Maryland Department of Health

§1115 HealthChoice Demonstration Evaluation Design

January 15, 2021

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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
CMS	Centers for Medicare and Medicaid Services
CoCM	Collaborative Care Model
CRISP	Chesapeake Regional Information System for our Patients
CY	Calendar year
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
HVS	Home Visiting Services
ICS	Increased Community Services
IMD	Institutions for mental disease
IT	Information technology
LARC	Long-acting reversible contraceptive
MCO	Managed care organization
NCQA	National Committee for Quality Assurance
OUD	Opioid use disorder
REM	Rare and Expensive Case Management
SBIRT	Screening, Brief Intervention and Referral to Treatment
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] (the Department) requested and received several program renewals—in 2002, 2005, 2008, 2011, 2013 and 2016. In June 2016, Maryland applied for its sixth extension of the HealthChoice demonstration, which CMS approved for the period of calendar years (CYs) 2017 to 2021. Approved effective January 1, 2017 through December 31, 2021, 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 substance use disorders (SUD), high-risk pregnant women and former foster care participants, among others.

As of December 2020, HealthChoice served over 1.33 million participants, constituting nearly 87 percent of Medicaid recipients in Maryland, over 367,000 of which receive coverage under the ACA's Medicaid expansion.

In June 2018, Maryland applied for an amendment to the HealthChoice demonstration, which CMS approved effective March 18, 2019 through December 31, 2021. This amendment approval authorizes the state to carry out the HealthChoice Diabetes Prevention Program (DPP); expand medical managed intensive inpatient services (ASAM 4.0); develop an adult dental pilot program; increase the Assistance in Community Integration Services (ACIS) pilot program annual enrollment cap; and modify the family planning program effective upon approval of MD SPA 18-0005 so that women of childbearing age who have a family income at or below 250 percent of the FPL and who are not otherwise eligible for Medicaid, CHIP or Medicare, but had Medicaid pregnancy coverage will be eligible for the HealthChoice family planning program for 12 months immediately following the two-month post-partum period.

In June 2019, Maryland applied for another amendment to the HealthChoice demonstration to establish the limited Collaborative Care Model (CoCM) Pilot Program. CMS approved the amendment in April 2020.

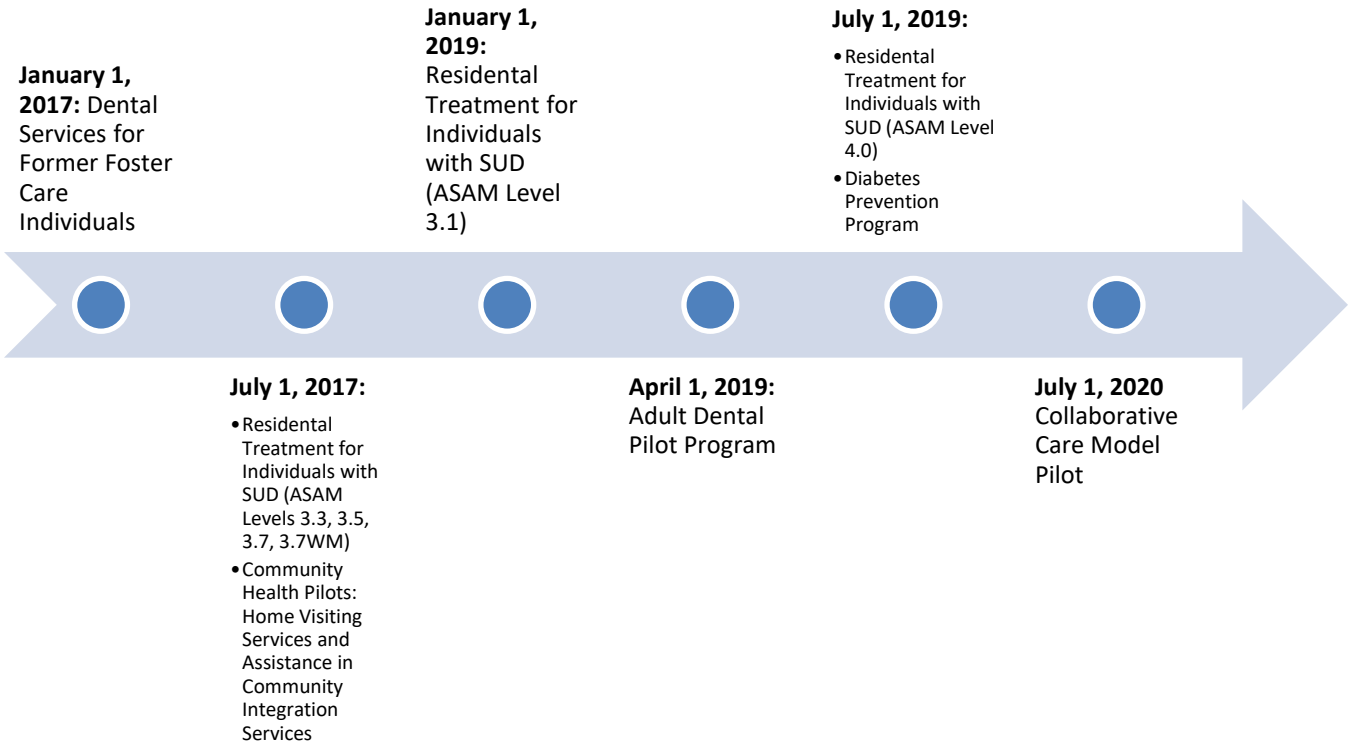
[1] CMS was then known as the Health Care Financing Administration.
[2] Formerly known as the Maryland Department of Health and Mental Hygiene.

