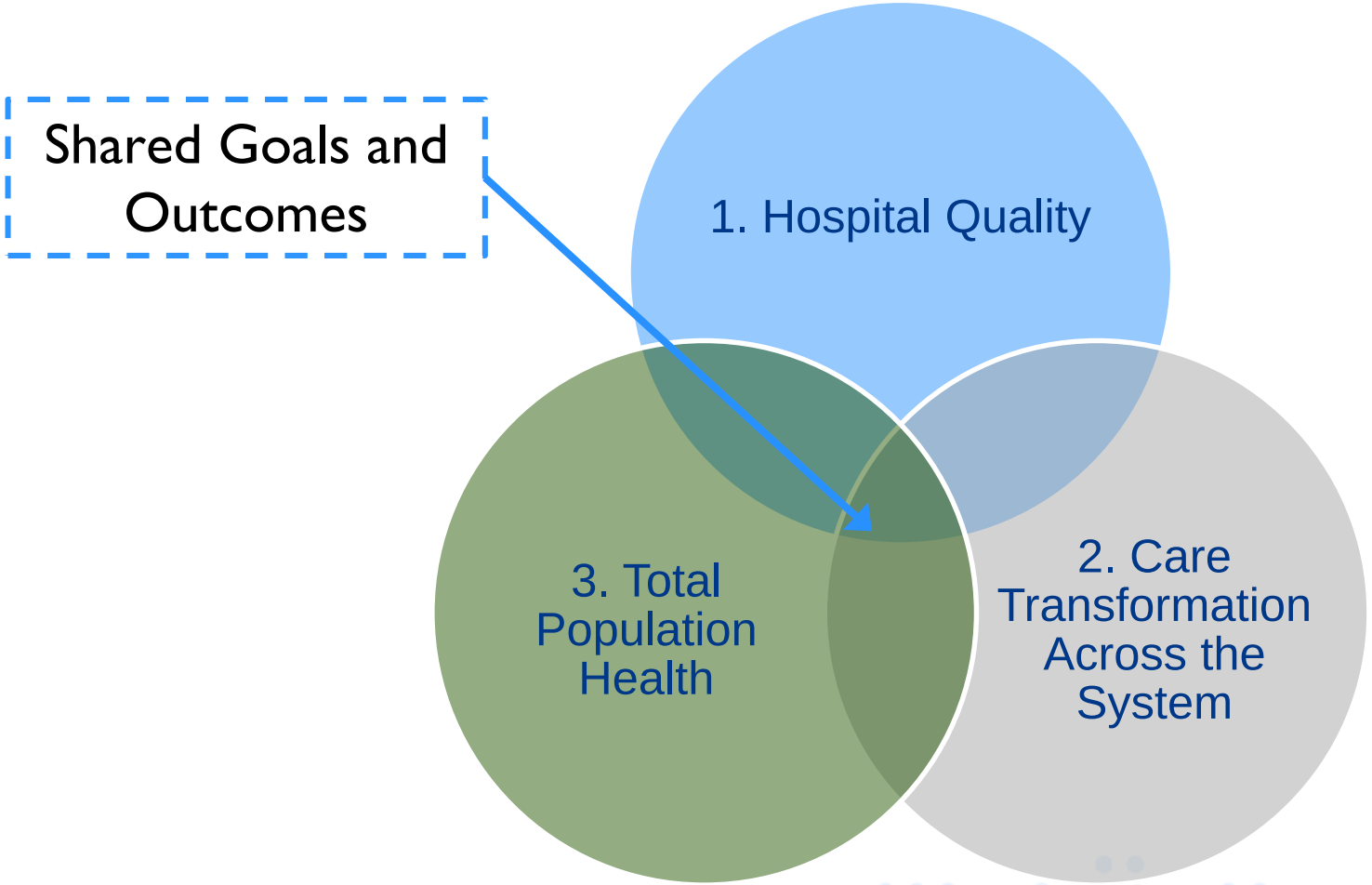
Background

- In December 2019, Maryland & CMS signed a Memorandum of Understanding (MOU) agreeing to establish a Statewide Integrated Health Improvement Strategy
- The Memorandum of Understanding (MOU) required that Maryland propose goals, measures, milestones and targets in three domains by the end of 2020
- Several stakeholder workgroups were run across the State to receive input on the proposal

Update

- The proposal was approved by the Governor, the MDH Acting Secretary, and the HSCRC Chairman
- The SIHIS proposal was submitted to CMMI on December 14, 2020
- CMS will inform the State in writing of its decision to approve or request modifications to the proposal within 90 days of receipt

Domains of Maryland's Statewide Integrated Health Improvement Strategy



Statewide Goals Across three Domains

Domain Area	Proposed Statewide Goal(s)
Domain 1 **Hospital Quality**	• Reduce avoidable admissions • Improve Readmission Rates by Reducing Within-Hospital Disparities
Domain 2 **Care Transformation Across the System**	• Increase the amount of Medicare TCOC or number of Medicare beneficiaries under Care Transformation Initiatives (CTIs), Care Redesign Program, or successor payment models • Improve care coordination for patients with chronic conditions
Domain 3 **Total Population Health "Diabetes"**	• Reduce the mean BMI for adult Maryland residents
Domain 3 **Total Population Health "Opioids"**	• Improve overdose mortality
Domain 3 **Total Population Health "Maternal and Child Health"**	• Reduce severe maternal morbidity rate • Decrease asthma-related emergency department visit rates for ages 2-17

Critical Success Factors

- COVID-19
  - The effects of COVID-19 may impact the State's ability to meet the goals and targets set under SIHIS
  - The proposal includes a section to request a review of proposed goals, measures, targets in Q1 2022 to determine any COVID-19 implications

- Total Population Health
  - Public and private partners must increase statewide investments and align activities to achieve population health improvement

Questions?

