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

October 14, 2026

Steven Ford
Medicaid Director
Virginia Department of Medical Assistance Services
600 E Broad St
Richmond, VA 23219

Dear Director Ford:

The Centers for Medicare & Medicaid Services (CMS) accepts the Commonwealth of Virginia's High Needs Supports Evaluation Design, which was required by the Special Terms and Conditions (STCs), specifically STC #61 "Draft Evaluation Design," of the section 1115 demonstration, "Building and Transforming Coverage, Services, and Supports for a Healthier Virginia" (Project No: 11-W-00297/3), for the amendment approved on July 9, 2020.

Virginia informed CMS that it did not implement the High Needs Supports program during the prior demonstration approval period. Furthermore, the program was neither requested nor approved as part of the renewal of the section 1115 demonstration, effective August 1, 2026 through December 31, 2031. Accordingly, CMS accepts the state's High Needs Supports Evaluation Design submission, recognizing that there are no implementation or program outcomes to evaluate.

The accepted Evaluation Design will be posted to Medicaid.gov under the demonstration's administrative record. In accordance with the STC titled, Public Access, the accepted Evaluation Design must be posted to Virginia's Medicaid website within 30 calendar days of the date of this letter.

Program Integrity

States are responsible for following all applicable federal law and regulations when they claim and use federal Medicaid funds and must fully comply with all applicable Medicaid statutes and regulations under a section 1115 demonstration, except where specific provisions have been expressly waived or identified as not applicable for that demonstration. This obligation includes all requirements in Title XIX of the Social Security Act and implementing regulations governing provider screening and enrollment activities, pre- and post-payment review claiming, payment methodologies and rate-setting, utilization controls, and program integrity including processes to identify, investigate, and refer suspected fraud, and methods to receive complaints and identify questionable practices. States must maintain effective systems and safeguards to prevent, detect,

and address any fraud, waste, or abuse (FWA) in the delivery of and payment for Medicaid services, including referrals to law enforcement when appropriate.

States should have heightened monitoring and oversight mechanisms in place featuring robust internal controls to identify and remediate all vulnerabilities (including, but not limited to, FWA and beneficiary access issues) inherent in service areas approved as part of a demonstration. At any time, CMS may request that the state provide a plan detailing the state's systems and safeguards to prevent, detect, and address any FWA relative to this demonstration. Failure to meet program integrity obligations under federal statutes and regulations or under the terms and conditions of this demonstration approval may result in compliance actions or other enforcement measures that could include requirements to develop and implement corrective action plans, withholdings, deferrals, disallowances, and termination of demonstration authority.

We look forward to our continued partnership on the ongoing Building and Transforming Coverage, Services, and Supports for a Healthier Virginia section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

DANIELLE DALY -S

Digitally signed by DANIELLE DALY -S
Date: 2026.10.14 04:55:05 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

cc: Margaret Kosherzenko, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

Virginia's 1115 Waiver for High Needs Supports: Evaluation Plan

Center for Health Systems Effectiveness

Oregon Health and Science University

July 14, 2021

OHSU

Table of Contents

Section A: General Background Information 3
Section B: Evaluation Questions and Hypotheses 4
Aim 1: Increase employment rates 4
Aim 2: Increase Stable Housing Rates 6
Aim 3: Improve Overall Healthcare Utilization 8
Section C: Methodology 9
C.1 Evaluation Methodologic Approach 9
C.2 Evaluation Period 11
C.3 Data Sources and Preparation 11
C.4 Quantitative Analysis Plan 12
C.5 Qualitative Analysis Plan 14
C.6 Evaluation Measures 16
C.7 Data Sources 16
D. Methodological Limitations 16
E. Attachments 17
E.1 Independent Evaluator Selection Process 17
E.2 Timeline 19
E.3 Support Tasks 21
E.4 Evaluation Budget 21
Appendix: Measures and Data Sources 22

Section A: General Background Information

Across the country, a subset of Medicaid beneficiaries have high social support needs related to complex behavioral and physical health conditions.[1] Health services providers have had difficulty meeting the needs of these patients, both because of the complexity of their needs and because their mix of medical and social needs does not fit well into the way healthcare is organized. As a result, these individuals tend to over-utilize emergency care, and often are repeatedly institutionalized.

These beneficiaries are often at high risk of homelessness, and they often have barriers to employment related to either physical or behavioral health conditions. The lack of stable housing and employment only exacerbates their overall complex of needs, and intervening in these areas provides an entry point for bringing more stability and improved health to all areas of the individuals' lives.

In 2018 the Virginia legislature directed the Department of Medical Assistance Services (DMAS) to seek federal approval for supportive employment and housing demonstration programs through an 1115 Medicaid waiver. DMAS submitted an application for High Needs Supports (HNS) benefits as part of the state's extension application for its existing 1115 waiver, entitled "Building and Transforming Coverage, Services, and Supports for a Healthier Virginia." (Project Number 11-W-00297/3, formerly "Addiction and Recovery Treatment Services (ARTS) Delivery System Transformation). The HNS demonstration was approved by the Center for Medicare and Medicaid Services (CMS) on July 9, 2020. This waiver demonstration will allow the state to develop supportive employment and housing interventions for Medicaid beneficiaries with certain needs, specifically those with behavioral health needs, need for assistance with Activities of Daily Living (ADLs), or complex physical health needs.

The goals of the demonstration are to increase employment rates, decrease homelessness or risk of homelessness, and improve overall healthcare utilization among the high-needs group of beneficiaries eligible to participate, such that their overall health is improved.

This demonstration was approved by CMS on July 9, 2020, and will extend through December 31, 2024.

The evaluation of this part of Virginia's 1115 waiver will be conducted by the Center for Health Systems Effectiveness (CHSE) at the Oregon Health and Science University (OHSU). CHSE is a research organization that uses economic approaches and big data to answer pressing questions about health care delivery. Our mission is to provide the analyses, evidence, and economic expertise to build a more sustainable health care system. Our team, which consists of quantitative and qualitative researchers, has extensive experience with Medicaid, 1115 waivers, and program evaluation.

---

[1] Mann, C. (2013). *Targeting Medicaid Super-Utilizers to Decrease Costs and Improve Quality* (CMCS Informational Bulletin). Centers for Medicare and Medicaid Services.

Section B: Evaluation Questions and Hypotheses

This demonstration project will include a subset of Medicaid beneficiaries with behavioral health needs, need for assistance with Activities of Daily Living (ADLs), or complex physical health needs. In this group of beneficiaries, the project's aims are:

Aim 1: Increase employment rates

Aim 2: Increase stable housing rates

Aim 3: Improve overall healthcare utilization

This section includes a driver diagram for each Aim, along with a table outlining the research questions and hypotheses which the evaluation will address.