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, the Department requested—and CMS approved—to implement or continue the following program expansions:

1) Increased Community Services (ICS) for individuals over the age of 18 who were determined 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;
2) Family Planning for women of childbearing age with a family income at or below 250 percent of the Federal Poverty Limit (FPL), who are not otherwise eligible for Medicaid, CHIP or Medicare but had Medicaid pregnancy coverage (per the 2018 amendment);
3) Dental Services for Former Foster Care Individuals up to 26 years old;
4) Residential Treatment for Individuals (21-64) with SUDs;
5) Community Health Pilots: Home-Visiting Services (HVS) for high-risk pregnant women and children up to age two;
6) Community Health Pilots: Assistance in Community Integration Services (ACIS) for individuals residing in institutions or at imminent risk of institutional placement;
7) Adult Dental Pilot Program for full dually-eligible adults (21-64);
8) Diabetes Prevention Program (DPP) for individuals (18-64) who have prediabetes or are at high risk of developing type 2 diabetes; and
9) 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) but have not received effective treatment.

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

Figure 1. Implementation Timeline for HealthChoice Demonstration Components



CMS requires evaluations of all §1115 waiver demonstrations. The Department 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, the Department 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.

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? 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 additions to value-based purchasing goals result in higher rates of achievement of those goals, without reducing the outcomes achieved by previously existing goals? Changes to the Value-Based Purchasing program went into effect starting in CY 2019.
- 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 in residential treatment in institutions for mental disease (IMDs) improve the control of SUDs? This benefit went into effect 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 in January and July 2019, respectively.

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

- Can home visiting services for new and expectant mothers improve outcomes for both children and their mothers? This program went into effect in July 2017, with awards to local Lead Entities first granted in November 2017.
- Does the ACIS pilot help the outcomes and living situations of persons at risk of institutionalization? This program went into effect in July 2017, with awards to local Lead Entities first granted in November 2017.
- If dental benefits are extended to currently non-covered populations—young adults aged out of foster care and dual eligibles—would these benefits also result in reduced incidence and costs of conditions related to dental disease? These programs went into effect in January 2017 and April 2019, respectively.
- Does ICS reduce the lengths of nursing facility stays for program participants? This program is a continuation from previous waiver periods; the current waiver increase the program's cap to 100 slots.
- Does coverage of contraception under family planning services result in increases in the use of contraceptive drugs and devices to help families plan their families? This program is a continuation from previous waiver periods; the amendment approved during the current waiver period modified program eligibility to women leaving Medicaid pregnancy coverage—but not otherwise eligible for Medicaid, CHIP or Medicare—for 12 months following the two-month postpartum period.
- 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.