Tequila Terry, MBA, MPH

Principal Deputy Director

Center for Payment Reform & Provider Alignment

Maryland Health Services Cost Review Commission

tequila.terry1@maryland.gov

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OPIOID OPERATIONAL COMMAND CENTER

Secretary's Vision Group

The OOCC and Maryland's Statewide Integrated Health Improvement Strategy

December 16, 2020

Goal: Improve Overdose Mortality in Maryland*

Measure	2018 Baseline	2021 Year 3 Milestone	2023 Year 5 Interim Target	2026 Year 8 Final Target
Annual change in overdose mortality as compared to a cohort of states with historically similar overdose mortality rates and demographics	Age-adjusted death rate: **37.2/100,000**	Implement SBIRT in 200 practices by the end of 2020 Increase the number of screenings and brief interventions from the baseline of 2018 (first year of the program) to 2021 Identify the cohort of states that will serve as our control group to measure progress. Enter into DUAs if necessary Launch Behavioral Health Crisis Programs track of the HSCRC Regional Partnership Catalyst Grant Program	Achieve a more favorable trend in overdose mortality rate as compared to the weighted average of control states	Achieve a more favorable trend in overdose mortality rate as compared to the weighted average of control states

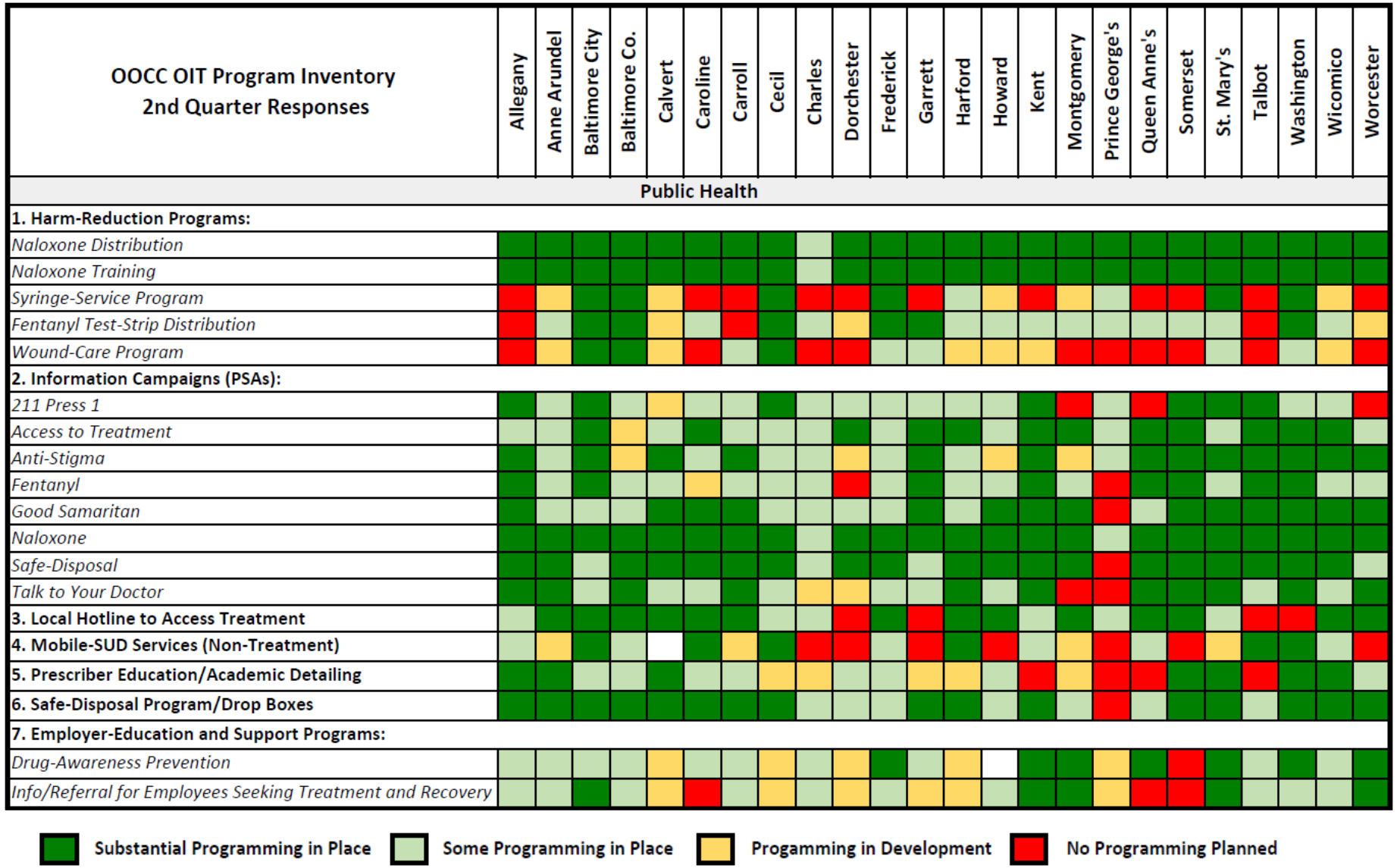
*As compared to a cohort of states in the control group

Maryland will utilize Centers for Disease Control data that measures age-adjusted overdose rates based on ICD-10 codes

Inter-Agency Opioid Coordination Plan Goals

- Prevent Problematic Substance Use
- Reduce Substance-Related Morbidity and Mortality
- Expand Alternatives to Incarceration for People with Substance Use Disorder
- Expand Access to SUD Treatment in the Criminal Justice System
- Monitor Substance-Use Trends
- Expand Access to Substance Use Disorder Treatment
- Ensure Access to Recovery Support Services

OUD Program Inventory



The OOCC is Easy to Reach

100 Community Place
Crownsville, MD 21032
Help.OOCC@Maryland.gov
443-381-3805

PREVENTION • TREATMENT • RECOVERY

Before it's **too late.**

WWW.BEFOREITSTOOLATE.MARYLAND.GOV

@BeforeItsTooLateMD | @BeforeIts2Late | #HERETOHELP

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SIHIS
Diabetes Priority

Anne Langley

Director, Center for Population Health Initiatives

December 16, 2020

Goal, Measure and Target

- Reduce the mean Body Mass Index (BMI) for adult Maryland residents
  - Mean BMI will be determined using the results of the Behavioral Risk Factor Surveillance System (BRFSS)
  - Target is to achieve a more favorable change from baseline mean BMI than a group of control states

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Key Activities

- Launch Diabetes track of the HSCRC Regional Partnership Catalyst grants
- Strengthen and support Local Health Improvement Coalitions (LHICs) to expand diabetes programming
- Expand National Diabetes Prevention Program (DPP) access and participation for Medicaid beneficiaries
- Develop and execute a communication strategy and campaign targeting prediabetes awareness and action
- Expand, adapt, and harmonize diabetes surveillance tools and capabilities with CRISP
- Establish the Diabetes Clinical Quality Task Force
- Partner with CareFirst in select targeted communities to connect with LHICs and address social barriers to effective prevention and management of diabetes

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Additional Opportunities

- Maryland Primary Care Program (MDPCP) – sharing measures, including new BMI measure used in SIHIS as a milestone
- Medicaid – growing Medicaid beneficiary enrollment and completion, explore social determinants of health (SDOH) strategies
- MedChi – discussing provider education strategies, *e.g.,* reimbursement opportunities
- CONNECTIONS, ALIGNMENT, COLLABORATION

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Broad Engagement and Commitment

Galvanizing support and action:

Who else can we bring to the table?