Aim 1: Increase employment rates

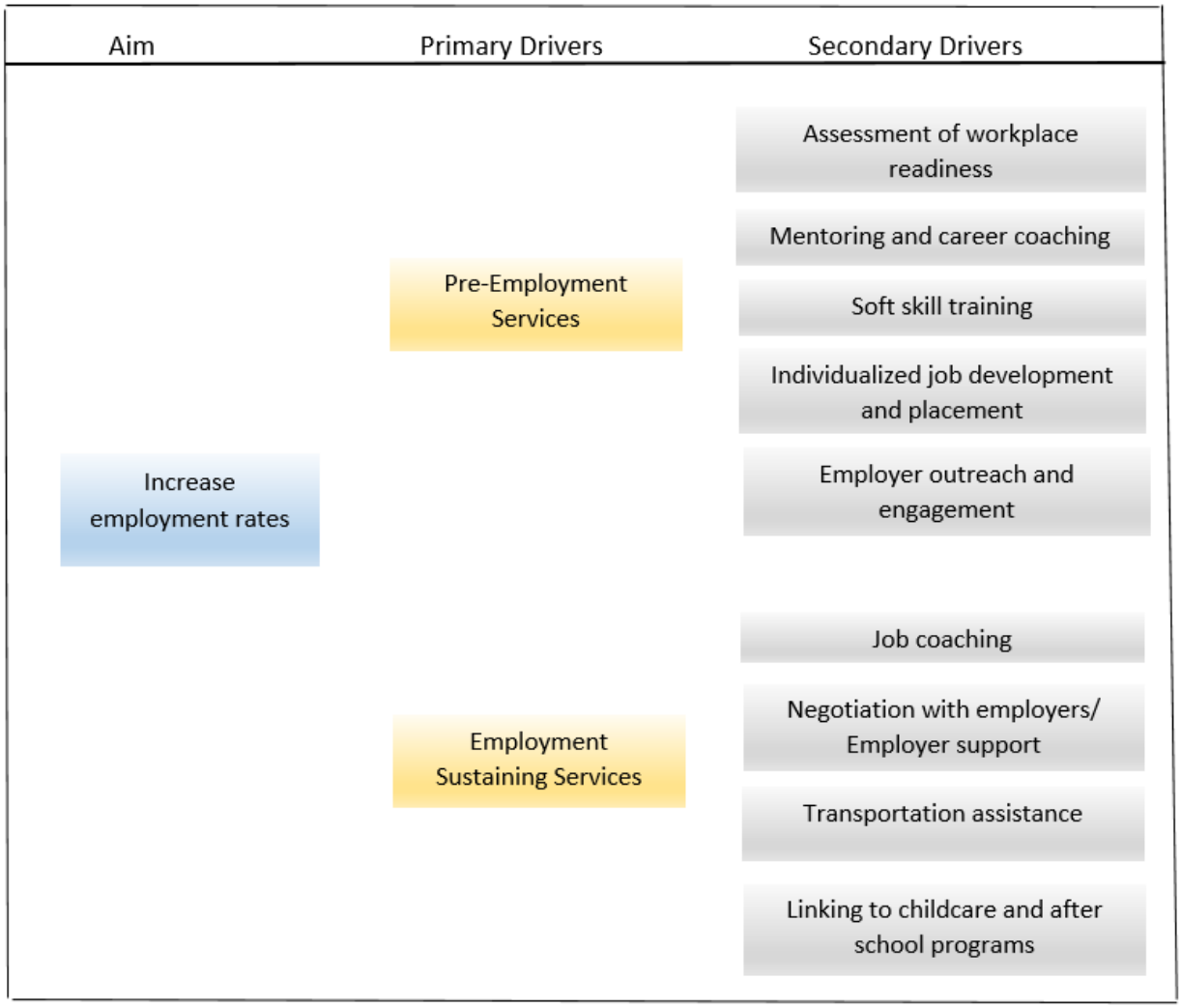


Table 1: Research Questions and Hypotheses Related to Aim 1

Research question	Hypotheses
1.1 Does the HNS program establish a provider network with sufficient capacity to serve Medicaid beneficiaries who are eligible for and apply to the program?	The HNS program will be able to establish a provider network with sufficient capacity to serve all Medicaid beneficiaries who are enrolled in the program.
1.2. Is participation in the employment program associated with improvement in employment? Specifically: - Higher initiation of employment - Higher level of employment (hours employed per week) - Employment stability over time	Program participation will be associated with higher: - Rates of employment - Rates of initiation and continuation of employment - Weekly hours worked
1.2a. Are certain approaches or programs more effective than others?	Specific hypotheses depend on approaches and programs implemented. May include both intra- and inter-MCO comparisons. May be limited by small sample size in some instances.
1.2b. Do subsets of the eligible population respond differently to different program approaches?	Best approaches will differ by reason for eligibility (e.g., SUD, disability, age, etc.) and by patient demographics. Best approaches will also differ for initiating employment vs. increasing level of employment vs. continuation of employment.
1.2c Do participants eligible only for employment assistance respond differently to the programs than those eligible for both housing and employment assistance?	Overall effectiveness of the programs related to initiation, level, and continuation of employment will differ between those eligible only for employment assistance and those eligible for both housing and employment assistance.