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 2017-2021 waiver period, along with a closer look at the measures that the Department intends to employ to assess HealthChoice's performance against the stated hypotheses. In addition to the proposed measures, the Department will continue to 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	Primary Drivers	Secondary Drivers
Eligibility and enrollment changes implemented during the current HealthChoice waiver period increase coverage and access to care for HealthChoice participants.	Auto-renewal process	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	Value-Based Purchasing (VBP) Program	Better rates of HbA1c control
		Increased well-child visits for children under 15 months in age
	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 targeting prescription drug abuse
Innovative programs address the social determinants of health and improve the health and wellbeing of the Maryland population	IMD Exclusion Waiver	Improving rates of initiation and engagement of alcohol and other drug dependence treatment among members with SUD
		Better follow-up care after ED visit for alcohol and other drug abuse or dependence
		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
		Increased rates of medication-assisted treatment (MAT) among participants with OUD
		Decreased rates of readmission to the same level of care or higher among members discharged from residential treatment facilities.
		Improved rates of members receiving any addiction treatment for SUD

		Decreased cost of care for individuals with SUD including co-morbid physical and mental health conditions
		Reduction in opioid-related mortality
	Evidence-Based Home Visiting Services Pilot	Increased well-child visits for children under 15 months in age
		Improved attendance at post-partum visits
		Increased screening for depression
		Decreased ED visits
		Increased dental utilization
		Increased post-partum contraceptive uptake
	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
	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
	Pilot for Adult Dental Benefits improves outcomes related to dental care	Reduction in utilization for other health conditions found to be highly related to oral health
		Reduction in ED use for dental-related conditions
	Increased Community Services Program	Reduction in nursing facility admissions and lengths of stay
	Family Planning Program	Increased uptake of contraceptive methods due to inclusion in Maryland Health Connection
	HealthChoice Diabetes Prevention Program	Improved medication utilization practices

		Appropriate reduction in total cost of care
		Decreased diabetes incidence
		Reduction in ED Services
		Reduction in hospital admissions where diabetes is the primary diagnosis
	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
		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. The Maryland Department of Health 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 Residential Treatment for Adults with SUD and HealthChoice Diabetes Prevention Program components. Such programs can identify non-participants—who might be selected randomly or matched using propensity scoring techniques—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 program participants, their number 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. In some cases (*i.e.*, for certain measures), it may be necessary to look at data from before the renewal period in order to better identify trends in the measure in question. 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 difference in difference methods or 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 the Department 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. The Department 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)

The Department 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 the Department's information technology office on receipt from providers, by Hilltop on the receipt of data from the Department and by the consulting actuaries who assess the validity and actuarial soundness of managed care rate development.

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 in 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 the Department. 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. The Department will collaborate with Maryland's Vital Statistics Administration to obtain the data necessary to populate this measure.

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 participants are excluded from the Department's analysis of foster care in the HealthChoice evaluation; therefore, the Department coordinates with the Maryland Department of Human Services to obtain updated foster care subsidized adoption lists on an annual basis.

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, the Department 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 the Department, including to Medicaid and local health departments as needed for case management.

[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).

HealthCare Effectiveness Data and Information Set (HEDIS®)

The Department requires HealthChoice MCOs to report all Medicaid measures applicable to Medicaid, except measures exempted by the Department 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 the Department, including ICS program, *LTSSMaryland* system and internal program quality surveys. Certain measures under the HSI Program 2 are sources from Local Health Departments, based on self-report questionnaires completed by program participants during home visits. The questionnaires consist of standardized national asthma control and management metrics.

