DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

November 14, 2024

Ryan Moran, DrPH, MHSA
Deputy Secretary, Health Care Financing and Medicaid Director
Maryland Department of Health
201 West Preston Street, Room 525
Baltimore, MD 21201

Dear Dr. Moran:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of the Evaluation Design, which is required by the Special Terms and Conditions (STC) #50 of Maryland's section 1115 demonstration, "Maryland HealthChoice " (Project No: 11-W-00099/3). CMS has determined that the evaluation design, which was submitted on June 30, 2022 and revised on January 20, 2023, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore approves the state's evaluation design.

CMS has added the approved evaluation design to the demonstration's Special Terms and Conditions (STC) as Attachment C. A copy of the STCs, which includes the new attachment, is enclosed with this letter. In accordance with 42 CFR 431.424, the approved evaluation design may now be posted to the state's Medicaid website within thirty days. CMS will also post the approved evaluation design as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with the approved evaluation design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the quarterly and annual monitoring reports.

We look forward to our continued partnership on the Maryland HealthChoice section 1115 demonstration. If you have any questions, please contact your CMS project officer, Mr. Felix Milburn, at Felix.Milburn@cms.hhs.gov.

Sincerely,

Danielle Daly -S

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Date: 2024.11.14 04:55:25 -05'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Nicole Guess, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

Maryland Department of Health

§1115 HealthChoice Demonstration Evaluation Design

August 24, 2023

Table of Contents

Acronyms

ACA	Patient Protection and Affordable Care Act
ACIS	Assistance in Community Integration Services
AIDS	Acquired immunodeficiency syndrome
ASO	Administrative services organization
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CLR	Childhood Lead Registry
CMC	Corrective Managed Care
CMS	Centers for Medicare and Medicaid Services
CoCM	Collaborative Care Model
CRISP	Chesapeake Regional Information System for our Patients
CY	Calendar year
DPP	Diabetes Prevention Program
ED	Emergency department
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
EQRO	External quality review organization
FFS	Fee-for-service
HEDIS®	Healthcare Effectiveness Data and Information Set
HMO	Health maintenance organization
HIE	Health information exchange
HIV	Human immunodeficiency virus
HSI	Health Services Initiative
ICS	Increased Community Services
IMD	Institutions for mental disease
IT	Information technology
LARC	Long-acting reversible contraceptive
MCO	Managed care organization
MDH	Maryland Department of Health
NCQA	National Committee for Quality Assurance
OUD	Opioid use disorder
REM	Rare and Expensive Case Management
SBIRT	Screening, Brief Intervention and Referral to Treatment
SMI	Serious Mental Illness
SUD	Substance use disorder

Background and History of Maryland's §1115 Demonstration

Following approval of the §1115 waiver by the Centers for Medicare and Medicaid Services (CMS) in October 1996, Maryland implemented the HealthChoice program and moved its fee-for-service (FFS) and health maintenance organization (HMO) enrollees into a managed care payment system in July 1997.[1] HealthChoice managed care organizations (MCOs) receive a predetermined monthly capitated payment in exchange for providing covered services to participants. Since the program's inception, HealthChoice has provided oversight to the continuing standards of high-quality coordination of care and controlling Medicaid costs by providing a patient-focused system with a medical home for all beneficiaries; building on the strengths of the established Maryland health care system; providing comprehensive, prevention-oriented systems of care; holding MCOs accountable for high-quality care; and achieving better value and predictable expenses.

Subsequent to the initial grant, the Maryland Department of Health[2] (MDH) requested and received several program renewals—in 2002, 2005, 2008, 2011, 2013, 2016, and 2021. In June 2021, Maryland applied for its seventh extension of the HealthChoice demonstration, which CMS approved for the period of calendar years (CYs) 2022 to 2026. Approved effective January 1, 2022 through December 31, 2026, the current waiver period builds on the innovations of the previous extensions by focusing on developing cost-effective services that target the significant and complex health care needs of individuals enrolled in Maryland Medicaid. Specifically, the demonstration will implement initiatives to address the social determinants of health, such as those encountered by individuals with severe mental illness (SMI), substance use disorders (SUD), high-risk pregnant women and former foster care participants, among others.

As of May 2022, HealthChoice served over 1.75 million participants, constituting nearly 86 percent of Medicaid recipients in Maryland, over 452,000 of whom receive coverage under the ACA's Medicaid expansion.

Initial evaluation of new participants in HealthChoice due to the ACA expansion have suggested that not only does this population have significant, complex health needs, but they may also have limited health literacy or struggle with homelessness, leading to challenges in the appropriate use of care. Therefore, in addition to assuring that efforts to improve the quality of care throughout the HealthChoice demonstration continue during the current waiver period, MDH requested—and CMS approved—to implement or continue the following program expansions:

1) Collaborative Care Model Pilot Program which integrates primary care and behavioral health services for HealthChoice participants who have experienced a behavioral health need (either a mental health condition or SUD).
2) Community Health Pilots: Assistance in Community Integration Services (ACIS) for individuals residing in institutions or at imminent risk of institutional placement.
3) Increased Community Services (ICS) for individuals over the age of 18 who were determined

[1] CMS was then known as the Health Care Financing Administration.
[2] Formerly known as the Maryland Department of Health and Mental Hygiene.

Medicaid-eligible while residing in a nursing facility, based on an income eligibility level of 300 percent of the Social Security Income Federal Benefit Rate.

4) Diabetes Prevention Program (DPP) for individuals (18-64) who have prediabetes or are at high risk of developing type 2 diabetes.
5) Dental Services for Former Foster Care Individuals up to 26 years old.
6) Expansion of SUD Residential and Inpatient Treatment Services to remove caps on lengths of stays for SUD treatment in an IMD and aim for a statewide average length of stay of 30 days or less.

Two additional programs have been approved for the demonstration period:

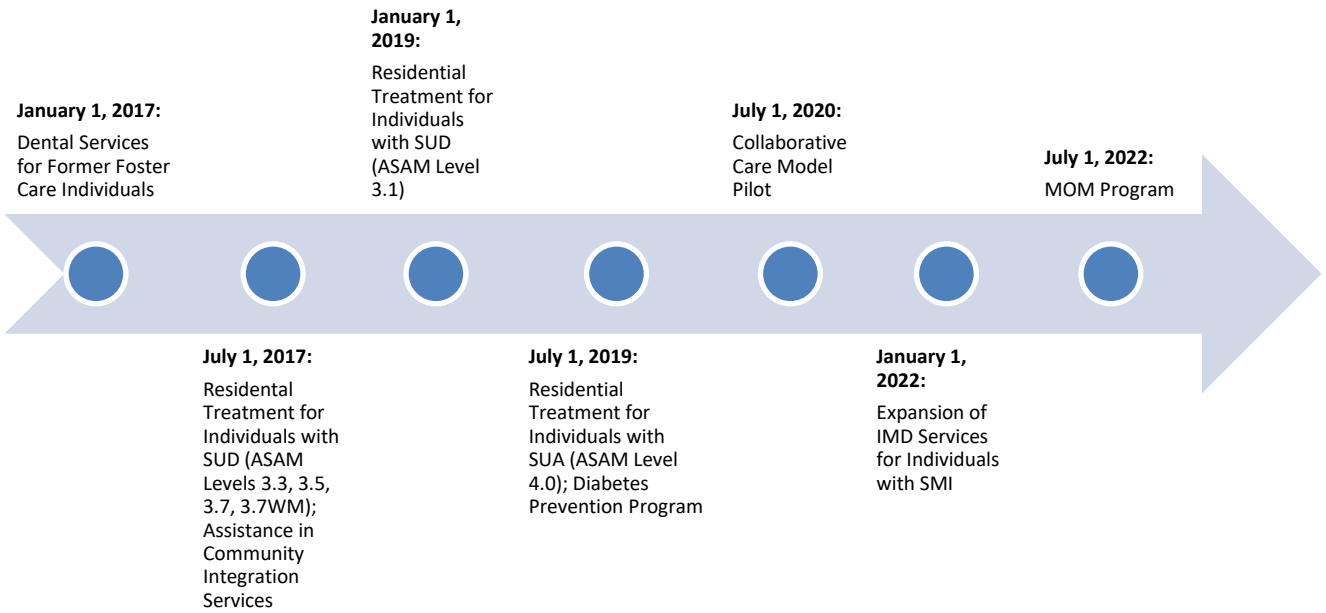
1) Expansion of IMD Services for Beneficiaries with SMI to cover short term stays of adults (21-64) who reside in a private IMD with an SMI diagnosis.
2) Maternal Opioid Misuse (MOM) program to provide a set of enhanced case management services, standardized social determinants of health screenings and care coordination to pregnant and postpartum beneficiaries with opioid use disorder (OUD).