Aim 2: Increase Stable Housing Rates

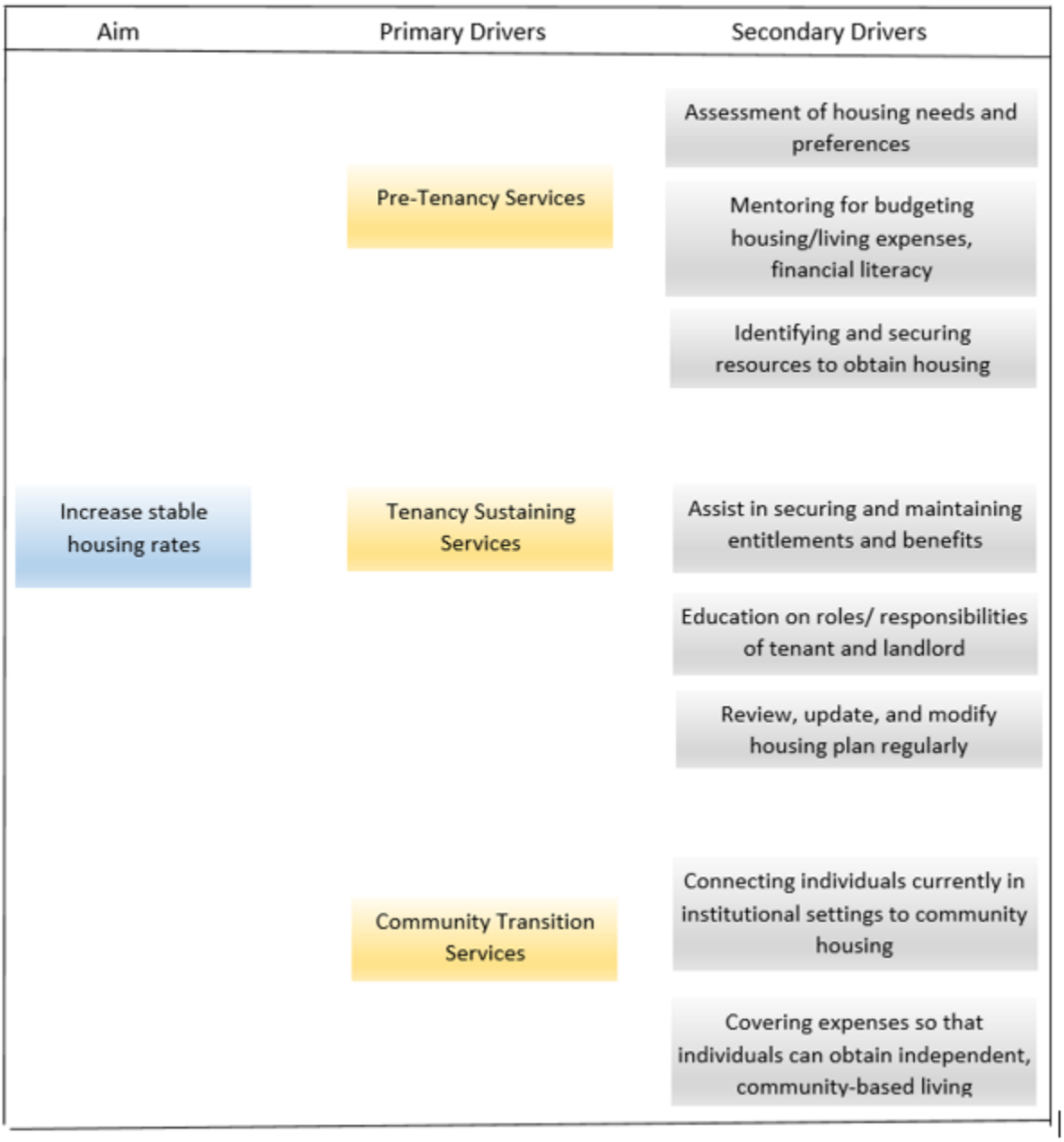


Table 2: Research Questions and Hypotheses Related to Aim 2

Research question	Hypotheses
2.1. Does the HNS program establish a provider network with sufficient capacity to serve Medicaid beneficiaries who are eligible for and apply to the program?	The HNS program will be able to establish a provider network with sufficient capacity to serve all Medicaid beneficiaries who enroll in the program.
2.2 Is the supply of available and appropriate housing adequate to meet program needs?	The type and volume of available housing resources will be sufficient to match all HNS-enrolled clients with appropriate housing supports.
2.2. Is participation in the housing program associated with improved housing situations?	Program participation will be associated with lower rates of homelessness or risk of homelessness.
2.2a. Are certain approaches or programs more effective than others?	(Specific hypotheses will depend on approaches and programs implemented. May include both intra- and inter-MCO comparisons.)
2.2b. Do subsets of the eligible population respond differently to different program approaches?	Best approaches will differ by reason for eligibility (e.g., SUD, disability, age, etc.) and patient demographics Best approaches will differ by housing needs category (homeless, coming from institution, etc.)
2.2c. Do participants eligible only for housing assistance respond different to the programs than those eligible for both housing and employment assistance?	Overall effectiveness of the programs will differ between those eligible only for housing assistance and those eligible for both housing and employment assistance.