At present, the Department 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, the Department will make 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.

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 a propensity scoring model, matching participants on their predicted propensity to join the program. The propensity score would be based on a multivariate probit regression model, which would generate an estimated probability for each individual participant to become a participant if the program were offered them. Cases and controls would then be matched on their predicted probability scores, and further multivariate modeling would then test the effects of the interventions. Once such approach available when there are distinct participants and non-participant comparison groups is the difference-in-differences model. This multivariate technique takes account of trends in exogenous factors that jointly affect both the study and the comparison, and

measures whether the differences between the groups change over time after controlling for these factors.

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.

Sole reliance on quantitative techniques risks missing some critical aspects of the projects undertaken. 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). The Department and its Independent Evaluator will use such mixed-methods as described in Table 2; additional detail will be submitted with upcoming HealthChoice Quarterly Reports.

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.

As noted above, certain measures under HSI Program 2 are sourced from self-reported questionnaires administered during home visits for environmental case management. These measures are complemented in the methodology by quantitative measures regarding utilization-related outcomes.

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. The evaluation will conduct qualitative environmental surveys after the policy changes take effect to assess implementation progress and the perceived outcomes of the policy. The Department 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.

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 through propensity scoring or other techniques. 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.							
Implementation of auto-renewal improved continuity of enrollment and reduced enrollment churn.	Spans of coverage without interruptions	All HealthChoice participants are subject to autorenewal. Separate analysis will be performed for the ACA expansion coverage groups	Uninterrupted Coverage Spans	All coverage spans coming due during a specific measurement year	N/A	MMIS	Interrupted time-series analysis of trends pre-and post- policy implementation.
	Persons disenrolling and reenrolling within six months		Persons disenrolling and reenrolling within six months	All Persons disenrolling within a specific measurement year			Interrupted time-series analysis of trends pre-and post- policy implementation.
The auto-assignment to MCOs after one-day policy improved service utilization among new participants.	Mean duration until services first used by new participants	New participants (>120 day six-month enrollment gap)	Duration Data	N/A	N/A	MMIS	Interrupted time-series analysis of trends pre-and post- policy implementation.

Hypothesis 2: Payment approaches implemented during the current HealthChoice waiver period improve quality of care for HealthChoice participants.							
Additions to Value Based Purchasing incentive payment program led to increases in utilization	HbA1c control (added in CY 2019)	Population diagnosed with diabetes, subanalysis by MCO	Persons in Denominator with HbA1c <=8.0	Persons identified with Diabetes (Patients ages 18 to 64 with diabetes who have at least two visits for this diagnosis in the last two years (established patient) with at least one visit in the last 12 months.	MN Community Measurement NQF ID: 0729	MMIS, HEDIS	Interrupted time-series analysis of trends pre-and post- policy implementation.
	Well-child visits for children under 15 months in age	Children < 15 months of age, subanalysis by MCO	The number of children who received 6 or more well-child visits (Well-Care Value Set), on different dates of service, with a PCP during their first 15 months of life. The well-child visit must	15 months old during the measurement year.	NCQA NQF ID: 1392	MMIS, HEDIS	Interrupted time-series analysis of trends pre-and post- policy implementation.

			occur with a PCP, but the PCP does not have to be the practitioner assigned to the child.				
CHIP Health Services Initiative improved outcomes related to lead and asthma	Percentage of children with elevated blood lead levels (BLL) who have received services	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	Difference-in-differences analysis of trends between participants and non-participants.
	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.	N/A	Children with elevated blood lead >=5µg/dL	N/A		
	Asthma: Fewer nights awakened; fewer days with shortness of breath; fewer days of rescue inhaler		N/A	N/A	N/A	Local Health Departments HEDIS MMIS	