Due to being expanded statewide and incorporated into Maryland's state plan, the following programs are no longer included in the demonstration and will not be included in the evaluation:

1) Medicaid Alternative Destination Transport Pilot Program.
2) Evidence-Based Home Visiting Services Pilot Program.
3) Adult Dental Pilot Program.

Figure 1 provides a timeline for the implementation of the components associated with the seventh waiver extension and amendments.

Figure 1. Implementation Timeline for HealthChoice Demonstration Components



CMS requires evaluations of all §1115 waiver demonstrations. MDH and its Independent Evaluator (the Hilltop Institute at the University of Maryland, Baltimore County) will prepare a summative evaluation comparing HealthChoice's performance results with the research hypotheses.

Through the implementation and continuation of the HealthChoice demonstration, MDH aims to improve the health status of low-income Marylanders by meeting the following goals:

1) Improve access to health care for the Medicaid population;
2) Improve the quality of health services delivered;
3) Provide patient-focused, comprehensive and coordinated care by providing Medicaid participants with a single medical home;
4) Emphasize health promotion and disease prevention; and
5) Expand coverage to additional low-income Marylanders with resources generated through managed care efficiencies.

MDH aims to meet the following goals related to SUD:

1) Increased rates of identification, initiation, and engagement in treatment for SUD;
2) Increased adherence to and retention in treatment;
3) Reductions in overdose deaths, particularly those due to opioids;
4) Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5) Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6) Improved access to care for physical health conditions among beneficiaries with SUD.

MDH also aims to meet the following goals related to SMI/serious emotional disturbance (SED):

1) Reduced utilization and lengths of stay in EDs among beneficiaries with SMI while awaiting mental health treatment in specialized settings;
2) Reduced preventable readmissions to acute care hospitals and residential settings;
3) Improved availability of crisis stabilization services including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric hospitals, and residential treatment settings throughout the state;
4) Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care; and
5) Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities.

Evaluation Questions and Hypotheses

As discussed above, the Maryland §1115 HealthChoice demonstration is a mature program, providing services to over one million participants annually. Evaluation questions will therefore focus on changes implemented during the waiver renewal period. The following three major questions, stated as hypotheses, will be addressed:

1. Eligibility and enrollment changes implemented during the current HealthChoice waiver period will increase coverage and access to care for HealthChoice participants;
2. Payment approaches implemented during the current HealthChoice waiver period will improve quality of care for HealthChoice participants; and
3. Innovative programs address the social determinants of health and will improve the health and wellbeing of the Maryland population.

Hypothesis 1 represents the continuing need for HealthChoice to assure and improve coverage and access to eligible populations. Because Maryland Medicaid participants, with a few excepted groups, are nearly completely covered by MCOs, improvements to access must now address more subtle and difficult barriers to enrollment and obtaining access to services. The evaluation study will ask whether the following two policy changes made an impact in improving access:

- Did the initiation of automated renewals of coverage—based on data indicating no substantial changes in participants' financial position—reduce the amount of time Medicaid-eligible individuals were without Medicaid coverage and improve the health and financial status of beneficiaries? The policy change commenced in CY 2016.
- Does automated selection of an MCO after one day for new participants, who in the past were permitted up to twenty-eight days to select an MCO, speed new participants' ability to access services? The policy change commenced in July 2018.

Hypothesis 2 concerns how incentivizing providers through larger and quicker payment would increase their provision of high-priority, high-quality care. This hypothesis will generate questions regarding these three policy initiatives:

- Do changes to the population health incentive program (formerly known as the value-based purchasing program) to an incentive only program result in higher rates of achievement of the program goals, without reducing the outcomes achieved by previously existing goals? Changes to the Value-Based Purchasing program went into effect starting in CY 2022.
- Do programs incentivizing greater attention to problems of particular concern among children (*e.g.*, asthma and lead exposure) help to reduce the incidence of those problems? Maryland's Health Services Initiative (HSI) went into effect on July 1, 2017.
- Do programs restricting access to prescription drugs that may be subject to misuse control the rates of such misuse? The policy change commenced on March 1, 2016.

Hypothesis 3 involves the largest number of policy initiatives, although many are currently being implemented as pilot programs and so will have relatively limited enrollment. Therefore, the research

questions around pilot programs will benefit from the ability to compare participants' results with the results of a control group. This hypothesis will produce the following policy questions:

- Does the opportunity to treat acute cases of SUD and SMI in residential treatment in institutions for mental disease (IMDs) improve the control of SUDs? The SUD benefit was phased into effect beginning in July 2017, covering ASAM Levels 3.3, 3.5, 3.7 and 3.7WM.[3] ASAM Levels 3.1 and 4.0 were phased in beginning in January and July 2019, respectively. The SMI benefit began January 2022.
- Does the ACIS pilot improve the living situations and reduce potentially unnecessary health care utilization for persons at risk of institutionalization or homelessness? This program went into effect in July 2017, with awards to local Lead Entities first granted in November 2017.
- If dental benefits are extended young adults aged out of foster care would these benefits also result in reduced incidence and costs of conditions related to dental disease? This program went into effect in January 2017.
- Does the Increased Community Services program increase transitions to the community? This program is a continuation from previous waiver periods and has been operating since 2009; the current waiver increased the program's cap to 100 slots.
- Does implementation of the National Diabetes Prevention Program (National DPP), proven to be sufficiently-effective to become a covered service under Medicare, work equally well with preventing diabetes diagnoses for a Medicaid population? The HealthChoice DPP was approved effective April 2019.
- Does a service model that integrates primary and behavioral health care and provides evidence-based therapeutic intervention and case management services for individuals with behavioral health conditions through the Collaborative Care Model result in improved outcomes for the target population? This pilot program went into effect on July 1, 2020 and will be transitioned out of the 1115 waiver to operate statewide on October 1, 2023.
- Does a service model that provides a set of enhanced case management services, standardized social determinants of health screenings and care coordination through the MOM program result in improved outcomes for the target population? This program went into effect on July 1, 2022.

All of these hypotheses and the research questions they generate are consistent with the goals of Title XIX and XXI in improving the health and wellbeing of low-income and chronically-ill populations.

Driver Diagram

Table 1 provides a driver diagram, offering a visual representation of the aims of the 2022-2026 waiver period, along with a closer look at the measures that MDH intends to employ to assess HealthChoice's performance against the stated hypotheses. In addition to the proposed measures, MDH will continue to

[3] 3.7WM licensed as 3.7D in Maryland.

monitor the development and release of new sources of information—such as upcoming surveys or HEDIS® measures—that may serve to evaluate the demonstration.