Aim 3: Improve Overall Healthcare Utilization

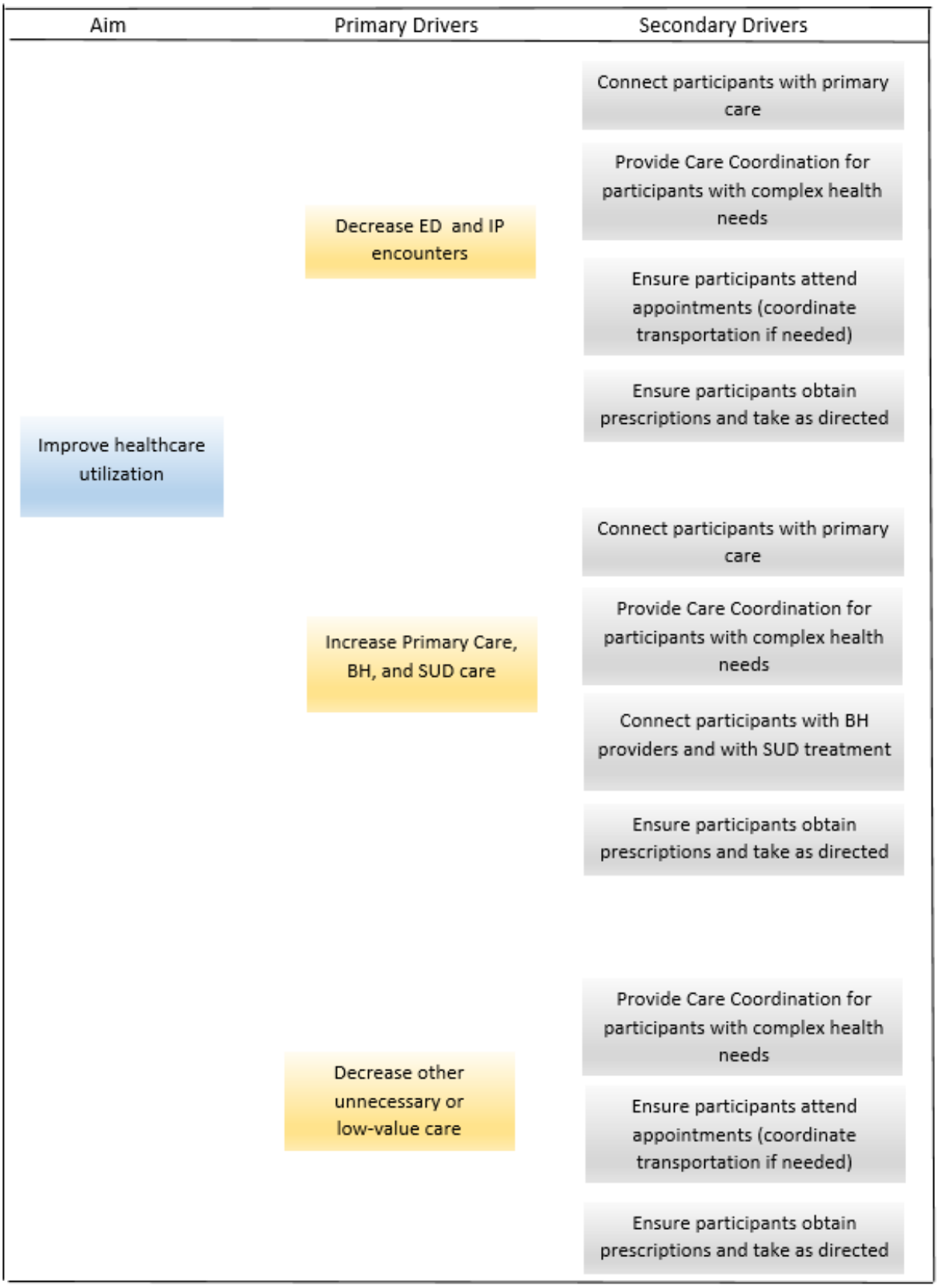


Table 3: Research Questions and Hypotheses related to Aim 3

Research question	Hypotheses
3. Does healthcare utilization change after participation in the program?	Program participation will be associated with decreases in: ED encounters IP encounters (If sample size permits, IP encounters for BH/SUD will be looked at separately from IP encounters for physical conditions.) Program participation will be associated with increases in: Use of Primary Care Participation in BH and SUD treatment Changes in healthcare utilization will be similar among those enrolled in employment programs and those enrolled in housing programs.
3a. Does the effect on healthcare utilization differ between subsets of the population?	Certain subsets of the population will demonstrate bigger changes in healthcare utilization than others. Changes in healthcare utilization will differ between those eligible for employment supports, housing supports, or both.

See the Appendix for a list of data sources that will be used to test these hypotheses.

Section C: Methodology

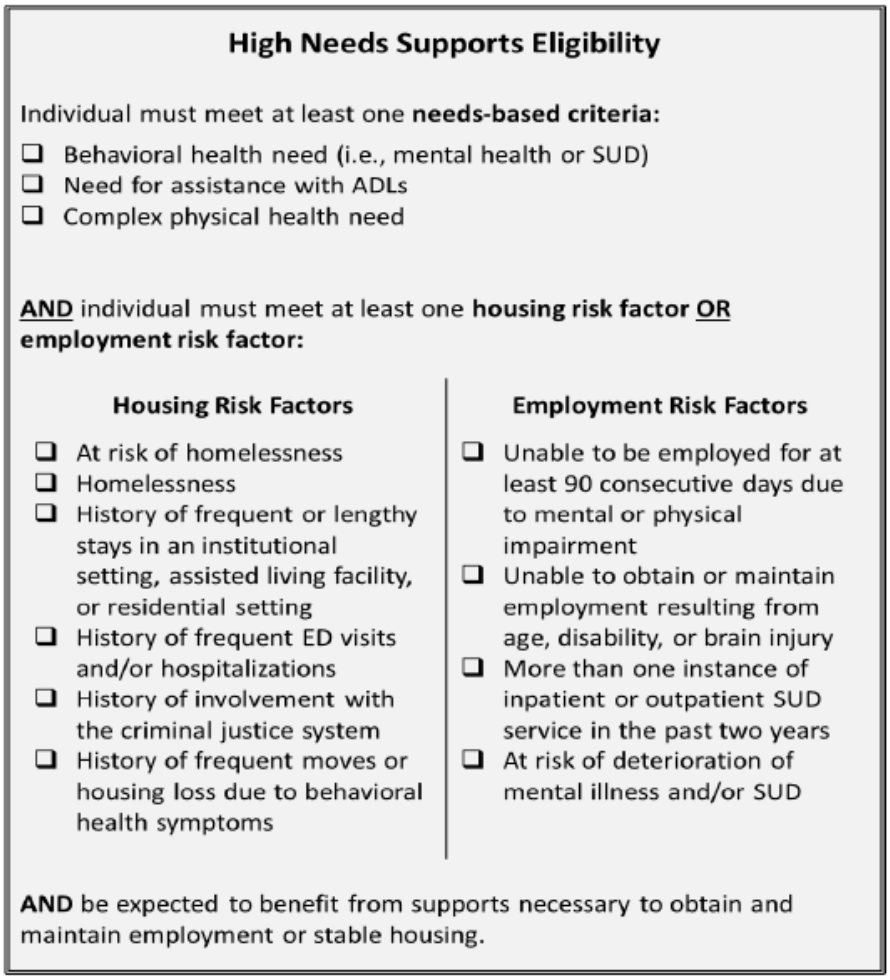
C.1 Evaluation Methodologic Approach

We will employ a sequential mixed methods approach that combines quantitative and qualitative data collection and analysis. We will examine trends over time for participants and a control group to estimate the effect of HNS participation. We will draw on program and policy documents and key informant interviews to characterize similarities and differences in HNS design and implementation across MCOs, and investigate whether these variations relate to observed differences in outcomes.

Cost neutrality of this demonstration will be evaluated separately; it is not part of the evaluation that CHSE will perform. Therefore, it is not addressed in the plan.

Eligibility: The target population will be comprised of beneficiaries who are eligible based on the criteria shown in Table 4.

Table 4: Eligibility Criteria for the High Needs Supports Program



Managed Care Organizations (MCOs) will identify members who meet these criteria and send their information to DMAS, where eligibility will be verified. Those who are eligible will then be placed on a waiting list and then enrolled in the programs, with the order of prioritization to be determined by DMAS in conjunction with their stakeholders.

Subgroups: Separate analyses will be carried out for each aim. In addition to analysis of the overall group of program participants, sub-analyses will look at individual MCOs. Any identified differences between MCOs will help to inform qualitative interviews as described below. We will also consider subgroup analysis for the following target eligibility groups: (1) new adult group; (2) aged, blind and disabled; (3) parents and other caretaker relatives; and (4) pregnant women. Other target eligibility groups not included in our subgroup analysis will either be evaluated separately by DMAS (former foster care youth), are not eligible for this program (children under age 19), or are enrolled in Medicaid for only four months (those receiving transitional medical assistance and those receiving extended Medicaid due to spousal support collections). We will also consider other important subgroups, such as racial and ethnic subgroups; rural and urban subgroups; and subgroups based on beneficiary affiliation with LTSS or aging programs (shown to be an important factor in previous work in a different state).