	use; reduced asthma-related ED and inpatient use	Subgroup analysis can be performed by gender, age and geographic location.					
	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 ***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 the Department • No. staff on-boarded at EHB for P1/P2 administration • No. of LHDs with staff that have been trained • No. Health Departments actively referring to P1 (DHCD) • No. LHDs conducting home visits						
Streamlined Corrective Managed Care	No. of persons on CMC	Persons using Rx identified for CMC, enrolled on	N/A	N/A	N/A	Point of Sale Pharmacy System	Difference-in-differences analysis of trends

decreases prescription drug abuse	No. of overdoses	CMC and not enrolled	N/A	N/A	N/A		between participants and non-participants.
Hypothesis 3: Innovative programs address the social determinants of health and improve the health and wellbeing of the Maryland population.							
IMD exclusion waiver results in improved outcomes for SUD	Probability of initiation and engagement of alcohol and other drug dependence treatment	Persons with SUD, users of IMD compared with non-users	Persons in denominator with claims for SUD treatment	All persons diagnosed with SUD	N/A	MMIS, HEDIS	Estimated odds ratio of IMD to Non-IMD users, controlling for level of care in IMD, using binary outcome regression.
	Follow-up after discharge from the ED for mental health or alcohol or other drug dependence		Persons in denominator with claims for SUD treatment after discharge	All persons diagnosed with SUD using ED services	N/A	MMIS	Odds ratio of follow up within seven and 30 days after discharge using binary outcome regression.
	ED utilization for consequences of SUD, including opioid overdoses		Frequency of SUD diagnoses in ED	N/A	N/A		Frequency of ED use with primary DX of SUD, controlling for IMD participation and level of care,

							using event-count regression models.
	Use of MAT services among persons with OUD and IMD placement		Persons in denominator receiving MAT	Persons with opioid SUD diagnoses	N/A		Frequency of ED use with primary DX of SUD, controlling for IMD participation and level of care, using event-count regression models.
	Presence of discharge planning in making effective linkages to community-based care[6]	IMD users		IMD users	N/A		Summary statistics of completed discharge planning, use of services post discharge, using Chi-square or t-tests.
	Readmission frequency to the same level		IMD users having readmissions		N/A		Pooled cross-sectional time-series counts of readmissions.

[6] The Department has limited resources to conduct record reviews, which may challenge the completion of this measure.

	of care or higher						Pooled cross-sectional time-series spending inclusive of IMD and outpatient treatment, controlling for persons with and without IMD use
	Overall cost of care for individuals with SUD including co-morbid physical and mental health conditions Tabulations of spending inclusive of IMD and outpatient treatment	Persons with SUD, users of IMD compared with non-users	N/A	N/A	N/A		
	Death by OUD	Deaths by OUD among Medicaid participants	Deaths of individuals in the denominator	All persons with SUD diagnoses		Vital Statistics	Incidence of OUD in binary regression model comparing IMD and non-IMD.

	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):
	  ○ 3.3 - 3.7D						

	○ 3.1 ○ 4.0 ○ Duals expansion • No. of grievances, appeals and critical incidents related to SUD treatment services						
The HVS Pilot improves health outcomes for participating families and children	Length of time between initiation of well child visits	Comparing participants in HVS to non-participants, *i.e.,* in counties where HVS is not active, matching control cases to intervention group with propensity scoring for HVS enrollment.	N/A	N/A	N/A	MMIS	Hazard rate or time to event models
	Frequency of well-child visits around appropriate ages in months						Event count models (Poisson regression) for counts of visits.
	Length of time to mother's first post-partum visit						Hazard rate models
	Mother's screening for depression						Hazard rate models
	Mother and newborn use of ED for all causes					MMIS	Binary outcome regression controlling for participation in HVS, with All Cause ED use or ED use with

							injury, poisoning, trauma
	Mother's use of dental services						Binary outcome regression, controlling for participation in HVS
	Post-partum contraceptive uptake						Binary outcome regression, controlling for participation in HVS
	Mothers and infants admission rates, within one year of birth						Event count models, controlling for participation in HVS

	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
	• No. of Lead Entities with NFP or HFA accreditation
	Envisioned Qualitative Approach: Key informant interviews with Local Health Departments, home-visitors						