- Employers – invest in benefits, lifestyle change programs, and other incentives proven to save employer money and improve employee health
- Payors –
- Philanthropy –
- School Systems
- Higher Education –
- ???

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Maternal and Child Health

Shelly Choo, MD, MPH

Prevention and Health Promotion Administration

Bureau of Maternal and Child Health

December 16, 2020

Prevention and Health Promotion Administration

MISSION

The mission of the Prevention and Health Promotion Administration is to protect, promote and improve the health and well-being of all Marylanders and their families through provision of public health leadership and through community-based public health efforts in partnership with local health departments, providers, community based organizations, and public and private sector agencies, giving special attention to at-risk and vulnerable populations.

VISION

The Prevention and Health Promotion Administration envisions a future in which all Marylanders and their families enjoy optimal health and well-being.

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Domain 3a: Total Population Health – Maternal and Child Health

Goal: To reduce severe maternal morbidity rate

Measure	2018 Baseline	2021 Year 3 Milestone	2023 Year 5 Interim Target	2026 Year 8 Final Target
Severe Maternal Morbidity (SMM) Rate per 10,000 delivery hospitalizations	242.5 SMM Rate per 10,000 delivery hospitalizations	Re-Launch of the Perinatal Quality Collaborative Pilot a Severe Maternal Morbidity Review Process with eight Birthing hospitals Complete Maryland Maternal Strategic Plan Regional Partnership Catalyst Grant for MCH, if funding available	219.3 SMM Rate per 10,000 delivery hospitalizations	197.1 SMM Rate per 10,000 delivery hospitalizations

Domain 3a: Total Population Health – Maternal and Child Health

Goal: To decrease asthma-related emergency department (ED) visit rates for ages 2-17

Measure	2018 Baseline	2021 Year 3 Milestone	2023 Year 5 Interim Target	2026 Year 8 Final Target
Annual ED visit rate per 1,000 for ages 2-17	9.2 ED visit rate per 1,000 for ages 2-17	Obtain Population Projections; Development of Asthma Dashboard Regional Partnership Catalyst Grant for MCH, if funding available Asthma-related ED visit is a Title V State Performance Measure and shift some of the Title V funds for Asthma-related interventions	Aim for achieving a rate reduction from 9.2 in 2018 to 7.2 in 2023 for ages 2-17	Aim for achieving a rate reduction from the 9.2 in 2018 to 5.3 in 2026 for ages 2-17

Priorities for 2021

1. Align and Coordinate Maternal and Child Health Efforts
   a. Maternal Health Improvement Task Force
   b. Maternal and Child Health Working Group
2. Increase Access to Care
   a. Maternal Health- Telemedicine
   b. Connection to the Medical Home
3. Bringing Care to the Home and Community
   a. Home & Environmental Health Assessments
   b. Public Health Systems of Care
   c. Role of Community Health Workers, Doulas
4. Improve accessibility and use of data
   a. Make data-informed decisions
   b. Stratified data by race, ethnicity, language, geography

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What are some activities underway?

- Addressing social needs; assess the environment; improve SDOH
- Exploring ways to increase workforce developments: Community Health Workers, Doulas
- Quality Improvement Initiatives
  - Surveillance Quality Initiatives
  - Perinatal Standards of Care
- Innovative Service Delivery
  - Telemedicine

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Maternal Health

- Pre-conception and Inter-conception
  - Maryland Family Planning
  - Maximizing pre-conception health – Hypertension, Diabetes
- Pregnancy and Birth
  - Perinatal Quality Collaborative and the Alliance for Innovations on Maternal Health
  - Severe Maternal Morbidity Review Process Pilot in birthing hospitals
  - Maternal, Infant, Early Childhood Home Visiting
  - Facilitate linkages to care particularly for Substance Use Disorder Treatment
- Postpartum
  - Maternal, Infant, Early Childhood Home Visiting
  - Facilitate linkages to care particularly for Substance Use Disorder Treatment

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Asthma

- Evidence-based Asthma Home Visiting in 9 jurisdictions and planning for expansion
  - Environmental and Home Assessments
- Improve linkages to care with the Medical Home, Local Health Departments, and families to promote a continuum of care for trigger reduction and improving medical management
- Examining the role of Title V in improving asthma outcomes
- Role of case finding for children eligible for available programs through the CRISP Encounter Notification System

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Moving Forward

Follow up for further discussion to improve maternal and child health outcomes to discuss

1) Alignment opportunities
2) Further connections
3) Improved data for improved case identification and increased linkages to care

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Prevention and Health Promotion Administration

https://phpa.health.Maryland.gov

Shelly.Choo@maryland.gov

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Medicaid Alignment

Laura Goodman

Division Chief, Medicaid Office of Innovation, Research and Development

December 16, 2020

Domain 1: Hospital Quality

- Participation in all-payer hospital quality programs
- Medicaid sits on HSCRC Performance Measurement workgroup
- Medicaid managed care organizations (MCOs) evaluated on plan all-cause readmissions as part of required National Committee for Quality Assurance (NCQA) accreditation

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Domain 2: Care Transformation Across the System

- Medicaid sits on several HSCRC and stakeholder workgroups
- Medicaid working with HSCRC to include Medicaid population in follow-up after acute care measure
- Exploration of shared savings approaches for dual eligibles and the inclusion of duals' Medicaid cost in HSCRC payment models

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Domain 3: Diabetes Prevention

- HealthChoice Diabetes Prevention Program (DPP): Implementation, technical assistance and development of prediabetes smart alert with CRISP
- Medicaid scale targets included in new diabetes Regional Partnerships
- MCOs evaluated on diabetes-related measures as part of required NCQA accreditation
- Value-based purchasing measure on HbA1c control (revenue-at-risk)