Table 1. Driver Diagram for Maryland §1115 Waiver Evaluation

Aims	Goals	Primary Drivers	Secondary Drivers
Eligibility and enrollment changes implemented during the current HealthChoice waiver period increase coverage and access to care for HealthChoice participants.	Improve access to health care for the Medicaid population; Expand coverage to additional low-income Marylanders with resources generated through managed care efficiencies	Auto-renewal process	Health status at enrollment
			Financial status of beneficiaries
			Periods of continuous enrollment without interruption
			Decreases in the frequency of disenrollment and reenrollment (churn)
		MCO auto-assignment after one day policy	Improved service utilization of new participants (>120 day six-month enrollment gap)
Payment approaches implemented during the current HealthChoice waiver period improve quality of care for HealthChoice participants	Improve access to health care for the Medicaid population; Improve the quality of health services delivered; Emphasize health promotion and disease prevention;	Value-Based Purchasing (VBP) Program/Population Health Incentive Program (PHIP)	Improved VBP/PHIP measures, such as diabetes management
			Increased preventive care visits, such as ambulatory care for children and adults with disabilities
		CHIP Health Services Initiative addressing lead and asthma	Healthy Homes for Healthy Kids (Program 1)
			Childhood Lead Poisoning Prevention and Environmental Case Management Program (Program 2)
		Statewide health IT solutions	Streamlined Corrective Managed Care (CMC) targeting prescription drug abuse
Innovative programs address the social determinants of health and improve the health and wellbeing of the Maryland population	Increased rates of identification, initiation, and engagement in treatment for SUD	Residential Treatment of Adults with SUD	Improving rates of initiation and engagement of alcohol and other drug dependence treatment among members with SUD

Aims	Goals	Primary Drivers	Secondary Drivers
			Improved rates of members receiving any addiction treatment for SUD
	Increased adherence to and retention in treatment		Better follow-up care after ED visit for alcohol and other drug abuse or dependence
			Increased rates of medication-assisted treatment (MAT) among participants with OUD
	Reductions in overdose deaths, particularly those due to opioids		Reduction in opioid-related mortality
	Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services		Lower rates of acute inpatient stays that had any SUD/opioid use disorder (OUD) diagnosis
			Reduced lengths of stay in acute inpatient and residential settings for treatment for SUD
	Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate		Decreased rates of readmission to the same level of care or higher among members discharged from residential treatment facilities.
	Improved access to care for physical health conditions among beneficiaries with SUD		Decreased cost of care for individuals with SUD including co-morbid physical and mental health conditions
	Reduced utilization and lengths of stay in EDs among beneficiaries with	IMD Services for Adults with SMI	Lower rates of ED visits and reduced ED lengths of stay for adults with SMI

Aims	Goals	Primary Drivers	Secondary Drivers
	SMI while awaiting mental health treatment in specialized settings Improved access to community-based services to address the chronic mental health care needs of beneficiaries with SMI or SED including through increased integration of primary and behavioral health care		
	Reduced preventable readmissions to acute care hospitals and residential settings Improved care coordination, especially continuity of care in the community following episodes of acute care in hospitals and residential treatment facilities		Reduced preventable readmissions to acute care hospitals among adults with an SMI
	Improved availability of crisis stabilization services including services made available through call centers and mobile crisis units, intensive outpatient services, as well as services provided during acute short-term stays in residential crisis stabilization programs, psychiatric		Increased number of call centers and mobile crisis units

Aims	Goals	Primary Drivers	Secondary Drivers
	hospitals, and residential treatment settings throughout the state		
	Improve access to health care for the Medicaid population; Improve the quality of health services delivered; and Emphasize health promotion and disease prevention	Assistance in Community Integration Services Pilot	Decreased ED visits (incl. potentially avoidable utilization)
			Decreased inpatient admissions
			Better follow-up care after hospitalization
			Reduced admissions to CFR 578.3 facilities
	Improve access to health care for the Medicaid population; Improve the quality of health services delivered	Increased Community Services Program	Reduction in nursing facility admissions and lengths of stay
	Provide patient-focused, comprehensive and coordinated care by providing Medicaid participants with a single case manager; Emphasize health promotion and disease prevention; Increased rates of identification, initiation, and engagement in treatment for SUD; Improved access to care for physical health conditions	MOM Program	Improved care coordination including comprehensive case management, care coordination, health promotion, individual and family supports, and linkages to community and support services

Aims	Goals	Primary Drivers	Secondary Drivers
	among beneficiaries with SUD.		
	Improve access to health care for the Medicaid population; Expand coverage to additional low-income Marylanders with resources generated through managed care efficiencies	Dental benefits for former foster care children	Increased use of dental services, including preventive/diagnostic, and restorative visits
			Reduction in ED use for dental-related conditions
	Improve access to health care for the Medicaid population; Improve the quality of health services delivered; and Emphasize health promotion and disease prevention	HealthChoice Diabetes Prevention Program	Reduction in total cost of care for prediabetic patients
			Decreased diabetes incidence
			Reduction in ED admissions for prediabetic patients.
			Reduction in hospital admissions where diabetes is the primary diagnosis
	Improve access to health care for the Medicaid population; Provide patient-focused, comprehensive and coordinated care by providing Medicaid participants with a single medical home; Expand coverage to	Collaborative Care Model Pilot Program	Increased rate of depression screening
			Increased monthly contact with enrolled pilot participants
			Improvement in depression diagnostic scores
			Increased case and treatment plan review
			Increased proportion of enrolled pilot participants in remission

Aims	Goals	Primary Drivers	Secondary Drivers
	additional low-income Marylanders with resources generated through managed care efficiencies.		Increased referral to and utilization of specialty behavioral health services by participants identified with high levels of acuity that cannot be appropriately addressed through the Collaborative Care Model

Methodology

Evaluation Design

Depending on the specific sub-population affected by policies and their related research questions, the evaluation will apply a mixed-method approach to create valid and rigorous tests of the programs in question. MDH recognizes that implementing a policy in pursuit of the driver diagram's predicted results must test whether those results occurred because of the policy or as a result of other factors (changes in economic or social conditions that could change the mix of participants, externally-driven trends in disease incidence and prevalence, or policies implemented outside of the HealthChoice program that pursue the same goals, among other factors). An environmental survey could identify policy changes and other economic and technological trends of potential impact.

Target and Comparison Populations

Because Medicaid is fluid in its enrollment of individuals, it is not always possible to maintain the programs' focus on particular participants or participant groups. Some of these programs evaluated apply to the HealthChoice populations as a whole, or a subpopulation which intrinsically cannot be divided into intervention and comparison groups, such as new participants. In this case, the best way to measure effects is to compare trends before and after the implementation of the program, using statistical methodologies such as pooled cross-section time series that separate between fixed effects and time-varying effects to control for exogenous changes outside of the program implementation.

On the other hand, a number of the programs are pilot studies with limited enrollment or implementation in specific geographic areas, for example, the Childhood Lead Poisoning Prevention and Environmental Case Management Program and the HealthChoice Diabetes Prevention Program components. Such programs can identify non-participants to serve as a comparison group. Specific decisions about which approach might be used to create a comparison group may need to await the availability of sufficient data on the number of program participants and their clinical, demographic, and geographic characteristics.

While mindful of these caveats, Table 2 (below) specifies how outcomes for each policy initiative will be measured, according to whether and how control groups will be specified, and which statistical techniques are best suited to measure outcomes validly and reliably.

Evaluation Period

The evaluation period covers outcomes measured during the renewal period of Maryland Medicaid's §1115 waiver. The time periods of analysis for most outcomes will be the years of the demonstration, CYs 2022-2026. In some cases (*i.e.*, for certain measures), it may be necessary to look at data from before the renewal period to better identify trends in the measure in question, such as with policies that were implemented before the start of the demonstration extension period and are continuing under the extension (such as the Diabetes Prevention Program). The pre-implementation period for these policies may extend 1-2 years prior to implementation. Because The Hilltop Institute at the

University of Maryland, Baltimore County is the repository for Maryland Medicaid's MMIS, it would require little additional effort to incorporate these additional data to improve the validity of an analysis relying on trends over time, such as pooled cross-section time series.

