Vermont Draft Evaluation Design
Section 1115 Substance Use Disorder (SUD) Demonstration
March 6, 2019

The Centers for Medicare & Medicaid Services (CMS) reviewed the draft evaluation design for Vermont's 1115 demonstration entitled "Global Commitment to Health Section 1115 Medicaid Demonstration Draft Evaluation Design." Vermont's special terms and conditions (STCs) for its current five-year demonstration period (July 1, 2017–June 30, 2021) were amended in June 2018 for the SUD component, requiring the state to develop an updated evaluation design for approval by CMS. CMS appreciates the state's commitment to rigorous and robust evaluation of its SUD demonstration.

CMS assessed Vermont's evaluation design based on the requirements specified by the demonstration's Special Terms and Conditions (STCs) and the evaluation design technical assistance guide prepared by CMS and dated February 22, 2018 (hereafter referred to as the "Evaluation Design TA document"). CMS finds VT's draft design is moderately responsive to the requirements specified in the STCs and the Evaluation Design TA document and identifies places where the state should make revisions or provide clarification in order to fulfill the requirements specified in these two documents. Below is a brief summary of the issues the state should address. The Appendix that follows presents a more detailed comparison against the STCs and Evaluation Design TA document.

1. **Reorganize table on evaluation goals, questions, and hypotheses**. The evaluation design includes a table (Exhibit 2-1) organized around the four demonstration goals, with evaluation questions, hypotheses and populations listed. Detailed information on measures, data sources, and analytic approaches is provided in exhibits 2-3 to 2-9 for each hypothesis and outcome. Exhibit 2-1 should be reorganized to align with table 1 in the Evaluation Design TA Document. Specifically, it should have a section for each of the four goals and subsections for each of the hypotheses, with the drivers associated with each goal and associated hypothesis in the first column. Measures (including specification of the steward, numerator, and denominator) and data sources and analytic approaches to test each hypothesis should also be included in this table. This revised and reorganized table will provide a complete and unified source for goals, hypotheses, drivers, and all of the components to test these hypotheses including measures, data sources, and measurement period.

2. **Provide more detailed information on planned designs and analyses.** The design provides a general description of the evaluation approaches under consideration, including pre/post assessment, interrupted time series designs, and difference in differences methods. Given the state's SUD-related evaluation questions and in-depth understanding of available data sources, the design should provide more detail about which of these approaches will be applied to test specific hypotheses, including which potential comparison groups may be applied and which analytic methods may be used in testing each of the SUD-related hypotheses. For example, the design could provide more detail on how it will examine changes in number of members who initiate in treatment (Exhibit 2-5), and whether this would be examined using a pre-post assessment or a difference-in-differences design, and if it uses the latter, which population might be a feasible comparison group. For both

approaches, it would be valuable to describe the analytic method that would be used to estimate impacts.

3. **Provide description of cost analyses.** The design does not describe its method for conducting cost analyses, beyond the question and metric listed in Exhibit 2-9. The design should provide more detail on how it will conduct cost analyses following the guidance in the Evaluation TA document.

Appendix A. Comparison of evaluation design requirements and Vermont's evaluation design

Requirements specified in Evaluation TA Guidance Document and STCs	Requirements addressed in report	Requirements not addressed in report
1. The draft evaluation design uses the following format: General Background Information; Evaluation Questions and Hypotheses; Methodology; Methodological Limitations; Attachments.	▪ The plan uses the same headings (or synonymous terms) as those specified in the Evaluation TA Document.	▪ Requirement satisfactorily addressed.
The ***General Background*** information section includes basic information about the demonstration, including:		
2. The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation	▪ The evaluation design specifies the name of the demonstration ("Global Commitment to Health Section 1115 Medicaid Demonstration") and indicates that it was approved by CMS on July 10, 2018 and will continue through June 30, 2023.	▪ Requirement satisfactorily addressed.
3. The purpose of the section 1115 demonstration and/or expenditure authorities; this should be state-specific, and include demonstration goals	▪ The purpose of the section 1115 demonstration as it relates to SUD is addressed on p.12. The goals for the demonstration's SUD programs in Vermont are to: 1. Increase rates of identification initiation, and engagement in treatment; 2. Increase adherence to and retention in treatment; 3. Reduce overdose deaths, particularly those due to opioids; 4. Reduce utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services; 5. Reduce readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and, 6. Improve access to care for physical health conditions among beneficiaries.	▪ Requirement satisfactorily addressed.
4. A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration	▪ A brief description of the demonstration and history of SUD treatment under 1115 demonstration is provided on p.11, and it indicates that the design applies to an amendment of the demonstration. Vermont's first 1115 waiver was approved in 1996. This most recent amendment allows	▪ Requirement satisfactorily addressed.