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Domain 3: Opioids

- Comprehensive behavioral health coverage, including Institutions for Mental Disease (IMD) exclusion waiver for residential SUD treatment
- Chronic Health Home program serves individuals with substance use disorder through participating psychiatric rehabilitation programs, opioid treatment programs and mobile treatment services
- Outpatient Mental Health Clinic (OMHC) Expansion Grant (supporting the expansion of OMHCs to provide additional crisis services)

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Domain 3: Maternal and Child Health

- MCOs required to provide enhanced care coordination to pregnant members
- Administrative Care Coordination Units provide outreach and support to pregnant members out of local health departments; Maryland Prenatal Risk Assessment screens for substance use and other risk factors in pregnancy
- MCOs evaluated on MCH-related measures as part of required NCQA accreditation
- Value-based purchasing measures on postpartum care and lead screening (revenue-at-risk)
- Health Services Initiative programs target lead remediation and environmental case management for Medicaid-eligible children
- Community Health Pilot: Home Visiting Services

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In Focus: MOM Model

- MCOs will provide enhanced case management services to pregnant and postpartum Medicaid participants with opioid use disorder.
  - Bridges both opioid- and MCH-related population health areas
  - Emphasizes increasing prenatal and postpartum care and encouraging medication for opioid use disorder
  - Includes screening and referral for SDOH needs
- Enrollment begins in July 2021.

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MDPCP Impacts on the State Integrated Health Improvement Strategy

Maryland Department of Health

Program Management Office

Howard Haft, MD – Executive Director

December 2020

MDPCP Foundational in Two Domains

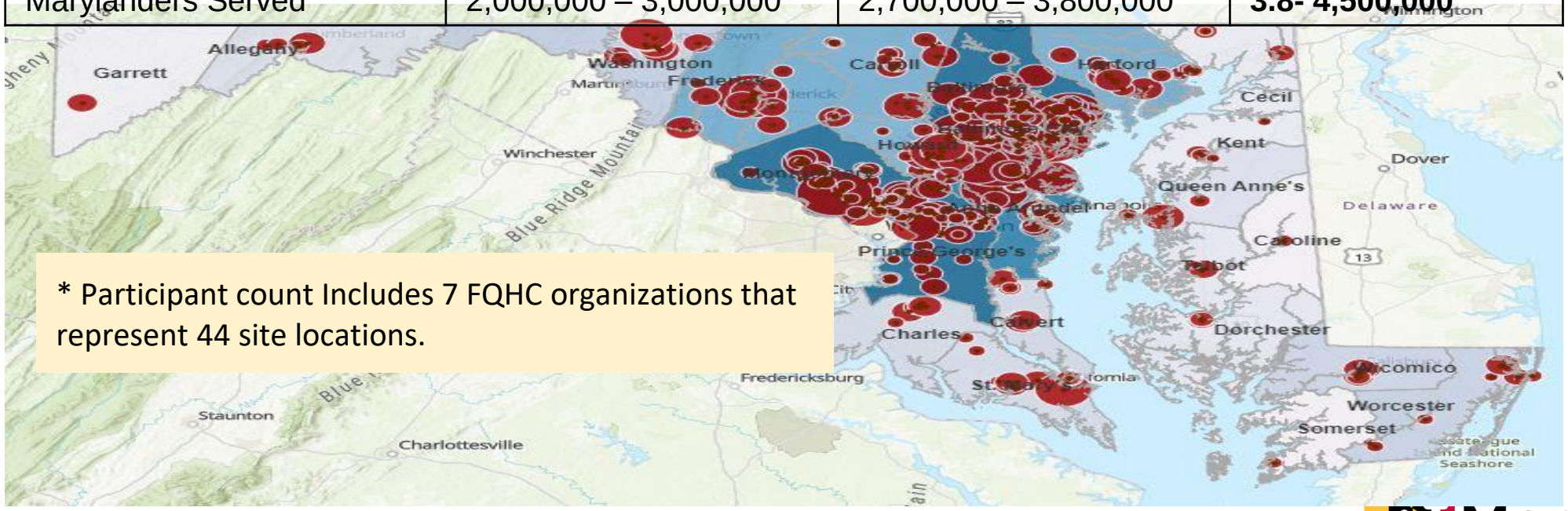
1) Hospital Quality – The establishment of enhanced hospital quality and value-based performance targets that build on historical performance targets to drive continued improvement in care quality.

2) **Care Transformation Across the System** – The implementation and measurement of **system-wide care transformation activities** and the degree to which **value-based payment models** are being used to improve care quality and reduce costs.

3) **Total Population Health** – The identification of **key health priorities** and the implementation of a statewide approach that mobilizes and **integrates public and private resources** to improve health outcomes for Marylanders.

Statewide Health Care Delivery Network Payer Agnostic Care Transformation

PARTICIPANTS	2019	2020 (Q4)	2021
Practices	**380**	**476**	**~563***
Providers in MDPCP	~1,500	~2,000	TBD
FFS Benes Attributed	220,000 (28,717 duals)	356,000 (45,031 duals)	TBD
Marylanders Served	2,000,000 – 3,000,000*	2,700,000 – 3,800,000*	**3.8- 4,500,000***



* Participant count Includes 7 FQHC organizations that represent 44 site locations.

Key Elements of Care Transformation:

- Care Management
- Telehealth
- Behavioral Health Integration
- Data-Driven Care

* *The Annals of Family Medicine, 2012*
http://www.annfammed.org/content/10/5/396.full

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MDPCP Facilitates Care Transformation By Working With Public and Private Partners

Domain 2

Care Transformation Across the System

- MDPCP essential to achieving success

Figure 2. ***Goal: Improve care coordination for patients with chronic conditions***[3]

Measure	2018 Baseline	2021 Year 3 Milestone(s)	2023 Year 5 Interim Target	2026 Year 8 Final Target
Timely Follow-up After Acute Exacerbations of Chronic Conditions^ (NQF# 3455)	71.59%	72.43% 1.17 percent improvement	73.28% 2.35 percent improvement	75.00% 4.76 percent improvement or 0.50 percent better than the national rate