In prior work with other states, we have found that some subgroups will have small sample sizes for some of the included metrics. Should this be the case in the Virginia evaluation, we will

work with DMAS to prioritize subgroups for published analyses and will only include metrics with sufficient sample size to permit meaningful analysis. We will also examine whether these subgroups are small because fewer individuals in them are eligible for the program, or because enrollment rates are particularly low for them (see section C.4 for details).

C.2 Evaluation Period

Because this demonstration is an amendment to an existing 1115 waiver, the time period for the demonstration is 4.5 years, from July 2020 – December 2024. It is anticipated that the Virginia state legislature will enact budgetary authorization for the HNS program in mid-2022, and participant recruitment and will begin January 2023. This will result in a study period for the evaluation that includes participants enrolled approximately January 2023 to December 2024.

The Evaluator will deliver Interim and Summative Evaluation Reports that are meaningful and accessible to the primary audiences for the evaluation. Given the six-month time lag for maturation of claims/encounters data and the time needed to analyze these data, we anticipate that the reports will cover results for the following time periods:

- The Interim Report due to CMS in December 2023 will include data through June 2023. This will include the first 6 months of program enrollment and assessment data but no claims data due to the lag in availability of claims data. Qualitative data related to program design and implementation will also be collected through June 2023. The Interim Report will present findings related to program design and implementation, including similarities and differences across MCOs, as well as a baseline assessment of the employment, housing and health care needs of HNS participants.
- The Summative Report due to CMS in June 2026 will present results for all participants enrolled through December 2024, the end of the demonstration period. Follow-up will continue through June 2025 to obtain at least 6 months of program and claims data for all participants. Claims data through June 2025 should be adequately complete for all participants by December 2025. However, if there are delays in data availability, we reserve the right to drop participants with incomplete data from the analysis.

C.3 Data Sources and Preparation

The quantitative portion of the evaluation will include member-level Medicaid data from the Virginia Department of Social Services (claims, enrollment, and pharmacy data), Medicare data if available (claims for dual eligible members), and program data provided by MCOs, program service providers, and DMAS. The qualitative portion of the evaluation will require collection of data from stakeholders through key informant interviews and policy and program document review. Methodology for the qualitative portion of the evaluation is described in a separate section below.

We will obtain all data for quantitative analysis via secure file transfer protocol (SFTP) or other approved, secure transfer methods, and prepare the data to be loaded into an analytic database, a process called staging. We will then organize the staged data into a relational database structure

that will enable us to track Medicaid members and their outcomes over time and across data sources.

For employment outcomes, this will include employment history prior to program enrollment, dates employment began (and ended, if applicable) once enrolled in the program, job category (e.g., service, retail, construction), hours worked per week, and hourly wage. For housing, outcome data will include housing history prior to the program, dates participants obtained housing, the type of housing, and any subsequent moves or return to unhoused status. In addition, we will obtain information on the type and volume of housing resources available. If any of the above data is not able to be obtained from the Commonwealth, we reserve the right to modify the evaluation plan to accommodate data availability.

For healthcare utilization outcomes, standard metrics from HEDIS or NCQA will be used whenever possible, and published definitions from the metric stewards will be used to create the metrics. See the Appendix for a complete list of measures and data elements.

MCOs will provide supplementary program data that we will use to evaluate program implementation. These include the overall number of Medicaid beneficiaries screened for eligibility for each program; number of beneficiaries determined eligible by eligibility reason (e.g., chronic disease); the number of beneficiaries who apply, are placed on a waitlist, or are enrolled in the program; demographic characteristics of enrolled and not enrolled eligible Medicaid beneficiaries; lists of contracted providers (for housing and employment services separately); and number of beneficiaries each provider can support. Program data will also include the number of Medicaid beneficiaries who are eligible, screened, have applied, are on a waitlist, and are enrolled stratified by subgroups described above. In addition, MCOs will be asked to provide program design characteristics, client enrollment approach and strategies, provider contracting approach and strategies, success/barriers in provider contracting, descriptions of contracted agencies/providers, implementation experiences and lessons learned.

C.4 Quantitative Analysis Plan

The detailed quantitative analysis plan will be completed by the evaluator prior to beginning the evaluation, once details about program designs are finalized. This plan will include specifics of:

- **Measure specifications:** Precise definitions for all measures to be used for the evaluation, as specified by the organization that defined the measure (e.g., NCQA HEDIS, AHRQ PQIs), or in discussion with DMAS for measures related to eligibility, enrollment and employment or housing outcomes that are specific to this demonstration.

- **Medicaid population definitions:** Criteria that will be used to identify the populations for whom measures will be reported (e.g., Medicaid eligibility codes, continuous enrollment criteria, and diagnosis or procedure codes that will be used to identify members with specific conditions).

- **Identification of comparison group:** We will consider various populations for constructing the comparison group (e.g., applicants who were not selected for the

program; applicants who did not apply for the program, applicants on the waiting list for the program but not enrolled). We will utilize propensity score matching methods to create comparison groups with balanced characteristics.

- **Subgroups:** Subgroups of interest for each measure, and criteria that will be used to identify these groups in the data (e.g., program eligibility category, geographic region, race/ethnicity).
- **Statistical models:** Statistical models that will be used to estimate change in outcomes associated with the demonstration, including functional form, control variables, and baseline periods. A general model is discussed below, and detailed models will be included in the detailed analysis plan.

A simple representation of our regression model is as follows:

$$y_{iq} = \beta_0 + \beta_1 Treat_i + \beta_2 Post_q + \beta_3 Treat_i \cdot Post_q + \gamma X_{iq} + \delta_t + \varepsilon_{iq},$$

where i denotes individuals and q quarter relative to first enrollment quarter (with $q < 0$ for pre-enrollment quarters, $q = 0$ for the quarter of enrollment, and $q > 0$ for post-enrollment quarters following the quarter of enrollment), y_{iq} is the outcome under consideration, $Treat_i$ is an indicator for being in the treatment group, $Post_q$ is an indicator for the post period, X_{iq} are other covariates, including demographic characteristics, δ_t are calendar quarter dummies, and ε_{iq} is the error term. The coefficient of interest is β_3, for the interaction between the post-enrollment period and treatment group. The coefficient measures covariate-adjusted changes in the outcome between the pre- and post-enrollment period among program participants relative to the comparison group. We will cluster standard errors at the individual level and consider higher levels of clustering based on a design perspective.[2]

An important modeling consideration is the choice of the pre- and post-enrollment period for the regression model. Using the full pre- and post-enrollment period implies a comparison of average outcomes between these time periods, which might not be desirable. We will consider refining the model based on our graphical analysis, for instance by including two separate post-enrollment indicators (to measure a short- and longer-term effect of the program), or by using a shorter pre-enrollment period (e.g., the last quarter before enrollment).