ACIS pilot improves health outcomes for participants	Pre- and post-living situation	ACIS participants vs Non-participants	N/A	N/A	N/A	Enrollment data on living arrangement	Interrupted time-series analysis.
	ED visits (incl. potentially-avoidable utilization)					MMIS, HEDIS	Event count models, controlling for participation.
	Inpatient admissions						Event count models, controlling for participation.
	HEDIS Follow Up after Hospitalization (FUH)		Submission Criteria 1: Patient Received Follow-Up within 30 Days after Discharge. A follow-up visit with a mental health practitioner within 30 days	Submission Criteria 1: Patients 6 years of age and older who were discharged from an acute inpatient setting (including acute care psychiatric	National Committee for Quality Assurance (HEDIS)		

			after acute inpatient discharge. Submission Criteria 2: Patient Received Follow-Up within 7 Days after Discharge: A follow-up visit with a mental health practitioner within 7 days after acute inpatient discharge.	facilities) with a principal diagnosis of mental illness or intentional self-harm on or between January 1 and December 1 of the measurement period Submission Criteria 2: Patients 6 years of age and older who were discharged from an acute inpatient setting (including acute care psychiatric facilities) with a principal diagnosis of mental illness or intentional self-harm on or between January 1 and December 1 of			

				the measurement period			
	Frequency of admissions to NH, Behavioral Health, inpatient acute care from users of CFR 578.3 facilities	Users of CFR 578.3 facilities compared to non-users	N/A	N/A	N/A		Event count models, controlling for participation

	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
	• 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
	Envisioned Qualitative Approach: Key informant interviews with lead entity and participating entity interviews, learning collaborative results						

Dental benefits for former foster care children reduced potentially-	Frequency of ED visits with dental diagnoses	Former foster care children	N/A	N/A	N/A	MMIS	Compare ED use for dental services, pre and post implementation.

avoidable utilization	Frequency of dental services, including preventive/diagnostic and restorative visits						Compare to similar age groups (REM and pregnant women), pre and post implementation in event count outcome regression
Pilot for Adult Dental Benefits improves outcomes related to dental care	Reduction in ED use for dental related conditions	Dual eligible pilot participant and non-participants	N/A	N/A	N/A	MMIS	Difference-in-differences for matched control group compared to pilot participants.
	Diagnoses of diabetes, MCH, inflammatory disease compared to similar age groups in multivariate regression						Participants compared to similar age groups in multivariate binary outcome regression

	Total Medicaid costs for dental benefit pilot participants vs non-participants						Pooled cross-section time series data of participants compared to matched control non-participants.
Increased Community Services increases transitions to the community	Transitions of long stay nursing facility residents to community settings	Nursing facility residents participating and not participating in the pilot	ICS participants	All nursing facility residents in pilot area	N/A	MMIS	Compare length of stay of ICS participants with similar nursing facility residents in a multivariate regression.
Family Planning increases utilization of family planning services	Effect of inclusion in Maryland Health Connection on enrollment and uptake of prescription contraceptives (daily and/or LARC)	Uptake of prescription contraceptives (daily and/or LARC)	Use of contraceptives by women of child-bearing age	All women of child-bearing age	N/A	MMIS	Multivariate difference in difference pre and post implementation, for binary outcome of daily prescription, LARC, and of any contraceptive

HealthChoice Diabetes Prevention Program improves health outcomes for participants	All-cause hospital admissions	Compare DPP participants to non-participants	All-cause hospital admissions for participants vs. eligible enrollees who did not participate in DPP	All eligible participants (comparing those that enrolled vs. those that did not enroll in DPP)	N/A	MMIS	Event count models
	Prescription adherence for participants who have progressed to type 2 diabetes		No. of participants who progressed to a type 2 diabetes diagnosis in adherence with medication regimen	All participants who progressed to a type 2 diabetes diagnosis	N/A		Frequency (count) of prescriptions
	Total cost of care		Total cost of care for participants vs. eligible enrollees who did not participate in DPP	All eligible participants (comparing those that enrolled vs. those that did not enroll in DPP)	N/A		Pooled cross-section time series analysis of costs
	Diabetes incidence		Diabetes incidence for participants vs. eligible enrollees who	All eligible participants (comparing those that enrolled vs.	N/A		Binary outcome regression