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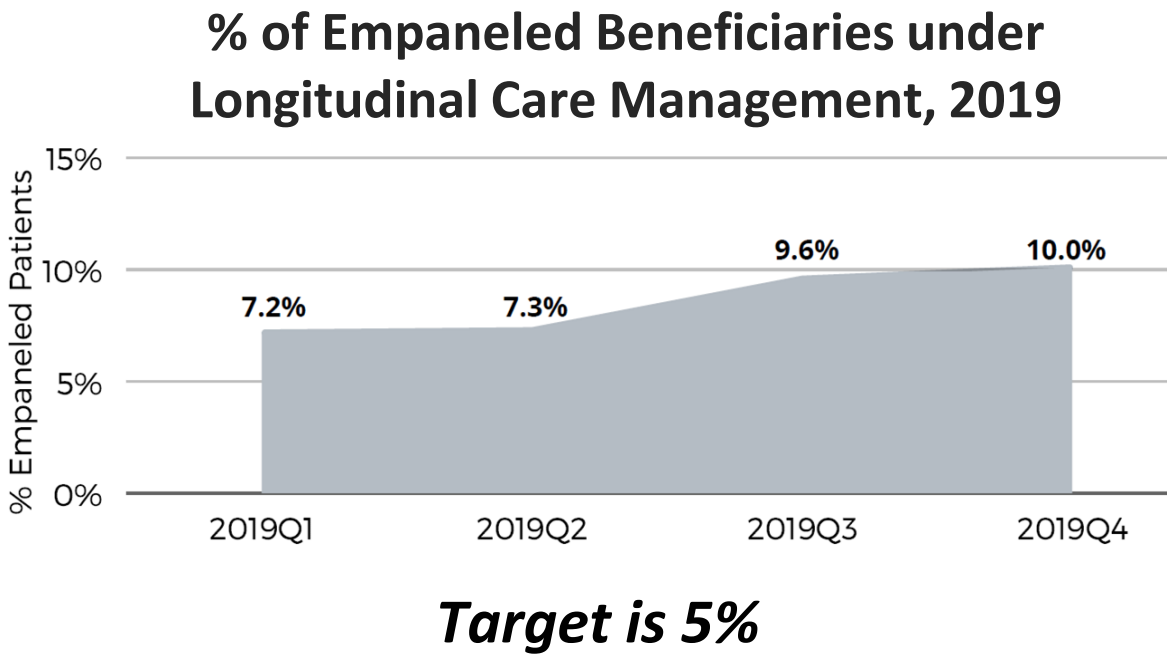
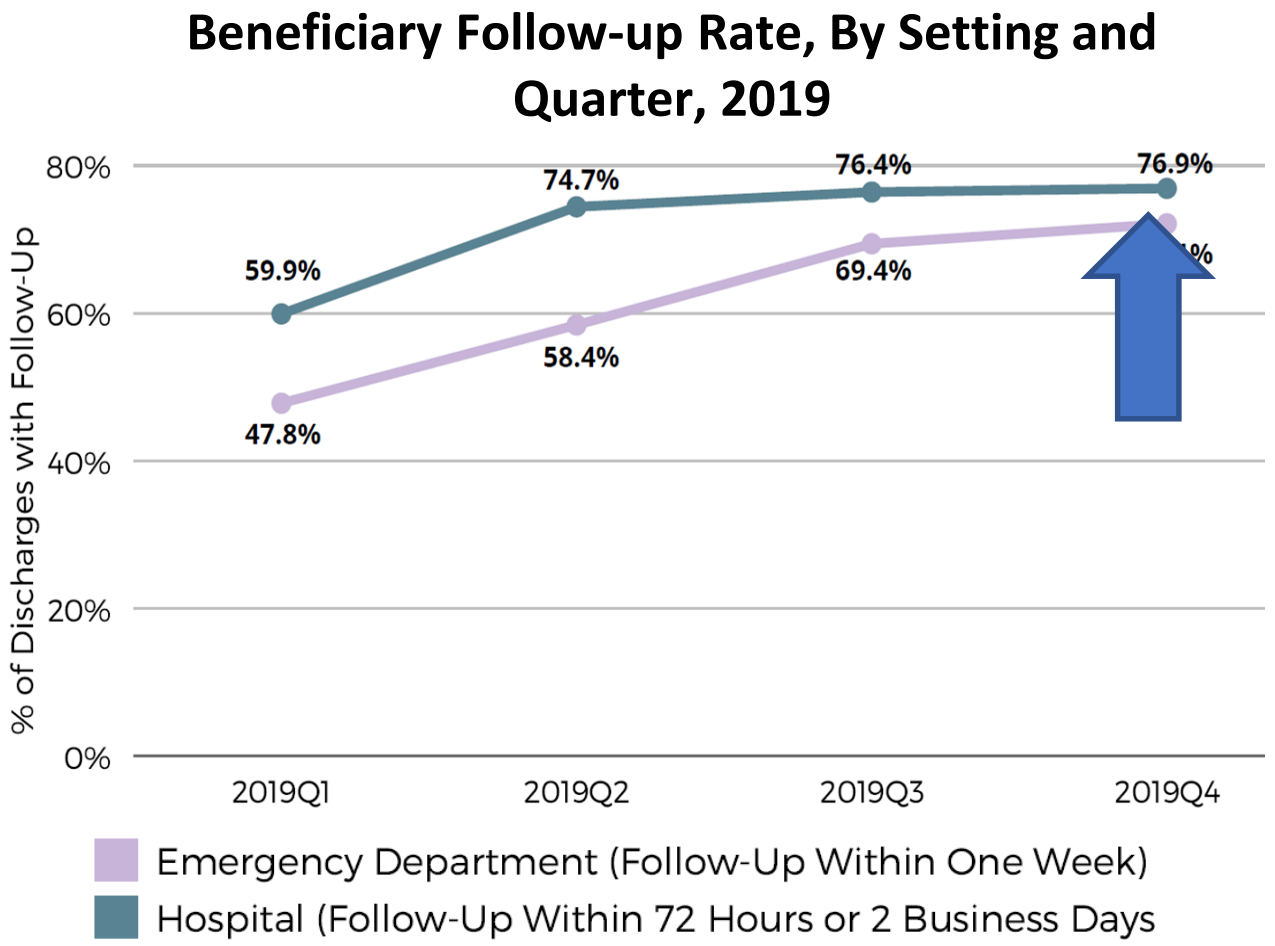
Care Management and Transitions