Data Sources

In general, Maryland's evaluation of the HealthChoice demonstration includes the entire population of participants, which supports a more robust evaluation than does a sampling-based methodology. This approach is facilitated by Hilltop, the Independent Evaluator. Hilltop maintains managed care encounters and FFS claims for the entirety of the Maryland Medicaid program. An overview of these and other data sources MDH will utilize follows. As with past reports, the evaluation will disaggregate certain sub-populations—such as foster care participants and dual eligibles—to assess programs focusing on these particular populations. The evaluation will also identify measures for stratification across MCOs to determine differences in the provision and quality of care.

Due to the distinct attributes of the HealthChoice population, the evaluation will not take into consideration any additional populations for purposes of comparison. MDH believes that year-to-year trend comparisons of the enrolled population provide a more meaningful analysis. Over 86 percent of Maryland Medicaid participants are enrolled in managed care. The remaining 14 percent consists largely of much smaller populations with greater health complexities: dual eligibles, spend-down recipients and participants in other partial benefit programs. Hence, the evaluation will not compare participants in the HealthChoice program with either the non-HealthChoice FFS population, Medicare beneficiaries or the commercially-insured.

Table 2 (Measurement Framework) identifies the anticipated source for each measure.

Fee-For-Service Claims and Managed Care Encounters (MMIS2)

MDH will leverage its existing relationship with Hilltop, which, in addition to conducting research, analysis and evaluation of publicly-funded health care, serves as the warehouse for Maryland Medicaid FFS claims and managed care encounters received via MMIS2 (and previously MMIS1). Claims and encounter data have been collected since Maryland began the HealthChoice demonstration in 1997, and are updated monthly and stored in analytic, SAS-ready data sets. Because these data are the basis for calculating payment rates under managed care, the data are validated through automated testing algorithms by MDH's information technology office on receipt from providers, by Hilltop on the receipt of data from MDH and by the consulting actuaries who assess the validity and actuarial soundness of managed care rate development. Hilltop has access to claims and encounter data from 1997 onwards to continue its evaluation and analysis of HealthChoice.

Hilltop's data warehouse contains person-level demographic information, which allows for matching with other databases. In addition, this arrangement facilitates a variety of analyses, including cost, service utilization, provider network adequacy, enrollment trends and access to and quality of care.

Because 86 percent of Maryland Medicaid recipients participate in HealthChoice and are enrolled with

an MCO, the majority of their somatic health services are covered through the managed care benefit and quantified via encounter submissions. Maryland's somatic MCO encounter reporting has been shown to be robust, correct and timely, with MCOs given six months to submit encounter data to MDH. Encounter data are used to determine medical loss ratios and, in rate-setting, give MCOs significant incentive to provide complete and accurate encounter data.

Several Medicaid benefits are carved out from the managed care package so that, even if enrolled with a HealthChoice MCO, a participant might receive some services outside of the MCO. Some of the key carved-out services include dental and behavioral health benefits, both of which are administered by administrative services organizations (ASOs), in addition to certain pharmacy benefits. Individuals participating in the Rare and Expensive Case Management (REM) program also receive their benefits on an FFS basis. FFS providers are allotted up to 12 months to submit claims, meaning that it is important to allow at least a year for claims run-out.

Cost data for FFS claims have been reliably captured since the beginning of Medicaid in Maryland. Since the beginning of the HealthChoice demonstration in 1997, encounter data have been continually improved and validated and are used for setting actuarially-sound capitation rates. Shadow-pricing for institutional claims relies on the all-payer payment rates set by the Maryland Health Services Cost Review Commission and are thus available to all MCOs. Physician and professional shadow prices are based on the current FFS Medicaid professional fee schedule, which is the most reliable source for estimating MCO payment rates to health care professionals.

Notes on data: Within the HealthChoice evaluation, measures identified as part of an established domain—such as HEDIS®—will follow the specifications of those domains unless otherwise noted. Measures evaluating the emergent nature of ED visits will utilize the classification methodology identified by Billings et al from New York University.[4] Individuals with behavioral health diagnoses will be identified using the criteria outlined in Maryland regulation.[5]

Vital Statistics Administration

One of the key requirements of the HealthChoice demonstration's Residential Treatment for Individuals with SUD is to monitor the incidence of opioid-related mortality. Maryland's MMIS2 does not contain information regarding cause of death. MDH will collaborate with Maryland's Vital Statistics Administration to obtain the data necessary to populate this measure. Hilltop has data available from CY 2015 onwards to use for evaluation.

Department of Human Services

Hilltop, while able to identify foster care participants by their coverage group in MMIS2, does not maintain access to foster care participants in the subsidized adoption program. Subsidized adoption

[4] Billings J, Parikh N, Mijanovich T. (2000). Emergency room use: The New York story. The Commonwealth Fund. Available https://wagner.nyu.edu/files/admissions/Billings%20-%20Emergency%20Room%20Use%20-%20The%20New%20York%20Story.pdf; accessed 5 April 2017.

[5] COMAR 10.09.70.02(L).

participants are excluded from MDH's analysis of foster care in the HealthChoice evaluation; therefore, MDH coordinates with the Maryland Department of Human Services to obtain updated foster care subsidized adoption lists on an annual basis, which will be available for all years of the demonstration period.

Maryland Department of the Environment

While Medicaid claims and encounters contain information regarding blood lead testing, they do not include information on the results of those tests. To report on the number of HealthChoice children with elevated blood lead levels, MDH will utilize the statewide Childhood Lead Registry (CLR). Maintained by the Maryland Department of the Environment, the CLR performs childhood blood lead surveillance for Maryland and provides results to MDH, including to Medicaid and local health departments as needed for case management. Hilltop has data from FY 2008 onwards to use for evaluation.

HealthCare Effectiveness Data and Information Set (HEDIS®)

MDH requires HealthChoice MCOs to report all Medicaid measures applicable to Medicaid, except measures exempted by MDH or if the services are carved out of the managed care benefit package (see Fee-for-Service Claims and Managed Care Encounters, above). HEDIS® requires input of high-quality encounter and enrollment data to construct comparison groups based on specific clinical criteria, as defined by diagnosis and procedure codes, and demographic characteristics such as age. MCOs follow the guidelines for HEDIS® data collection and specifications for measure calculations and receive an annual HEDIS® compliance audit by a competitively-procured organization licensed by the National Committee for Quality Assurance (NCQA). The Hilltop Institute uses a competitively- procured HEDIS® software (HEDIS Volume 2: Technical Specifications for Health Plans) to efficiently generate both HEDIS® and Consumer Assessment of Healthcare Providers and Systems (CAHPS) sample survey data used for Medicaid program monitoring and evaluation.

Maryland Department of Health Sources

Several of the measures proposed for the HealthChoice evaluation will rely on systems and programs internal to MDH, including the *LTSSMaryland* system and internal program quality surveys. ACIS enrollment data are submitted by participating entities, and data are available for 2018 and all subsequent years. At present, MDH is actively investigating the possibility of obtaining and sharing with Hilltop quantitative data from other sources, such as state-only claims in support of evaluating the IMD exclusion waiver (residential SUD treatment). If this is not possible, MDH will make a note in the Methodological Limitations section. Residential SUD treatment may also be covered in commercial behavioral health claims, but the Maryland All-Payer Claims Database relies on submissions from fully-insured carriers and voluntary submission from self-funded plans. In addition to potential bias from the data excluded, before submission to Maryland's APCD system there is a lag at least 18 months from dates of service delivery. These factors will result in challenges for comparing to Medicaid claims. Data to support the evaluation of the CoCM Pilot Program will be sourced from the contracted CoCM vendor for the years of the demonstration period. The point of sale pharmacy system provides real-time claims processing continuity to providers and recipients, which includes the comprehensive prescription

pharmacy needs of the HealthChoice population, including data on patients in the CMC program as well as overdose information. Hilltop will have access to reports from the point-of-sale system to evaluate the CMC program for CYs 2022-2026. Hilltop will also use beneficiary surveys conducted as part of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Member Experience Survey to evaluate the perceived health and financial status of beneficiaries. The State of Maryland Executive Summary Reports on the CAHPS Member Experience Survey include beneficiary ratings of overall health, overall mental/emotional health, and several CAHPS survey measures of beneficiary access, quality of care, and satisfaction for the HealthChoice population. Reports will be available for all years of the demonstration. To support evaluation of the MOM program, Hilltop will use newborn processing data (1184), a monthly dataset of newborns and their birthing parent that includes information on birth weight and other outcomes. Hilltop has access to these files from December 2017 onwards.

