



COLORADO

**Department of Health Care
Policy & Financing**

Regional Accountable Entities (RAEs)
for the Colorado Accountable Care Collaborate

Fiscal Year 2018–2019 PIP Validation Report

for

Health Colorado, Inc.

Region 4

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1. Executive Summary

The Code of Federal Regulations at 42 CFR Part 438—managed care regulations for Medicaid programs, with revisions released May 6, 2016, and effective July 1, 2017, for Medicaid managed care require states that contract with managed care health plans (health plans) to conduct an external quality review (EQR) of each contracting health plan. Health plans include managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), primary care case management entities (PCCM entities), and prepaid ambulatory health plans (PAHPs). The regulations at 42 CFR §438.350 require that the EQR include analysis and evaluation by an external quality review organization (EQRO) of aggregated information related to healthcare quality, timeliness, and access. Health Services Advisory Group, Inc. (HSAG) serves as the EQRO for the State of Colorado, Department of Health Care Policy and Financing (the Department)—the agency responsible for the overall administration and monitoring of Colorado’s Medicaid program. Beginning in fiscal year (FY) 2018–2019, the Department entered into contracts with Regional Accountable Entities (RAEs) in seven regions throughout Colorado. Each Colorado RAE meets the federal definition of a PCCM entity.

Pursuant to 42 CFR §438.350, which requires states’ Medicaid managed care programs to participate in EQR, the Department required its RAEs to conduct and submit performance improvement projects (PIPs) annually for validation by the state’s EQRO. One RAE, **Health Colorado, Inc. Region 4**, referred to in this report as **HCI R4**, a RAE holds the contract with the State of Colorado for provision of healthcare services for Health First Colorado, Colorado’s Medicaid program.

For FY 2018–2019, the Department required RAEs to conduct performance improvement projects (PIPs) in accordance with 42 CFR §438.330(b)(1) and §438.330(d)(2)(i-iv), and each PIP must include:

Measurement of performance using objective quality indicators.

- Implementation of systematic interventions to achieve improvement in quality.
- Evaluation of the effectiveness of the interventions.
- Planning and initiation of activities for increasing or sustaining improvement.

As one of the mandatory EQR activities required by 42 CFR §438.358(b)(1)(i), HSAG, as the State’s EQRO, validated the PIPs through an independent review process. In its PIP evaluation and validation, HSAG used the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) publication, *EQR Protocol 3: Validating Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR)*, Version 2.0, September 2012.¹⁻¹

¹⁻¹ Department of Health and Human Services, Centers for Medicare & Medicaid Services. *EQR Protocol 3: Validating Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR)*, Version 2.0, September 2012. Available at: <https://www.medicare.gov/medicaid/quality-of-care/medicaid-managed-care/external-quality-review/index.html>. Accessed on: Jan 23, 2019.

Over time, HSAG and some of its contracted states identified that while the MCOs had designed methodologically valid projects and received *Met* validation scores by complying with documentation requirements, few MCOs had achieved real and sustained improvement. In July 2014, HSAG developed a new PIP framework based on a modified version of the Model for Improvement developed by Associates in Process Improvement and modified by the Institute for Healthcare Improvement.¹⁻² The redesigned PIP methodology is intended to improve processes and outcomes of healthcare by way of continuous quality improvement. The redesigned framework redirects MCOs to focus on small tests of change to determine which interventions have the greatest impact and can bring about real improvement. PIPs must meet CMS requirements; therefore, HSAG completed a crosswalk of this new framework against the Department of Health and Human Services CMS publication, *EQR Protocol 3: Validating Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR)*, Version 2.0, September 2012.

HSAG presented the crosswalk and new PIP framework components to CMS to demonstrate how the new PIP framework aligned with the CMS validation protocols. CMS agreed that given the pace of quality improvement science development and the prolific use of Plan-Do-Study-Act (PDSA) cycles in modern improvement projects within healthcare settings, a new approach was needed.

PIP Components and Process

The key concepts of the new PIP framework include forming a PIP team, setting aims, establishing a measure, determining interventions, testing interventions, and spreading successful changes. The core component of the new approach involves testing changes on a small scale—using a series of PDSA cycles and applying rapid-cycle learning principles over the course of the improvement project to adjust intervention strategies—so that improvement can occur more efficiently and lead to long-term sustainability. The duration of rapid-cycle PIPs is 18 months.

PIP Terms

SMART (Specific, Measurable, Attainable, Relevant, Time-bound) Aim directly measures the PIP's outcome by answering the following: *How much improvement, to what, for whom, and by when?*

Key Driver Diagram is a tool used to conceptualize a shared vision of the theory of change in the system. It enables the MCO's team to focus on the influences in cause-and-effect relationships in complex systems.

FMEA (Failure Modes and Effects Analysis) is a systematic, proactive method for evaluating processes that helps to identify where and how a process is failing or might fail in the future. FMEA is useful to pinpoint specific steps most likely to affect the overall process, so that interventions may have the desired impact on PIP outcomes.

PDSA (Plan-Do-Study-Act) cycle follows a systematic series of steps for gaining knowledge about how to improve a process or an outcome.