Target is 5%



Domain 3: Population Health

Diabetes Prevention - BMI

- MDPCP essential to achieving milestones and targets

Figure 4. ***Goal: Reduce the mean BMI for adult Maryland residents***[6]

Measure	2018 Baseline	2021 Year 3 Milestone(s)	2023 Year 5 Interim Target	2026 Year 8 Final Target
Mean BMI in the population of adult Maryland residents	State mean BMI for 2018	Identify the cohort of states that will serve as the control group to measure progress. Enter into DUAs if necessary. Launch the Diabetes Prevention and Management Program track of the HSCRC Regional Partnership Catalyst Grant Program. Incorporate a quality measure for all MDPCP practices requiring BMI measurement for all patients, and for patients with an	Achieve a more favorable change from baseline mean BMI than a group of control states	Achieve a more favorable change from baseline mean BMI than a group of control states

2021 MDPCP Diabetes Quality Measures

- Diabetes Control - HbA1c
  - Abundant technical assistance for practices on patient management
  - Resources with Care Managers and electronic referral to community partner organizations for DM management
  - **Existing eCQM:** CMS 122v8: *Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)*
- BMI elevated and referral to management
  - Over **8 million** annual visits and measurements (estimated)
  - Abundant support through linkages to community partner organizations and electronic referral to DPP, diabetes self management programs, nutrition
  - **New eCQM for 2021:** CMS 69v8: *Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan*

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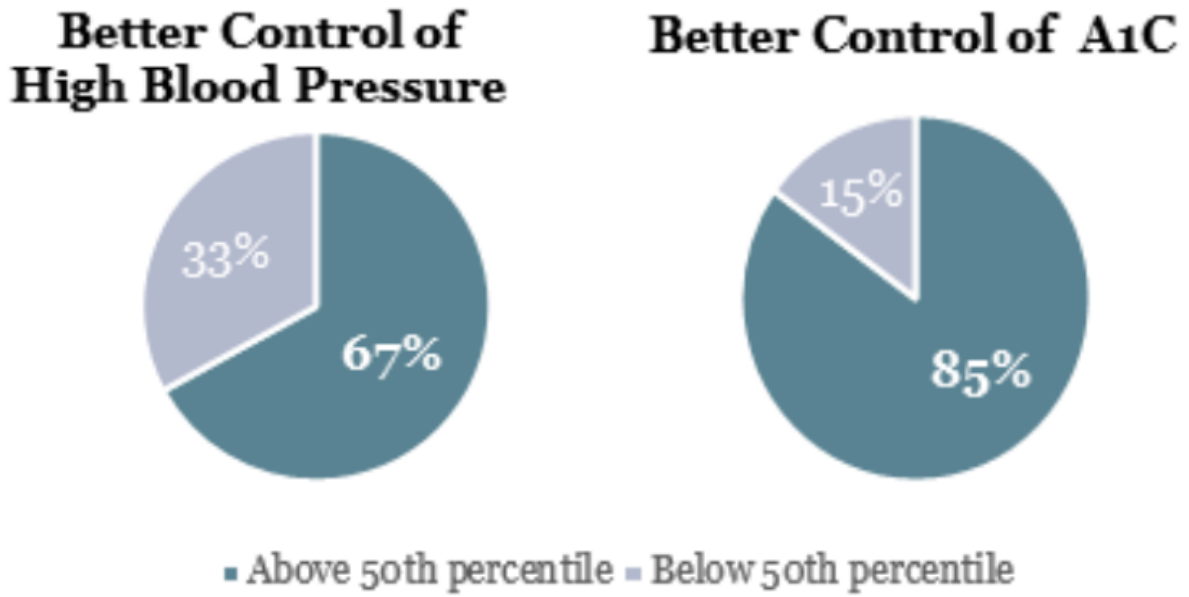
In 2019, the majority of MDPCP practices had clinical quality outcomes above median primary care practices

Clinical Quality Outcomes:

Percentage above the 50th percentile in national Merit-Based Incentive Payment System (MIPS) Reporting.



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Domain 3: Population Health

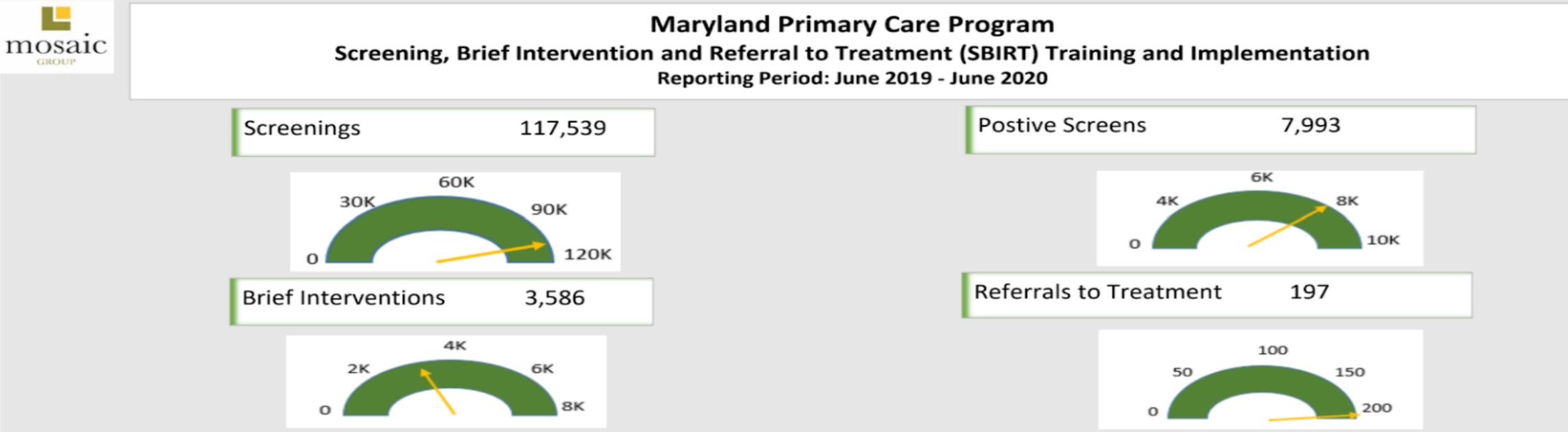
Opioid Overdose Mortality

Figure 5. ***Goal: Improve overdose mortality in Maryland[8]***

Measure	2018 Baseline	2021 Year 3 Milestone(s)	2023 Year 5 Interim Target	2026 Year 8 Final Target
Annual change in overdose mortality as compared to a cohort of states with historically similar overdose mortality rates and demographics	Age-adjusted death rate of 37.2/100,000	Implement SBIRT in 200 MDPCP practices by the end of 2021. Increase the number of screenings and brief interventions performed by MDPCP practices from the baseline of 2019 (first year of the program) to 2021. Identify the cohort of states that will serve as our control group to measure progress. Enter into DUAs if necessary. Launch Behavioral Health Crisis Programs track of the HSCRC Regional Partnership Catalyst Grant Program.	Achieve a more favorable trend in overdose mortality rate as compared to the weighted average of control states	Achieve a more favorable trend in overdose mortality rate as compared to the weighted average of control states