	Requirements specified in Evaluation TA Guidance Document and STCs	Requirements addressed in report	Requirements not addressed in report
		for treatment, detoxification and residential treatment for SUD, in IMD settings.	
5.	The population groups impacted by the demonstration.	▪ The design describes the population impacted by the demonstration as Medicaid beneficiaries who's SUD needs align with the American Society of Addiction Medicine (ASAM) placement criteria and treatment guidelines (p. 11).	▪ Requirement satisfactorily addressed.
	The ***Evaluation Questions and Hypotheses*** section:		
6.	Includes a Driver Diagram to depict the relationship between the demonstration's purpose, the primary drivers that contribute directly to realizing that purpose, and the secondary drivers that are necessary to achieve the primary drivers. .	▪ The design includes four Driver Diagrams to depict the primary and secondary drivers that contribute to the demonstration's impact on (1) access to care, (2) quality of care, and (3) community integration; and (4) cost of care.	▪ Requirement satisfactorily addressed.
7.	Describes the core evaluation questions, hypotheses, and recommended data sources and analytic approaches.	▪ Exhibit 2-1 lists evaluation questions and hypotheses for the demonstration as a whole, with specific hypotheses for SUD service recipients (p.19)	▪ The table should have additional columns for data sources and analytic approaches.
8.	In a table, the design should show how drivers align with the evaluation hypotheses under each evaluation question; identify the measures applicable to the demonstration goals and hypotheses; confirm the data sources it will use to test each hypothesis.		▪ Exhibits 2-1, and 2-3 to 2-9 should be reorganized to align with Table 1 in the Evaluation Design TA Document. Specifically, it should have a section for each of the goals (SUD amendment goals are identified in Exhibit 1-2) and subsections for each of the hypotheses, with the drivers associated with each goal and associated hypothesis in the first column. Measures (including specification of the steward, numerator, and denominator), data sources, and analytic approaches to test each hypothesis should also be added. Information on metrics and data sources may be abstracted from Exhibits 2-4 to 2-9.
	The ***Methodology*** section describes in detail. The methodology should flow from each of the stated goals for the demonstration, followed by measurable evaluation questions and testable hypotheses.		
9.	*Evaluation Design*: provides information on how the evaluation will be designed (i.e., pre/post, post-only, with or without comparison groups).	▪ The design provides a general description of the design approaches under consideration, but states that the "[f]inal determination of methods and analytics will be made following the review of sample size and available data points over the life of the demonstration" (p. 31). It proposes to use pre/post assessment, interrupted time series designs, and difference in differences methods when data exists before and after intervention for a group of individuals similar to participants.	▪ Given the SUD-related hypotheses and an in-depth understanding of the state's available data sources, the design should provide more detail about which of these designs will be applied to test specific hypotheses.
10.	*Target and Comparison Populations*: describes the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria.	▪ The design indicates that it will study the impact of the demonstration on the total Medicaid population for the full demonstration, and Medicaid enrollees	▪ The design does not describe how these potential comparison groups may be applied in answering each of the SUD-related evaluation questions.