Analytic Methods

Where there are pilot interventions or benefits limited to certain populations, a sample of participants and non-participants may be selected based on demographic characteristics, such as age, race and ethnicity, sex, and county of residence, enrollment factors, like coverage duration and coverage group, and service utilization, such as diagnosis or procedure criteria. Cases and controls can then be analyzed to compare the effects of the interventions using descriptive analysis. For interventions that effect the entire HealthChoice population, or where a comparison group cannot be created, descriptive analysis and event count models will be used to analyze changes over the course of the demonstration. Subgroup analysis will be conducted for various demographic sub-populations to enrich the evaluation of certain programs.

To measure program effects for populations that cannot be separated into case and control groups, an interrupted time-series analysis is suitable for program measurements that are frequently repeated and can be measured prior to the initiation of the HealthChoice policy intervention. Policies evaluated using an interrupted time-series approach will utilize at least eight data points across the pre and post implementation periods, and outcomes will be measured monthly, quarterly, or annually depending on the timeframe of program implementation.

Sole reliance on quantitative techniques risks missing some critical aspects of the projects undertaken. Policy context will be included in the narrative portions of the evaluation for certain measures. For example, Maryland is unique in that the Health Services Cost Review Commission (HSCRC) builds uncompensated care costs into the hospital rates that are paid by all payers (including Medicaid). Additionally, Maryland is a Medicaid-expansion state that has recently taken legislative action to reduce medical debt. Policy context will be important to include in an assessment of the demonstration on measures such as provider uncompensated care and beneficiary medical debt. Data such as the reports of the qualitative impressions of key informants on implementation issues and program outcomes, program documents and literature or site visits by the evaluators, can be collected systematically and analyzed along with quantitative measures (although certain analyses are administrative and not suitable for qualitative approaches). MDH and its Independent Evaluator will use such mixed-methods as described in Table 2.

Methodological Limitations

Within evaluation study designs, multiple potential limitations to data and analytic techniques threaten the validity of conclusions drawn from the measures that rely on them. Among these are limits on the data itself: transcription and input errors, variable definitions that are too broad or not well-specified and missing data that may be random or systematic and must be evaluated to determine how best to compensate for them. Some data may be missing because they represent populations or services not served through Medicaid. The target populations for a policy themselves may be difficult to identify and might be identified only when they come forth to receive waiver services, so that there is a threat to validity from biased selection. Although techniques such as matching controls to participants can help in part to hold measures affected by selection bias constant, there are not techniques that can completely control for all threats to validity.

One major concern is whether the effects of an intervention can be separated from other activities and external influences that may affect the measured outcomes of that intervention. External changes that may affect HealthChoice performance include the following:

- Economic trends, such as changes in employment or inflation;
- Introduction of new medical care standards or technology (*e.g.*, a new pharmaceutical protocol for behavioral health issues);
- Epidemiology of disease patterns, such as a flu epidemic or COVID-19;
- Simultaneous implementation of other physical health and behavioral health models, such as accountable health organizations and behavioral health homes;
- Changes in case-mix (*e.g.*, relative severity of illness); and
- State and federal policy changes.

Any external changes beyond the control of the HealthChoice program make isolating the effects of HealthChoice more difficult. MDH and the Independent Evaluator will consult with interest groups in communities of concern to define the counterfactual; *i.e.*, if measurable changes observed would have occurred without the HealthChoice program, and if those changes could be explained by the causes suggested in a systematic survey of alternatives. If not, then the analysis can conclude that the HealthChoice program had an impact.

The effects of the COVID-19 pandemic pose methodological challenges for evaluation. The public health emergency (PHE) led to increased enrollment in HealthChoice, as participants werenot disenrolled from the program during the PHE. Enrollment measures, such as spans of coverage without interruptions and persons disenrolling and reenrolling within six months, are likely to be most affected by the PHE and subsequent unwinding. Hilltop will describe the overall effects of the PHE and unwinding periods on HealthChoice eligibility trends during the evaluation period. To account for potential confounding effects of the PHE and unwinding periods, Hilltop will use sensitivity analyses to analyze policies with implementation periods during these timeframes. Hilltop may exclude time periods most affected by the PHE and unwinding or adjust time periods for evaluation purposes.

Special Methodological Considerations

Certain pilot studies are small in scope, having relatively-low enrollment observable at this point in time. The analysis will likely need to pool the experience of pilot program participants over several years, along with that of any comparison group than can be constructed. Pooled cross-sectional time series may be used when the outcomes of interest—*e.g.*, a healthy birth weight or cumulative expenditures—can be measured on a yearly (or some other regular) basis.

Nevertheless, even pooled over the five-year time period, some of the pilots may not have attained enough participation to have sufficient statistical power in order to measure whether the outcomes observed are truly the effect of the intervention or simply occurred by chance. There may also be a lack of data necessary to build a truly "comparable" comparison group. This will limit the external validity of the evaluation and not allow for drawing conclusions about the policy's effectiveness or ineffectiveness. Although we cannot predict which policy evaluations will face this dilemma, should evaluators be unable to observe statistically-significant differences in a given pilot, we will report whether the policy results occurred in the expected direction and magnitude.

Table 2. Measurement Framework

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
Hypothesis 1: Eligibility and enrollment changes implemented during the current HealthChoice waiver period increase coverage and access to care for HealthChoice participants.							
Did the initiation of automated renewals of coverage—based on data indicating no substantial changes in participants' financial position—reduce the amount of time Medicaid-eligible individuals were without Medicaid coverage?	Spans of coverage without interruptions	All HealthChoice participants are subject to autorenewal. Separate analysis will be performed for the ACA expansion coverage groups Subgroup analysis can be performed by gender, age, race, ethnicity and geographic location.	Uninterrupted Coverage Spans	All coverage spans coming due during a specific measurement year	N/A	MMIS	Descriptive analysis Multiple linear regression to analyze effects by subgroup
	Persons disenrolling and reenrolling within six months	All HealthChoice participants are subject to autorenewal. Separate analysis will be performed for the ACA expansion coverage groups Subgroup analysis can be performed by gender, race, ethnicity, age and	Persons disenrolling and reenrolling within six months	All Persons disenrolling within a specific measurement year	N/A	MMIS	Descriptive analysis Multiple linear regression to analyze effects by subgroup

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
		geographic location.					
	Process Measures Total cost of care for all Medicaid beneficiaries under the demonstration over time Total health expenditures and administrative costs over time Provider uncompensated care: policy context/narrative Incidence of beneficiary medical debt: policy context/narrative Perceived health and financial status of beneficiaries over time: use of CAHPS survey reports						
Does automated selection of an MCO after one day for new participants, who in the past were permitted up to twenty-eight days to select an MCO, speed new participants' ability to access services?	Mean duration until services first used by new participants	New participants (>120 day six-month enrollment gap)	Duration Data	N/A	N/A	MMIS	Descriptive analysis of trends over the demonstration period