SBIRT Implementation - Statewide

- Largest statewide primary care SBIRT implementation in the nation
- 115 practices fully implemented in Program Year 1
- Target 200 by mid-year 2021



Discussion

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Maryland Referral Form
Ambulatory Monoclonal Antibody Infusion Treatment for COVID-19

If your patient could benefit from monoclonal antibody treatment, please complete the information below. This form should be sent to the infusion site with closest proximity to the patient and follow the referral process as noted below according to the appropriate site. The Infusion Site will review the referral form upon receipt and contact the patient to coordinate services as soon as possible.

Region 1: UPMC Western Maryland Hospital	Email form to WMD-COVIDantibody@upmc.edu
Region 2: Meritus Regional Infusion Center	Fax form to 301-790-9229
Region 3: Baltimore Convention Center Field Hospital	Go to umms.org/ICReferral to submit form via secure, HIPAA-compliant upload.
Region 4: TidalHealth Peninsula Regional	Email form to COVIDTX@TidalHealth.org or Fax: 410-912-4959
Region 4: Atlantic General Hospital	Fax form to 410-641-9708
Region 5: Adventist HealthCare Takoma Park Alternative Care Site Infusion Center	Fax form to 301-891-6120

**First Name: ** Last Name:

**DOB: Age:

**Sex: ☐ M ☐ F ☐ Other _____ ☐ Unknown

**Patient's Preferred Language ☐ English ☐ Spanish ☐ Other _____

**Address Line 1:

Address Line 2:

City: State: County: **Zip:

County:

**Phone: ☐ cell ☐ home Secondary Phone: ☐ cell ☐ home

Allergies (medication/food/other):

Please include any additional historical patient health information. You may free text, copy/paste, or you may attach a recent clinic note or other documentation, as necessary.

The (**) indicates a required field.

**Weight (lbs): Kg: **Height (feet/inches): BMI:

**Patient has had a recent SARS-CoV2 PCR or Rapid Antigen Positive Test Result: □ Yes □ No
Note: Test must be first known positive test result.

** SARS-CoV2 PCR or Rapid Antigen test date (date specimen was obtained): _____

****SARS-CoV2 symptom onset date (best approximation)**: _____

**Patient Symptoms (check all that apply):
□ Fever □ Cough □ SOB □ Loss of taste/smell □ Malaise/Fatigue
□ Nausea/Vomiting □ Diarrhea □ Throat pain □ Congestion □ Myalgia
□ Headache □ Other _____

SpO2: ____ (If < 94%, patient should be referred for hospitalization due to need for supplemental O2 and thus would not be appropriate for monoclonal antibody treatment.)

□ On RA or □ On chronic O2 therapy – Baseline O2 Flow rate: _____

Has the patient required an increase in O2 flow rate since becoming symptomatic with COVID? □ Yes □ No

*****High Risk for Severe COVID Illness (check all that apply, continued on page three):***
□ Age ≥ 65 y/o □ BMI ≥ 35 □ Diabetes Mellitus □ Type II □Type I
□ CKD Disease Stage ____ Baseline [Cr]____
□ Immunosuppressive Disease (e.g. leukemia, lymphoma, asplenia, neutropenia, AIDS if CD4 < 200, etc.) / Specify: _____
□ Immunosuppressive Treatment (e.g. chronic steroid, chemotherapeutic, biologic immunomodulator) / Specify: _____

□ Age ≥ 55 y/o *and:*
□ Cardiovascular Disease / Specify (e.g. CAD, CVD, PVD, cardiomyopathy): _____
□ HTN
□ COPD
□ Other Chronic Respiratory Disease (e.g. Pulmonary Sarcoid, Pulmonary Fibrosis) / Specify: _____

□ Age 12 – 17 y/o *and:*
□ BMI ≥85th percentile for their age and gender based on CDC growth charts
□ Sickle Cell Disease
□ Congenital or acquired heart disease / Specify: _____
□ Neurodevelopmental Disorder (e.g. cerebral palsy, muscular dystrophy) / Specify: _____
□ Medical-related technological dependence (e.g. trach, g-tube dependence, shunt dependence, chronic infusion dependence) / Specify: _____
□ Asthma/Reactive Airway Disease/Chronic Respiratory Disease Requiring daily medication for control / Specify: _____

The (**) indicates a required field.

I, the referring provider, am the patient's PCP or other continuity provider and have arranged for the patient to follow up with me/my designee following Antibody infusion. Or I am an ED or Urgent Care provider who will update the patient's PCP about his/her Antibody infusion in order to arrange follow up. If the patient does not have a PCP, I will refer him/her to an appropriate provider and ensure that follow up has been arranged. [Note: Ideal timing of follow up visit is approximately 7 days post-infusion.]
☐ **Indicates Provider Agreement

I, the referring provider, have advised or will advise the patient that if his/her clinical status declines by the time of the infusion appointment, the treatment may no longer be appropriate for him/her. The patient's clinical status will be re-evaluated at the infusion center at the appointment time. If the patient is deemed in need of hospital care, s/he will be referred immediately.
☐ **Indicates Provider Agreement

**** Please provide the following information:**

☐ If patient meets the above criteria give bamlanivimab 700 mg IV times 1 dose over 60 minutes OR Casirivimab 1200 mg/Imdevimab 1200 mg IV times 1 dose over 60 minutes (depending on supply/infusion site protocol).