We anticipate that we will be able to observe a six-month post-enrollment period for all program participants during the waiver's enrollment period (January 2023 to December 2024) for the summative report. Based on our evaluation of similar programs for the state of Washington, we think that this post-enrollment period will be sufficient to identify salient program effects. However, we will also consider a longer post-enrollment period (e.g., 9 or 12 months) to examine longer-term effects of the program. We note that extending the post-enrollment period beyond six months would likely imply excluding program participants who enrolled during the second half of 2024 to avoid right-censoring. Thus, extending the post-enrollment period would result in lower power due to a smaller sample size.

[2] Abadie, A., Athey, S., Imbens, G. W., and Wooldridge, J., When Should You Adjust Standard Errors for Clustering? NBER Working Paper No 24003 (2017)

We will repeat this regression for each program group (those eligible for employment; those eligible for housing; and those eligible for both employment and housing). We will also estimate the regression for specific subprograms or subpopulations where sample size permits, to shed light on whether certain approaches are more effective or whether specific subpopulations are differentially affected by the programs.

The difference-in-differences requires parallel trends in outcomes between the treatment and comparison group in the absence of an intervention. While this assumption cannot be directly tested (post-enrollment outcomes absent of the intervention are not observed for the treatment group), we can test for parallel trends in the pre-enrollment period using the following specification:

$$y_{iq} = \lambda_0 + \lambda_1 q + \lambda_2 Treat_i + \lambda_3 Treat_i \cdot q + \gamma X_{iq} + \mu_{iq},$$

where $\lambda_3 = 0$ implies parallel trends and we only use pre-enrollment quarters (i.e., $q < 0$). In the context of the employment and housing program, the most likely violation of parallel trends is due to short-term fluctuations, or shocks, in outcomes that are correlated with program participation, also called the Ashenfelter dip.[3] In the case of non-parallel trends, we will interpret findings as partly being influenced by such short-term shocks. We will also consider refinements of the comparison group and sensitivity checks using alternative matching approaches.

Supplementary to this analysis that focuses on participants, we will also conduct two descriptive analyses. The first one will be an analysis of program data, including number and characteristics of Medicaid beneficiaries eligible for each program, number of eligible beneficiaries who are screened for eligibility, have applied, are on a waitlist and are enrolled in a program, and the number of contracted providers and their capacity. We will also conduct a subgroup analysis of the number of Medicaid beneficiaries who are eligible, screened, have applied, are on a waitlist, and are enrolled. This analysis will shed light on whether there is overall sufficient supply to meet demand for the programs, and whether some subgroups have low enrollment numbers because they are small, or because few of them enroll in the programs. We anticipate that we will be able to include results from this descriptive analysis in both the interim and summative report because they are based on readily available program data.

Our second descriptive analysis will compare program participants and non-participants at baseline, i.e., before program enrollment. This analysis will inform selection of an appropriate comparison group, describe (propensity-score adjusted) characteristics of participants and non-participants and compare trends in outcomes prior to enrollment for the two groups. Given a six-month lag for claims data, we anticipate that we will only be able to include findings from this analysis in the summative report.

C.5 Qualitative Analysis Plan

[3] Heckman, J. J. and Smith, J. A. The Pre-programme Earnings Dip and the Determinants of Participation in a Social Programme. Implications for Simple Programme Evaluation Strategies, *The Economic Journal*, 109(457), 313-348 (2001).

Evaluation activities will include qualitative analysis to identify themes related to program design, implementation and operations. This will be achieved through the following approaches:

- Collection and systematic review of program and policy documents from state agencies, MCOs and other relevant stakeholders will be collected through June 2024 (spanning periods of program planning, design, implementation and early participant enrollment). Narrative descriptions of program design, provider recruitment strategy and implementation progress will also be collected from all MCOs on a quarterly basis beginning January 2022. Key constructs of interest at different phases and levels of analysis (e.g., state, organizational, and provider) will be iteratively identified through review of documents and discussion with DMAS staff. Documents will be catalogued and reviewed for relevant text by the research team to develop a matrix of preliminary findings. This matrix will be further analyzed within and across categories to develop and refine key findings.
- Key informant interviews will be conducted with representatives from the state, the HNS program, MCOs and/or provider organizations to understand implementation experiences from multiple organizational and professional perspectives. A sampling frame will be developed through consultation with DMAS staff to ensure similarity or variation on interviewee characteristics of interest. Interviews will be conducted by a member of the research team, recorded, and transcribed. Transcripts will be analyzed using *a priori* coding analyzed in qualitative analysis software such as ATLAS.ti. The research team will review data, compare results within and across dimensions from the sampling frame, and develop key findings.

Qualitative analysis will address questions such as:

- Is there variation in attributes of HNS program design or provider recruitment across MCOs or geographic regions, and if so, what are the dimensions of this variation?
- Is there variation in HNS implementation or client enrollment strategies across MCOs or geographic regions, and if so, what are the dimensions of this variation?
- What organizational or contextual factors contribute to readiness of the state, MCOs and providers to implement the HNS program?
- What challenges arise related to designing and implementing the HNS program?
- How do these challenges affect progress with HNS implementation?
- What strategies do stakeholders employ to prevent or overcome challenges, and to what extent do these strategies appear to be effective?

Qualitative analysis will provide an early snapshot of successes and challenges to help inform the state's implementation of HNS and generate lessons learned from the demonstration. These findings will also help to provide context for quantitative results, including why the demonstration and its component projects did or did not achieve the expected effects.

Synthesis of the qualitative and quantitative analyses will support the effective translation of evaluation data and results, reinforcing quantitative findings in a non-technical format (e.g., through key-informant quotes in addition to measures) and helping to open the "black box" of program effects with supporting contextual information.

The appropriate design and execution of qualitative methods supporting the evaluation will ultimately depend on the State of Virginia's stage of implementation in early 2023 when data collection will occur. Finalizing key elements of qualitative data collection and analysis will be the responsibility of the independent external evaluator. This responsibility will include: defining the number of key informant interviews; determining the universes and/or sample frames from which participants will be selected; determining when and how interviews will be conducted; aligning data collection instruments to specific research questions and hypotheses; and designing the specific data collection and analysis instruments.

C.6 Evaluation Measures

The quantitative measures that will be used to evaluate the demonstration are included in the Appendix.

C.7 Data Sources

Data sources for the evaluation are listed in the Appendix.

D. Methodological Limitations

While the evaluators have taken steps to strengthen the evaluation design, including through the reliance on multiple sources and types of data, there are limitations to this approach.