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
Hypothesis 2: Payment approaches implemented during the current HealthChoice waiver period improve quality of care for HealthChoice participants.							
Do changes to the population health incentive program (formerly known as the value-based purchasing program) to an incentive only program result in higher rates of achievement of the program goals, without reducing the outcomes achieved by previously existing goals?	HPC-AD: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)	Population eligible for measure, with possible sub analysis by MCO	Persons in denominator with HbA1c >9.0%	Persons identified with diabetes ages 18 to 64 based on NCQA's Comprehensive Diabetes Care measure	NCQA	MMIS, HEDIS	Descriptive quantitative analysis of trends over time during the demonstration
	Ambulatory Care Visits for SSI Adults and Children	Participants with SSI, with possible subanalysis by MCO	Persons in the denominator with ambulatory care visits	Participants with SSI	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
Do programs incentivizing greater attention to problems of particular concern among children (*e.g.*, asthma and lead exposure) help to reduce the incidence of those problems?	Percentage of children with elevated blood lead levels (BLL) who have received a follow-up lead test	Participants in Healthy Homes for Healthy Kids versus non- participants (Program 1)	Children receiving lead remediation	Children with elevated blood lead >=5µg/dL	N/A	MMIS using ICD-10 coding of BLL, Blood Lead matching, Local Health Departments, Childhood Lead Registry	Descriptive quantitative analysis of trends over time during the demonstration
	Among those will elevated BLL, the proportion whose follow up blood lead test was below 5µg/dL	Expansion of the Childhood Lead Poisoning Prevention and Environmental Case Management Program versus non-participants (Program 2). Non-participant comparison group will be selected from counties not participating in the program. Subgroup analysis can be performed by gender, age and geographic location.	Children in the denominator with a follow up blood test below 5µg/dL	Children with elevated blood lead >=5µg/dL	N/A	MMIS using ICD-10 coding of BLL, Blood Lead matching, Local Health Departments, Childhood Lead Registry	Descriptive quantitative analysis of trends over time during the demonstration

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	Asthma: Fewer nights awakened; fewer days with shortness of breath; fewer days of rescue inhaler use; Reduced asthma- related ED and inpatient use	Expansion of the Childhood Lead Poisoning Prevention and Environmental Case Management Program versus non-participants (Program 2). Non-participant comparison group will be selected from counties not participating in the program. Subgroup analysis can be performed by gender, age and geographic location.	Children in the denominator with asthma-related ED visits Children in the denominator with asthma-related inpatient use Children in the denominator with fewer nights awakened, fewer days with shortness of breath, and fewer days of rescue inhaler use	Children with asthma	N/A	Local Health Departments; MMIS	Descriptive quantitative analysis of trends over time during the demonstration
	Process Measures ***Program 1 (Lead Remediation)*** • IA and DUA signed between DHCD and MDH • DHCD procurement of abatement companies to work on program • DHCD procurement of lead inspector company to perform work for Program 1 • Successful completion of invoicing and billing payment • No. of lead remediation contractors procured for task order according to National HUD and local MDE guidelines • New provider type established in Maryland Medicaid's provider enrollment system: Lead Risk Assessor						

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	Program 2 (Environmental Case Management) • IA and DUA IRD to EHB • No. of IAs and DUAs established between IRD, EHB and LHDs • Successful completion of billing and payment mechanism, i.e. through IGT • No. of LHDs with MMIS and EVS access to screen for current Medicaid enrollment • No. of LHDs with staff onboarded based on quotas established by MDH • No. of LHDs with staff that have been trained						
Do programs restricting access to prescription drugs that may be subject to misuse control the rates of such misuse?	No. of persons on CMC	Subgroup analysis can be performed by gender, age and geographic location.	N/A	N/A	N/A	Point of Sale Pharmacy System	Descriptive quantitative analysis of trends over time during the demonstration
	No. of overdoses	Subgroup analysis can be performed by gender, age and geographic location.	N/A	N/A	N/A	Point of Sale Pharmacy System	Descriptive quantitative analysis of trends over time during the demonstration
Hypothesis 3: Innovative programs address the social determinants of health and improve the health and wellbeing of the Maryland population.							
Does the opportunity to treat acute cases of SUD and SMI in residential treatment in institutions for mental disease (IMDs) improve the control of SUDs?	Probability of initiation and engagement in SUD treatment following IMD discharge	IMD users with a primary diagnosis of SUD in each year Subgroup analysis can be performed by level of care in the IMD as well as gender, age and geographic location.	Number of IMD users in the year with claims for non-emergency department, non-inpatient SUD treatment within 45 days of discharge from IMD where SUD was	All IMD users with primary diagnosis of SUD	N/A	MMIS, HEDIS	Descriptive analysis of percentage, reported annually

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
			primary diagnosis				
	ED visit for SUD	Newly enrolled or first time IMD users with primary diagnosis of SUD pre/post participation Subgroup analysis can be performed by gender, age and geographic location.	Number of ED visits for SUD for IMD users	All newly enrolled or first time IMD users with a primary diagnosis of SUD	N/A	MMIS or HEDIS	Event count models with interrupted time series, controlling for level of care in the IMD
	Probability of initiation and engagement in SMI treatment following IMD discharge	IMD users in each year with primary SMI diagnosis Subgroup analysis can be performed by level of care in the IMD as well as gender, age and geographic location.	Number of IMD users with primary SMI diagnosis in the year with claims for non-emergent, non-inpatient SMI treatment within 45 days of discharge from IMD where SMI was primary diagnosis	All IMD users in the year with primary diagnosis of SMI	N/A	MMIS, HEDIS	Descriptive analysis of percentage, reported annually

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	ED visits for SMI	Newly enrolled or first time IMD users with SMI primary diagnosis pre/post participation Subgroup analysis can be performed by gender, age and geographic location.	Number of ED visits for SMI	All newly enrolled or first time IMD users with a primary diagnosis of SMI	N/A	MMIS or HEDIS	Event count models with interrupted time series, controlling for level of care in IMD
	ED visits and ED length of stay for SMI immediately following IMD	IMD users in each year with SMI primary diagnosis Subgroup analysis can be performed by level of care in the IMD as well as gender, age and geographic location.	Persons in denominator who are admitted or transferred from an IMD for ED visit with	IMD users in the year	N/A	MMIS or HEDIS	Descriptive analysis of percentage, reported annually
	Use of MAT services among persons with OUD and IMD placement	IMD users with primary diagnosis of SUD Subgroup analysis can be performed by gender, age and geographic location.	Persons in denominator receiving MAT	IMD users with opioid SUD diagnoses before and after IMD placement	N/A	MMIS or HEDIS	Descriptive quantitative analysis of trends over time during the demonstration

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	Use of Intensive Outpatient and Partial Hospitalization Mental Health Services	IMD users with MH diagnosis Subgroup analysis can be performed by gender, age and geographic location.	Persons in denominator with IOP utilization	IMD users with MH diagnoses before and after IMD placement	N/A	MMIS or HEDIS	Descriptive quantitative analysis of trends over time during the demonstration
	Readmission frequency to the same level of care or higher	IMD users	IMD users having readmissions	IMD users	N/A	MMIS or HEDIS	Descriptive quantitative analysis of trends over time during the demonstration.
	Overall cost of care for individuals with SMI/SUD including co- morbid physical and mental health conditions Tabulations of spending inclusive of IMD and outpatient treatment	Persons with SMI/SUD, users of IMD Subgroup analysis can be performed by gender, age and geographic location.	N/A	N/A	N/A	MMIS or HEDIS	Summary statistics of spending inclusive of IMD and outpatient treatment, reported annually
	Death by OUD	Deaths by OUD among IMD users with SUD diagnoses Subgroup analysis can be performed by gender, age and geographic location.	Deaths of individuals in the denominator	All IMD users with SUD diagnoses		Vital Statistics	Summary statistics of incidence of OUD death, reported annually