Provider Signature_____ Date_____

The Infusion Center staff will communicate with the referring provider regarding such matters as treatment inappropriateness for patient, ultimate completion of treatment for patient, adverse events, etc.

Name of Referring Site:	Point of Contact:
Address:	
Phone Number:	Fax Number:
Email address:	Preferred mode of contact: ☐ Phone ☐ Fax ☐ Email

Patient's Primary/Continuity Care Provider (if different from above)

Office Name:	
Address:	Phone Number:
Email address:	Fax Number:

There are two Antibody treatments on our formulary. Patients will be scheduled for one or the other treatment based on availability of medications and logistics.

Information about both monoclonal antibody medications, including Fact Sheets and Manufacturer Instructions/Package Inserts for Healthcare Providers and for Patients/Parents/Care Givers, can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs (scroll to section on Drugs and Biologic Products).

The (**) indicates a required field.

Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Acting Secretary

December 16, 2020

Dear Colleague,

We are writing to provide updated information regarding the referral process and available Maryland infusion sites for the two FDA EUA-approved monoclonal antibody (mAb) treatments for COVID-19: bamlanivimab (Eli Lilly) and the antibody combination, casirivimab/imdevimab (Regeneron). Early data for these therapeutics suggest that they may reduce the risk of hospitalization for people at high risk who have tested positive for COVID-19 and have only mild to moderate symptoms.

The United States Government (USG) has purchased a limited number of doses and is coordinating the weekly allocation of the mAbs therapeutics to state and territorial health departments. The Maryland Department of Health (MDH) is working closely with the Maryland Hospital Association (MHA) and other partners to implement an allocation and distribution process to serve residents across the state as there may be a greater demand than supply of COVID-19 therapeutics. This should be taken into consideration by prescribing providers and communicated to patients. Maryland healthcare providers should communicate that mAb treatments will be in greater demand than can be satisfied by the supply at the present time.

If you have a patient that may benefit from a COVID-19 therapeutic as described, please use the standard referral form in the attachments section on page three to refer a patient to one of the currently available infusion sites. Initial regional infusion locations across the state have been designated to allow both temporal and geographic equity distribution for a scarce therapeutic.

It is recommended that patient referrals are made as soon as possible and no later than 7 days after symptom onset to allow time for infusion center clinician review and scheduling. Based on the individual patient's clinical factors and the mAbs supply, infusion site staff will schedule the patient. Given the limited doses and infusion appointment that may be available, it is possible that some referrals may not be able to be accommodated. Referring providers are expected to follow their patients closely by telephone and in person following the infusions.

I. Monoclonal Antibody Treatments for COVID-19 Overview

Other than the difference that the Regeneron mAb is a combination treatment, the two EUAs are almost identical with equivalent patient outcomes. The FDA authorizes use of the investigational mAbs for treatment of high-risk COVID-19 outpatients (ages ≥12 y/o, weight ≥40 kg) with mild-to-moderate symptoms at risk for progressing to severe disease/hospitalization based on the following criteria:

- Direct SARS-CoV-2 test (e.g., PCR, rapid antigen test) must be positive
- Administered as soon as possible after positive test result and within 10 days of symptom onset
- Provider to review EUA fact sheet, including risks and benefits, with the patient
- Patient/caregiver to be provided with EUA fact sheets
- Administered in a setting where healthcare providers have direct access to medications to manage severe reactions

Please note that bamlanivimab and Regeneron mAbs are not authorized for use in patients:

- who are hospitalized due to COVID-19; or
- who require oxygen therapy due to COVID-19; or
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

High-risk summary definitions are as follows, however all healthcare providers should reference the authorized FDA materials related to the appropriate monoclonal antibody treatment prior to administration.

All Patients (who meet at least 1 of the following criteria):

- BMI ≥35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatment
- Age ≥ 65 years
- Age ≥ 55 years AND have any of the following: cardiovascular disease, hypertension, COPD/other chronic respiratory disease

Adolescents (age 12-17 years) who meet at least 1 of the following criteria:

- BMI ≥85th percentile for age/gender
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (e.g. cerebral palsy)
- Medical-related technological gastronomy, or positive pressure ventilation (not related to COVID-19)
- Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

Dosage

- **Bamlanivimab**: The dosage of bamlanivimab in adults and pediatric patients 12 years of age and older weighing at least 40 kg is a single IV infusion of 700 mg bamlanivimab administered over at least 60 minutes.
- **Regeneron mAbs**: The dosage in adults and in pediatric patients (12 years of age and older weighing at least 40 kg) is 1,200 mg of casirivimab and 1,200 mg of imdevimab

administered together as a single intravenous infusion over at least 60 minutes. Casirivimab and imdevimab solutions must be diluted prior to administration.

As we increase the number of infusion sites across the state available for patient referrals, we will provide you with updates. Please see the attached Maryland Referral Form for the most current list of sites. The State of Maryland continues to work to respond to the COVID-19 pandemic, including providing access to important resources for patients. We thank you for your dedication to protecting the health of Maryland residents as COVID-19 regains momentum in our communities.

Sincerely,

Jinlene Chan, MD, MPH
Act. Deputy Secretary
Public Health Services

Howard Haft, MD, MMM, CPE, FACPE
Executive Director
Maryland Primary Care Program

Attachments

Please reference the following FDA materials and review with patients prior to referral. Infusion site clinicians will also review the information with the patient, based on the selected therapeutic.

- Referral form standard for monoclonal antibody treatment across all sites
- Bamlanivimab (LY-CoV55):
  - FDA Fact Sheet for Healthcare Providers: bamlanivimab
  - FDA Fact Sheet for Patients, Parents and Caregivers: bamlanivimab
  - FDA Letter of Authorization: bamlanivimab
  - FDA Frequently Asked Questions for the Emergency Use Authorization for bamlanivimab for the clinical definition of high-risk patients and other critical information.
- Casirivimab and imdevimab
  - FDA Fact Sheet for Healthcare Providers-Regeneron MAbs
  - FDA Fact Sheet for Patients, Parents and Caregivers: casirivimab and imdevimab
  - FDA Letter of Authorization: Regeneron MAbs
  - FDA Frequently Asked Questions for the Emergency Use Authorization for the clinical definition of high-risk patients and other critical information.
- Operation Warp Speed Therapeutics: Monoclonal Antibody Playbook for outpatient administration (Version 2.0)