Requirements specified in Evaluation TA Guidance Document and STCs	Requirements addressed in report	Requirements not addressed in report
	with SUD treatment needs for the SUD amendment. ▪ For comparison group, the design indicates that synthetic control techniques may be used "if suitable comparison states and/or data exists. (p.33)" When feasible given sample size, sub-sets of program participants may be compared to statewide or national benchmarks.	
11. *Evaluation Period*: describes the time periods for which data will be included.	▪ The evaluation includes multiple study periods across calendar years 2016-2021, with an extensive IMD study previously conducted for years 2012-2017.	▪ Requirement satisfactorily addressed.
12. *Evaluation Measures:* lists all process and outcomes measures that will be calculated to evaluate the demonstration; includes the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets.); and includes numerator and denominator information. Uses Medicaid specific metrics from nationally recognized sources (e.g., Medicaid Adult and Child Core Sets, Medicaid Health Home Core Set, National Behavioral Health Quality Framework National Quality Forum, HEDIS).	▪ Exhibits 2-4 through 2-9 list the SUD-related metrics that will be used to evaluate the demonstration, including their data sources, alignment with state or national recognized data sources, sampling methodology (i.e. denominator information), and baseline years for each measure. ▪ The state's quality improvement activities include an SUD Monitoring Protocol (SUD MP) and SUD mid-point assessment. As described on p.14, the SUD MP will include monthly, quarterly and annual descriptive detail; annual outcome and quality metrics; and milestone specific process measures.	▪ Requirement satisfactorily addressed.
13. *Data Sources:* explains where the data will be obtained, and efforts to validate and clean the data. It discusses the quality and limitations of the data sources. If primary data (data collected specifically for the evaluation) - the methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection.	▪ The design indicates that encounter, claims and cost data are available through the MMIS and will be made available to evaluators as needed for purpose of evaluation (p.21). Existing agreements require that all IGA partners, ACOs and SUD programs make data available to support evaluations and performance monitoring efforts. ▪ Exhibit 2-3 lists the Vermont data sources that will be used to evaluate performance against demonstration goals.	▪ Requirement satisfactorily addressed.
14. *Data analysis:* describes the analytic methods that will be utilized to answer the evaluation questions.	▪ On p.34, the design provides a general overview of the analytic methods that will be applied through descriptive, bivariate, and multivariate approaches.	▪ The analytic methods laid out in the design do not describe their application to specific SUD-related questions and hypotheses.
15. *Cost analyses:* The design describes how the evaluation will conduct cost analyses to determine whether the demonstrations result in higher, lower, or neutral health care spending. Cost analyses should examine total costs; SUD and non-SUD costs; and sources of treatment cost drivers.	▪ In Exhibit 2-9, the design includes a research question related to cost and budget neutrality for SUD IMD services.	▪ The design does not describe its method for conducting cost analyses, beyond the question and metric listed in Exhibit 2-9. The design should provide more detail on how it will conduct cost analyses. Following the guidance in the Evaluation TA document, analyses should examine total costs; SUD and non-SUD costs; and source of treatment cost drivers. Cost outcome measures for SUD services should be expressed in

Requirements specified in Evaluation TA Guidance Document and STCs	Requirements addressed in report	Requirements not addressed in report
		terms of dollars per member per month (PMPM).
The ***Methodological Limitations*** section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods.		
16. The state should also identify any efforts to minimize the limitations. 17. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review.	▪ On p.36, the design identifies four challenges for the evaluation design of the overall demonstration— including presence of dual eligible members and access to Medicare claims; existing payment reforms and data completeness; isolating the effect of this demonstration from other initiatives; and potential limitations of administrative data. Efforts to address these limitations are also described.	▪ Requirement satisfactorily addressed.
The attachments should include sections on the following: Independent Evaluator, Evaluation Budget, and Timeline and Major Milestones.		
18. The attachment on the ***Independent Evaluator*** should describe the process the state will use for obtaining an independent entity to conduct the analysis and write the Evaluation Report, including a description of the qualifications the entity must possess. 19. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest.	▪ The design describes the state's process for procurement of a contractor to conduct summative evaluation activities (p.39). It describes how bidders will be evaluated based on the capacity to conduct the evaluation, prior experience with similar evaluations, and other relevant criteria.	▪ Requirement satisfactorily addressed.
20. The attachment on the ***Evaluation Budget*** should include a budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation.	▪ The design provides a detailed draft budget (p. 43) that includes the total estimated costs, as well as breakdowns for specific tasks, including the IMD sub-evaluation and SUD mid-point assessment, by year.	▪ Requirement satisfactorily addressed.
21. The attachment on the ***Timeline and Major Milestones*** should describe the timeline for conducting the various valuation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. This timeline should also include the date by which the Final Summative Evaluation report is due.	▪ The design presents an evaluation timeline (p.40) and major milestones provides dates for all evaluation-related milestones, including procurement of the evaluation contractor, data collection, and an interim and summative evaluation.	▪ Requirement satisfactorily addressed.