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	Number of crisis call centers and mobile crisis units	IMD users	IMD users indicating use of crisis call centers and mobile crisis units	IMD users	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration

	Process Measures
	• Fee schedule created of Medicaid reimbursement rates
	• No. of IMDs billing Medicaid under the demonstration
	  ○ By region
	  ○ By ASAM level
	  ○ Compared with before demonstration implementation
	• No. of IMDs having participated in a Medicaid onboarding training (*e.g.*, how to bill):
	  o 3.3 - 3.7D
	  o 3.1
	  o 4.0
	  o Duals expansion
	• No. of grievances, appeals and critical incidents related to SUD treatment services
	  o 3.1
	  o 4.0
	  o Duals expansion
	• No. of grievances, appeals and critical incidents related to SUD treatment services						

Does the ACIS pilot improve the living situations and reduce potentially unnecessary health care utilization for persons at risk of institutionalization or homelessness?	Achieved stable housing	Newly enrolled ACIS participants in each year	Number of ACIS participants newly enrolled in the year who achieved stable housing	Number of newly enrolled ACIS participants in the year	N/A	ACIS data collected by LEs; Specifically, living situation at enrollment and at ACIS service delivery	Descriptive analysis of percentage, reported annually

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	ED visits (incl. potentially-avoidable utilization)	ACIS participants pre/post participation	Number of ED visits	All ACIS participants	N/A	MMIS	Event count models with interrupted time series
	Inpatient admissions	ACIS participants pre/post participation	Number of inpatient admissions	All ACIS participants	N/A	MMIS	Event count model with interrupted time series. If outcome frequency is insufficient, then descriptive analysis.
	Inpatient admissions with substance abuse or mental health primary diagnosis	ACIS participants pre/post participation	Inpatient admissions with substance abuse or mental health primary diagnosis	All ACIS participants	N/A	MMIS	Descriptive analysis of event counts
	Nursing facility admissions	ACIS participants pre/post participation	Number of nursing facility admissions	All ACIS participants	N/A	MMIS	Event count model with interrupted time series
	Ambulatory care services	ACIS participants pre/post participation	Number of ambulatory care services	All ACIS participants	N/A	MMIS	Event count model with interrupted time series

	Process Measures
	• No. of Lead Entities participating
	  ○ Signed IA/DUA
	  ○ Successful completion of inter-governmental transfer (IGT) of funds for local match
	  ○ Completion rate of monthly implementation report						

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	• No. of Learning Collaboratives held and Lead Entity participation rate in each • No. of Lead Entities and Participating Entities with signed DUAs/contracts • No. of Lead Entities trained, licensed, and using Homeless Management Information System						
If dental benefits are extended young adults aged out of foster care would these benefits also result in reduced incidence and costs of conditions related to dental disease?	Frequency of ED visits with dental diagnoses	Former foster care children	N/A	N/A	N/A	MMIS	Compare ED use for dental services over the demonstration period
	Frequency of dental services, including preventive/di agnostic and restorative visits	Former foster care children	N/A	N/A	N/A	MMIS	Compare to similar age groups (REM and pregnant women) over the demonstration period
Does the Increased Community Services program increase transitions to the community?	Transitions of long stay nursing facility residents to community settings who are eligible to apply to the ICS program	ICS participants	ICS participants with transition from nursing facility to community	Individuals who meet the technical eligibility to apply for the ICS program	N/A	MMIS	Descriptive analysis
Does implementation of the National Diabetes Prevention Program (National DPP), proven to be sufficiently-effective to become a covered service under	All-cause hospital admissions	Compare DPP participants to cohort of prediabetic participants not enrolled in DPP	All-cause hospital admissions for DPP participants vs. prediabetic participants not in DPP	All prediabetic individuals	N/A	MMIS	Event count models

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
Medicare, work equally well with preventing diabetes diagnoses for a Medicaid population?	Total cost of care	Compare DPP participants to cohort of prediabetic participants not enrolled in DPP	Total cost of care for DPP participants vs. eligible enrollees vs. prediabetic participants not in DPP	All prediabetic individuals	N/A	MMIS	Pooled cross- section time series analysis of costs
	Diabetes incidence	Compare DPP participants to cohort of prediabetic participants not enrolled in DPP	Diabetes incidence for DPP participants vs. prediabetic individuals not in DPP	All prediabetic individuals	N/A	MMIS	Binary outcome regression
	ED visit rate	Compare DPP participants to cohort of prediabetic participants not enrolled in DPP	ED visits for DPP participants vs. prediabetic patients not in DPP	All prediabetic individuals	N/A	MMIS	Event count models

	Process Measures
	• New provider type established in Maryland Medicaid's provider enrollment system: DPP provider
	• No. of DPP providers enrolled in Maryland Medicaid, by delivery mode (in-person or virtual)
	• No. of MCOs with at least one DPP provider contracted in their network
	• No. of DPPs contracted with each MCO, disaggregated by in-person and virtual, and in each:
	  ○ No. of individuals enrolled
	  ○ No. of individuals retained at six months
	  ○ No. of individuals with at least one follow-up visit
	  ○ No. of individuals with 5 or more visits
	  ○ No. of individuals with 10 or more visits						

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
Does a service model that integrates primary and behavioral health care and provides evidence- based therapeutic intervention and case management services for individuals with behavioral health conditions through the Collaborative Care Model result in improved outcomes for the target population?	Monthly contact: Counts of contacts each month and proportion of participants receiving active treatment in CoCM each quarter	CoCM Pilot Program participants	No. of participants with at least one clinical contact per month.[6]	Total no. of CoCM Pilot Program-enrolled participants in that quarter	N/A	CoCM provider	Event counts
	Depression screening rate: Proportion of participants receiving a depression screening per quarter	CoCM Pilot Program participants	No. of participants who received a PHQ-2 or PHQ-9 screening per quarter	No. of participants enrolled in CoCM Pilot Program who had a clinical contact during the quarter	N/A	CoCM provider	Event count models
	Depression diagnosis: Proportion of participants demonstrating clinically- significant improvement	CoCM Pilot Program participants	No. of participants enrolled in CoCM Pilot Program for 70 days or greater with either: 1) a 50% reduction from first recorded to last recorded PHQ-9; or 2) a drop from first recorded to last recorded	No. of participants enrolled in CoCM Pilot Program for 70 days or more	N/A	CoCM provider	Descriptive analyses

[6] A "clinical contact" is defined as a contact in which monitoring may occur and treatment is delivered with corroborating documentation in the patient chart. This includes individual or group psychotherapy visits and telephonic engagement as long as treatment is delivered.