Our quantitative analysis has several limitations. First, it rests on the assumption that outcome trends of the comparison group accurately reflect outcome trends of the treatment group, were they not exposed to treatment. To address this concern, we will consider alternative comparison groups and check for parallel trends. However, despite these efforts we cannot fully rule out that some of our difference-in-differences estimates may reflect short-term changes in outcomes unrelated to program participation. We will carefully interpret findings accordingly.

Second, we might have a small sample size for some of our analyses. A small sample size reduces power, i.e., our ability to detect existing program effects. We anticipate that small sample size issues will be limited to specific subgroup analyses and healthcare utilization measures with restrictive denominator definitions.

Third, we might have an insufficiently long post-enrollment period to detect program effects. We think that this limitation is unlikely based on our evaluation of similar programs for the state of Washington, where most program effects were visible within six months of post-enrollment. Still, we might consider extending the post-enrollment period to capture longer-term effects of the program. We note that extending the post-enrollment period beyond six months will likely result in a smaller sample size to avoid right-censoring for individuals enrolled in the program during the second half of 2024.

Fourth, our measures are based on administrative records and might not fully reflect all positive program changes. To the extent possible, we will use our qualitative analysis to shed light on additional, quantitatively unmeasured program effects.

There are two limitations to the qualitative analytic approach described above. First, the evaluation team resides outside the State of Virginia. There is a risk that the research team may misinterpret elements of the qualitative data because they lack context for local conditions, customs or histories. To mitigate this risk, the research team will work closely with representatives from DMAS and the HNS program staff to develop our baseline understanding of the context and conditions in which the HNS program will be designed and implemented. If appropriate, the evaluation team will conduct member checking or participant validation of qualitative findings to ensure accurate and appropriate interpretation of data.

Second, establishing rapport with participants is an important element of rigorous qualitative research that can be made more difficult when conducting qualitative research from a distance; lack of rapport may undermine the willingness of key informants to provide candid or complete responses during data collection activities such as interviews. Participants' fear of disclosure or identification in published results when discussing sensitive subjects can also lead to self-censorship in interviews. To mitigate this limitation, the evaluation team will work with DMAS and other HNS stakeholders as needed to obtain introductions or conduct outreach to potential key informants for the evaluation. Outreach materials such as an evaluation fact sheet will be developed collaboratively with DMAS to explain the role of the evaluation team and the purpose of the evaluation. The evaluation team will take appropriate steps to protect participant confidentiality, including the de-identification of participants in published findings and the protection of raw data (such as recordings or transcripts). The evaluation team will obtain approval from an Institutional Review Board for all data collection instruments and activities prior to initiation of qualitative data collection. Potential risks and benefits of participation will be discussed with key informants, and informed consent will be obtained prior to participation.

E. Attachments

E.1 Independent Evaluator Selection Process

The Center for Health Systems Effectiveness (CHSE) at Oregon Health & Science University (OHSU) is a proven Independent External Evaluator (IEE) of Medicaid 1115 waivers. We successfully completed the evaluation of Oregon's Medicaid 1115 waiver in 2017, producing a report that Oregon's Medicaid agency relied on heavily in planning and implementing its waiver renewal. We recently submitted the interim report for Washington's 1115 Medicaid waiver, receiving high praise from CMS on the quality of the report.

Since 2011, CHSE has provided evidence and analyses to help policymakers build better health care systems. CHSE is uniquely qualified to serve as the IEE:

Medicaid focus:

1. The Project Team has worked extensively with Medicaid programs and policy makers. A hallmark of our evaluation approach is providing timely feedback to state Medicaid agencies and delivering analyses and recommendations to state agency staff and community stakeholders, as we did with Oregon during its health care transformation.

2. Deep Expertise: Our Project Team is led by Dr. Stephan Lindner, a health economist and expert in using quantitative data to evaluate health care policy. He has worked on two previous complex, multi-faceted evaluations: The Washington 1115 waiver evaluation mentioned above, and Evaluating System Change to Advance Learning and Take Evidence to Scale (ESCALATES), an evaluation of efforts to improve cardiovascular preventive care in seven regions across the United States. He has deep expertise in difference-in-differences analyses and other econometric methods. Co-investigator Dr. Shauna Petchel is a qualitative and mixed methods researcher with extensive experience in state Medicaid policy evaluations and research related to health and human services integration. She currently leads the Center's waiver evaluation in Washington State and has previously led or supported mixed methods evaluations of Oregon's Medicaid Value-Based Payment initiative, statewide primary care transformation initiatives, and research related to CMS Accountable Health Communities. In addition to her research experience, Dr. Petchel brings nearly twenty years of experience working directly with policymakers, community-based organizations and health care providers to develop and implement programs serving vulnerable populations. Dr. Lindner and Dr. Petchel currently collaborate on the evaluation of Washington State's Foundational Community Supports program that bears many similarities to Virginia's High Needs Supports program; their experience and insights from conducting that evaluation will provide important context for Virginia's HNS evaluation.
3. Data Capability: CHSE projects leverage our best-in-class data management and analysis capabilities. We have received, staged, and analyzed Medicaid claims data from four states for peer-reviewed publications and state-sponsored evaluations. Our analysts have coded, produced, and validated over 100 measures from claims and survey data, and used propensity score methods for a range of projects.
4. Data Security: The Project Team uses OHSU's data infrastructure and follows OHSU's security protocols. CHSE stores and analyzes all sensitive or confidential administrative data for its studies and evaluations on secure servers maintained by OHSU's Advanced Computing Center (ACC). The servers are physically located at an off-site facility with emergency power, regular backup, multiple firewalls, and physical security. Electronic data for studies and evaluations are transmitted electronically via secure file transfer protocol to ACC secure servers. Storage and analysis of sensitive or confidential data on ACC servers eliminates the need to house data on local computers and greatly reduces security risk. Sensitive or personally identifiable qualitative data are similarly collected and stored on secure, password protected OHSU devices in compliance with study protocols and Institutional Review Board requirements. Only staff listed on data use agreements (DUAs) receive access to sensitive or confidential data for specific studies and evaluations. Staff lock computer work stations when unattended and do not share their passwords. All OHSU staff complete annual research integrity trainings, which include courses dedicated to data security and confidentiality. CHSE staff have managed and analyzed health care claims and electronic health record data from federal agencies, state agencies, private health plans, employers, and clinics, resulting in more than 100 publications, with no record of security breaches or complaints.

DMAS initially connected with CHSE through professional networks and asked them to serve as the IEE due to DMAS' knowledge of CHSE experience and reputation.

E.2 Timeline

The following timeline presents anticipated start and end dates for tasks described in the work plan based on deadlines in the CMS-approved Evaluation Design.