			did not participate in DPP	those that did not enroll in DPP)			
	ED visit rate		ED visits for participants vs. eligible enrollees who did not participate in DPP	All eligible participants (comparing those that enrolled vs. those that did not enroll in DPP)	N/A		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 achieving five-percent weight loss
	  ○ No. of individuals achieving nine-percent weight loss
	Envisioned Qualitative Approach: Key informant interview with MCOs, DPP providers						

Integrated delivery of primary and behavioral health care through the Collaborative	Monthly contact: Proportion of participants receiving active	CoCM Pilot Program participants	No. of participants with at least one clinical contact per month[7]	Total no. of CoCM Pilot Program-enrolled participants in that month	N/A	CoCM provider	Event counts

[7] 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.

Care Model Pilot Program improves health outcomes for participants	treatment in CoCM						
	Depression screening rate: Proportion of participants receiving a depression screening		No. of participants who received a PHQ-2 or PHQ-9 screening in the past 12 months	No. of participants enrolled in CoCM Pilot Program	N/A		Event count models
	Depression diagnosis: Proportion of participants demonstrating clinically-significant improvement		No. of participants enrolled in CoCM Pilot Program for 70 days or greater with either: 1) a 50% reduction from baseline PHQ-9; or 2) a drop from baseline PHQ-9 to less than 10	No. of participants enrolled in CoCM Pilot Program for 70 days or more	N/A		Interrupted time-series analysis
	Case review: Proportion of participants without improvement whose case and/or		No. of participants enrolled in CoCM Pilot Program for 70 days or greater, who did not	No. of participants enrolled for 70 days or greater who did not meet clinical improvement	N/A		Interrupted time-series analysis

	treatment plan were reviewed		show improvement, whose case was reviewed by the Consulting Psychiatrist with treatment recommendations provided to the primary care provider or BH care manager OR had a documented change made to their treatment plan in the month of non-improved screening	criteria that month			
	Remission rate: Proportion of participants who achieved remission criteria		No. of participants whose last-recorded PHQ-9 score was below 5	No. of participants	N/A		Event count models
	Specialty behavioral health utilization rate		No. of participants 1) referred to the ASO for	No. of participants	N/A	MMIS	Event count models

			specialty behavioral health services and 2) of those referred, the number with a with a behavioral health claim paid by the ASO within 30 days				

	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						

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.

The Department 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 the Department 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 the Department in managing 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.

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 $628,667.

The relationship between the Department 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, 2021. 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, 2023. With the summative evaluation due to CMS in June 2023, 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.

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	April 21, 2017
Draft evaluation design re-submitted	July 9, 2019
Draft evaluation design re-submitted	July 1, 2020
Draft evaluation design re-submitted	January 15, 2021
Last day of the HealthChoice demonstration period	December 31, 2021
Last day for MCO providers to submit encounters for inclusion in analysis	June 30, 2022
Last day for fee-for-service providers to submit claims for inclusion in analysis	December 31, 2022
Last day for Vital Statistics Administration data run-out	December 31, 2022
Last day for Maryland Department of the Environmental data run-out	December 31, 2022
Due data for draft of summative evaluation report	June 30, 2023
Due date for final summative evaluation report	*(Within 30 days of receipt of CMS comments)*
Final approved summative evaluation posted to the Department'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: 7/1/22 – 6/30/23
Budget Justification

This is the estimated budget for the final HealthChoice Summative evaluation due June 30, 2023. 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 ($44,342): 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 ($56,902): 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 ($42,214): 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 ($92,511): 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 ($198,218): 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 ($5,666): 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 the Department.

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 2023: $628,667