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
			PHQ-9 to less than 10				

	Process Measures
	• Signed contract with at least one entity to implement CoCM Pilot Program
	• No. of pilot sites established
	  ○ No. of rural sites
	  ○ No. of urban sites
	  ○ No. of Ob/Gyn provider sites
	• No. of participants enrolled per site						

Does a service model that provides a set of enhanced case management services, standardized social determinants of health screenings and care coordination through the MOM Model result in improved outcomes for the target population?	Postpartum Care: The percentage of deliveries in which women had a postpartum visit on or between 7 and 84 days after delivery.	MOM program participants	No. of participants with a delivery with a postpartum visit on or between 7 and 84 days after delivery	No. of participants with a delivery	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration
	Rate of Cesarean Sections: The percentage of deliveries that were cesarean section	MOM program participants	No. of participants with a delivery by cesarean section	No. of participants with a delivery	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	Severe maternal morbidity (SMM): Percentage of pregnancies associated with Severe Morbidity CDC-defined codes	MOM program participants	No. of participants with SMM	No. of participants	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration
	Rate of birth complications: Percentage of deliveries that had birth complications	MOM program participants	No. of participants with birth complications	No. of participants with a delivery	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration
	Birth weight: Percentage of children born normal, low and very low birth weight	MOM program participants	No. of children born to participants by birth weight	No. of children born to participants	N/A	MMIS, 1184 newborn processing data	Descriptive quantitative analysis of trends over time during the demonstration
	Timeliness of Prenatal Care: The percentage of deliveries in which women had a prenatal care visit in the first trimester, on or before the enrollment start date or within 42 days of enrollment in Medicaid.	MOM program participants	No. of participants with a delivery with timely prenatal care	No. of participants with a delivery	N/A	MMIS	Descriptive quantitative analysis of trends over time during the demonstration
	Caregiver risk assessment: Participants who had at least one caregiver-focused	MOM program participants	No. of participants with a caregiver-focused risk	No. of participants with a delivery	N/A	MMIS, 1184 newborn processing data	Descriptive quantitative analysis of trends over time during the demonstration

Research Question	Outcomes used to address the research question	Sample or subgroups to be compared	Numerator	Denominator	Measure Steward	Data sources	Analytic methods
	risk assessment completed during a follow-up visit after the child's birth.		assessment after birth				
	Neonatal intensive care unit (NICU) average length of stay	MOM program participants	No. of days in NICU for children born to participants with a NICU admission	No. of children born to participants with a NICU admission	N/A	MMIS, 1184 newborn processing data	Descriptive quantitative analysis of trends over time during the demonstration

Attachments

Independent Evaluator and Evaluation Budget

Selection of the Independent Evaluator

The Hilltop Institute is an independent non-partisan health research organization dedicated to advancing the health and wellbeing of people and communities. Hilltop conducts research, analysis, and evaluations on behalf of government agencies, foundations and nonprofit organizations at the national, state, and local levels. Hilltop is committed to addressing complex issues through informed, innovative and objective research analysis. Hilltop follows the professional, ethical, and conflict of interest expectations and responsibilities outlined in the Code of Ethics of the University of Maryland, Baltimore County. The Code of Ethics complies with the Maryland Public Ethics Law, the Maryland Whistleblower Law, and policies of the Board of Regents of the University System of Maryland (USM).

MDH chose Hilltop as the evaluator due to Hilltop's extensive experience and knowledge of Maryland Medicaid data and program policy. Hilltop has provided impartial consultation, technical support and program assistance to MDH since 1994 with the overarching goal of objectively evaluating and improving the Maryland Medicaid program without conflict of interest. The responsibilities of Hilltop are to: 1) assist MDH in analysis of the HealthChoice program, including conducting evaluations; 2) provide data analyses, rate-setting support and policy development of innovative proposals for the delivery of long-term services and supports; 3) provide administrative support activities; 4) facilitate database development; and 5) produce and disseminate studies, reports and analyses. While Hilltop provides support for various activities, MDH holds ultimate responsibility for determining program policy and operations independent of Hilltop.

While MDH and Hilltop work closely together, MDH makes all of the policy choices regarding the HealthChoice program.

Evaluation Budget

The list of assigned personnel and their respective contributions and work effort is contained in Appendix A. The cost for the evaluation, inclusive of salary, fringe benefits and university overhead totals approximately $683,205.

The relationship between MDH and The Hilltop Institute is governed by a multi-year Master Agreement and Business Associate Agreement, with a scope of work and budget negotiated on an annual basis.

Timeline and Major Milestones

As described in the Data Sources section above, Medicaid claims and encounters for health care services are not immediately available for analysis. FFS providers are allowed 12 months to submit claims for payment, and MCOs are permitted six months to submit encounters. MMIS2 data are not considered completed until 12 months have passed for submission of FFS claims. Hilltop receives MMIS2 data on a

monthly basis. For example, a claim or encounter paid on May 15, 2022 would be included in the data submission to Hilltop in early June 2022.

The evaluation period for participants will extend thru December 31, 2026. To accommodate the FFS claims run-out period, Hilltop will delay its analysis until 12 months have passed from the culmination of the demonstration period, until after January 1, 2028. With the summative evaluation due to CMS in June 2028, this will allow approximately six months for data processing and analysis for those measures that rely on claims and encounters. Maryland receives data from Local Health Departments—for the Community Health Pilots and HSI—on an ongoing, quarterly basis.

The interim evaluation report will be completed by July 2026. The report will cover the research questions and hypotheses above for an evaluation period covering CYs 2022-2024. Table 3 provides a summary of the schedule of state deliverables for the demonstration period.

Table 3. Summary of Milestones for Completion of the Summative Evaluation Report

Milestone	Date
Draft evaluation design submitted	June 30, 2022
Last day for MCO providers to submit encounters for inclusion in interim analysis	June 30, 2025
Last day for fee-for-service providers to submit claims for inclusion in interim analysis	December 31, 2025
Last day for Vital Statistics Administration data run-out for interim analysis	December 31, 2025
Last day for Maryland Department of the Environmental data run-out for interim analysis	December 31, 2025
Due date for interim evaluation report	June 30, 2026
Last day of the HealthChoice demonstration Period	December 31, 2026
Last day for MCO providers to submit encounters for inclusion in analysis	June 30, 2027
Last day for fee-for-service providers to submit claims for inclusion in analysis	December 31, 2027
Last day for Vital Statistics Administration data run-out	December 31, 2027
Last day for Maryland Department of the Environmental data run-out	December 31, 2027
Due data for draft of summative evaluation report	June 30, 2028
Due date for final summative evaluation report	*(Within 30 days of receipt of CMS comments)*
Final approved summative evaluation posted to the MDH's website	*(Within 30 days of CMS approval)*

Appendix A. Budget Justification for The Hilltop Institute

Estimated Personnel Effort and Other Costs for Summative HealthChoice Evaluation
Period of Performance: 7/1/27 – 6/30/28
Budget Justification

This is the estimated budget for the final HealthChoice Summative evaluation due June 30, 2028. During years 1-4 of the waiver, data collection and analysis will be ongoing and will culminate in interim annual reports.

Personnel and Other Costs:

Executive Direction, .21 FTE ($52,455): The executive direction team will be responsible for overall supervision of the project and will provide assistance with project management and coordination with MDH. The team will provide management oversight of the evaluation team and final review and approval of the evaluation analysis.

Project Supervision and Direction, .32 FTE ($55,280): This team will be responsible for overall supervision of the project and will provide assistance with project management and expertise on the analysis of Medicaid utilization data and risk adjustment.

Methodology and Methods Team, .29 FTE ($35,043): The methodology and methods team will develop methodologies needed for the evaluation, and will work with the Maryland Department of Health to coordinate new data collection outside of encounter reporting. The team will advise on the application of appropriate statistical methods to the analysis of the evaluation data.

Programming Team, .7 FTE ($75,101): The programming team will have primary responsibility for SAS programming to calculate HealthChoice outcome measures, including HEDIS and other quality measures.

Policy Analysts, 1.42 FTE ($169,024): The policy analyst team will collaborate with MDH on stakeholder communication, analyze Medicaid utilization data, participate in the development of information needed for the evaluation, and will work with MDH to coordinate new data collection outside of encounter reporting. The team will provide technical support to SAS programmers on data analysis and risk adjustment and will contribute to data analysis, regression analysis, and interrupted time series analyses.

Editor, .03 FTE ($2,849): The editor will provide editorial services and graphics support for the evaluation report.

Fringe Benefits: Fringe benefit charges are estimated at 35%.

Travel and Conference Calls: Local travel and conference calls are estimated at $400 annually to meet with MDH.

Programming Subcontracts: Additional programming subcontracting costs are estimated at $20,000 annually.

Overhead: Facilities and Administrative (F&A) recovery rate applied to this project is 25%.

Annual Estimated Budget in FY 2028: $683,205