Table 5. Evaluation Timeline

TASK	START	END
Support Tasks		
Facilitate kickoff and planning meetings with Virginia	01/01/22	1/31/22
Prepare Quantitative Analysis Plan	07/01/22	12/31/22
Obtain IRB approval (enrollment and qualitative)	07/15/22	10/31/22
Execute data use agreements	07/01/22	11/30/22
Facilitate bimonthly check-in	02/01/22	12/31/24
Submit IRB amendment (claims) and update DUAs	3/31/2023	06/30/2023
Qualitative Data Collection and Analysis		
Prepare interview guide and recruitment materials	07/01/22	08/15/22
Prepare and submit IRB application	8/16/22	10/31/22
Recruit informants, conduct interviews, and collect documents	11/01/2022	3/31/2023
Analyze data	2/1/2023	5/30/2023
Develop key themes	6/01/2023	9/15/2023
Quantitative Analysis for Interim Evaluation Report		
Preparation and analysis of enrollment and assessment data for Interim Report	07/01/23	09/15/23
Deliver Interim Report		
Prepare Draft #1 for DMAS review	07/01/23	10/31/23
DMAS reviews Draft #1 (assume 30 days)	11/01/23	11/30/23
Prepare Draft #2 for CMS review (**OFFICIAL DUE DATE**)	12/01/23	**12/31/23**
CMS reviews Draft #2 (assume 60 days)	01/02/24	03/01/24
Prepare final report based on CMS comments	03/02/24	04/15/24
Build database (db) and process data		
Design database structures and schema	10/1/2023	12/31/2023
Create db, obtain baseline data (Jan – Dec 2022), calculate quality measures and add to staging process	01/01/2024	12/31/2024
Obtain 2023 data, process, & prep for analysis	1/01/25	6/31/2025
Obtain 2024 data, process, & prep for analysis	9/01/2025	10/31/2025
Obtain data for Jan – June 2025, process & prep for analysis	12/01/2025	01/31/2026
Quantitative Analysis for Summative Evaluation Report		
Calculate measures for Summative Report	7/01/2025	12/31/2025
Carry out quantitative analysis for Summative Report	1/1/2026	02/28/2026
Deliver Summative Evaluation Report		
Prepare Draft #1 for DMAS review	03/31/26	05/15/26
DMAS reviews Draft #1 (assume 30 days)	05/15/26	06/15/26
Prepare Draft #2 for CMS review (**DUE DATE**)	06/15/26	**06/30/26**
CMS reviews Draft #2 (assume 60 days)	07/01/26	09/01/26
Prepare final report based on CMS comments	09/02/26	10/25/26

E.3 Support Tasks

The Evaluator will carry out the following tasks to support the quantitative and qualitative evaluations and deliver Interim and Summative Evaluation Reports:

- Facilitate kickoff meeting and regular meetings with state staff: The Evaluator will facilitate a kickoff meeting with Virginia's Department of Medical Assistance Services (DMAS) to introduce the evaluation team and clarify scope as needed. In addition, the Evaluator will facilitate bi-monthly check-ins with the division to provide progress updates and address any challenges with the evaluation.
- Manage research compliance**:** The Evaluator will obtain necessary permissions to collect and use data needed for the evaluation. This includes obtaining IRB approval for the evaluation protocol and executing any data use agreements needed to obtain and use the data.
- Provide project management: The Evaluator will provide general project management to ensure deliverables are high-quality and delivered on time.

E.4 Evaluation Budget

Component	FY 2023	FY 2024	FY 2025	FY 2026	Total
Project management/PI	$37,629	$40,874	$32,253	$48,107	$158,863
Qualitative data collection & analysis	$69,203	$43,810	$0	$0	$113,013
Database/data processing	$31,031	$22,187	$22,565	$6,683	$82,467
Quantitative analysis	$0	$70,200	$86,511	$59,404	$216,115
Policy analysis/reporting	$10,862	$29,624	$41,697	$91,384	$173,567
Other	$4,000	$1,500	$0	$0	$5,500
Total Direct Cost	**$152,726**	**$208,195**	**$183,027**	**$205,578**	**$749,525**
Indirect costs @ 20%	$30,545	$41,639	$36,605	$41,116	$149,905
Total Cost	**$183,271**	**$249,834**	**$219,632**	**$246,694**	**$899,430**

Appendix: Measures and Data Sources

Data Elements Needed for Analysis of Process Measures

Quantitative Measures	Data Source	Definitions
# Providers/agencies contracted with: Housing services providers Employment services providers Other providers	MCOs*	Supplied by DMAS
Type and volume of available housing resources	HMIS	
Capacity of contracted providers/ agencies # and type of clients agencies can support	MCOs*	Supplied by DMAS
# Members screened for eligibility for programs # Members awaiting screening	MCOs*	Supplied by DMAS
Enrollment measures (at member level): Enrollment status (# enrolled, not eligible, refused, on waiting list, etc.) Dates enrolled and dis-enrolled	Program data from DMAS*	Supplied by DMAS
# members eligible for: Housing, employment, both	Program data from DMAS*	Supplied by DMAS
# members by eligibility reason: ADL, BH, chronic disease	Program data from DMAS*	Supplied by DMAS
Demographics for enrolled and unenrolled: ADL needs Age, gender, race, zip code, chronic diseases, behavioral health conditions	Program data from DMAS* Medicaid enrollment data	HEDIS definitions
Qualitative Measures	**Data Source**	**Definitions**
MCO Program design characteristics, by MCO MCO client enrollment approach and strategies MCO provider contracting approach and strategies Success in provider contracting/ barriers MCO-reported implementation experiences and lessons learned MCO-reported implementation facilitators and barriers at the statewide, MCO and provider organization level MCO Training provided to contracted providers/ agencies	Program data from MCOs (collected via narrative reports and/or key informant interviews)	

Data Elements Needed for Analysis of Program Outcomes

Aim	Measure	Data Source	Definition
1	Employment information: Employment prior to program Employment initiation dates Hours per week Wages Type of employment (e.g., service, construction, retail) Employment end dates	Program data from DMAS	Supplied by DMAS
2	Housing information: Housing prior to program Program initiation date Date housed Type of housing Dates of subsequent moves	Program data from DMAS	Supplied by DMAS
3	Healthcare Utilization ED encounters prior to enrollment ED encounters after enrollment IP encounters prior to enrollment IP encounters after enrollment PC encounters prior to enrollment PC encounters after enrollment BH encounters prior to enrollment BH encounters after enrollment SUD treatment prior to enrollment SUD treatment after enrollment	Medicaid claims data	HEDIS definitions for all types of encounters.