¹⁻² Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* (2nd edition). San Francisco: Jossey-Bass Publishers; 2009. Available at: <http://www.ihl.org/resources/Pages/HowtoImprove/default.aspx>. Accessed on: Mar 26, 2019.

For this PIP framework, HSAG developed five modules with an accompanying reference guide. Prior to issuing each module, HSAG held technical assistance sessions with the MCOs to educate about application of the modules. The five modules are defined as:

- **Module 1—PIP Initiation:** Module 1 outlines the framework for the project. The framework includes the topic rationale and supporting data, building a PIP team, setting aims (Global and SMART), and completing a key driver diagram.
- **Module 2—SMART Aim Data Collection:** In Module 2, the SMART Aim measure is operationalized and the data collection methodology is described. SMART Aim data are displayed using a run chart.
- **Module 3—Intervention Determination:** In Module 3, there is increased focus into the quality improvement activities reasonably thought to impact the SMART Aim. Interventions in addition to those in the original key driver diagram are identified using tools such as process mapping, failure modes and effects analysis (FMEA), and failure mode priority ranking, for testing via PDSA cycles in Module 4.
- **Module 4—Plan-Do-Study-Act:** The interventions selected in Module 3 are tested and evaluated through a thoughtful and incremental series of PDSA cycles.
- **Module 5—PIP Conclusions:** In Module 5, the MCO summarizes key findings and outcomes, presents comparisons of successful and unsuccessful interventions, lessons learned, and the plan to spread and sustain successful changes for improvement achieved.

Approach to Validation

HSAG obtained the data needed to conduct the PIP validation from **HCI R4**'s module submission forms. In FY 2018–2019, these forms provided detailed information about **HCI R4**'s PIPs and the activities completed in Module 1 and Module 2. (See Appendix A, Module Submission Forms.)

Following HSAG's rapid-cycle PIP process, the health plan submits each module according to the approved timeline. Following the initial validation of each module, HSAG provides feedback in the validation tools. If validation criteria are not achieved, the health plan has the opportunity to seek technical assistance from HSAG. The health plan resubmits the modules until all validation criteria are met. This process ensures that the PIP methodology is sound prior to the health plan progressing to intervention testing.

The goal of HSAG's PIP validation is to ensure that the Department and key stakeholders can have confidence that any reported improvement is related to and can be directly linked to the quality improvement strategies and activities conducted by the health plan during the PIP. HSAG's scoring methodology evaluates whether the health plan executed a methodologically sound improvement project and confirms that any improvement achieved could be clearly linked to the quality improvement strategies implemented by the health plan.

Validation Scoring

During validation, HSAG determines if criteria for each module are *Achieved*. Any validation criteria not applicable (*N/A*) were not scored. As the PIP progresses, and at the completion of Module 5, HSAG will use the validation findings from modules 1 through 5 for each PIP to determine a level of confidence representing the validity and reliability of the PIP. Using a standardized scoring methodology, HSAG will assign a level of confidence and report the overall validity and reliability of the findings as one of the following:

- **High confidence** = The PIP was methodologically sound, the SMART Aim was achieved, the demonstrated improvement was clearly linked to the quality improvement processes conducted and intervention(s) tested, and the MCO accurately summarized the key findings.
- **Confidence** = The PIP was methodologically sound, the SMART Aim was achieved, and the MCO accurately summarized the key findings. However, some, but not all, quality improvement processes conducted and/or intervention(s) tested were clearly linked to the demonstrated improvement.
- **Low confidence** = (A) the PIP was methodologically sound; however, the SMART Aim goal was not achieved; or (B) the SMART Aim goal was achieved; however, the quality improvement processes conducted and/or intervention(s) tested were poorly executed and could not be linked to the improvement.
- **Reported PIP results were not credible** = The PIP methodology was not executed as approved.

PIP Topic Selection

In FY 2018–2019, **HCI R4** submitted the following PIP topics for validation: *Increasing Well Checks for Members 21–64 Years of Age* and *Increasing Mental Healthcare Services After a Positive Depression Screening*.

HCI R4 defined a Global Aim and SMART Aim for each PIP. The SMART Aim statement includes the narrowed population, the baseline rate, a set goal for the project, and the end date. HSAG provided the following parameters to the health plan for establishing the SMART Aim for each PIP:

- **Specific**: The goal of the project: What is to be accomplished? Who will be involved or affected? Where will it take place?
- **Measurable**: The indicator to measure the goal: What is the measure that will be used? What is the current data figure (i.e., count, percent, or rate) for that measure? What do you want to increase/decrease that number to?
- **Attainable**: Rationale for setting the goal: Is the achievement you want to attain based on a particular best practice/average score/benchmark? Is the goal attainable (not too low or too high)?
- **Relevant**: The goal addresses the problem to be improved.
- **Time-bound**: The timeline for achieving the goal.

Table 1-1 summarizes the PIP topics selected by **HCI R4** and the progress the health plan has made in completing the five PIP modules.

Table 1-1—PIP Topics and Module Status

PIP Topic	Module	Status
<i>Increasing Well Checks for Adult Members 21–64 Years of Age</i>	1. PIP Initiation	Completed and achieved all validation criteria.
	2. SMART Aim Data Collection	Completed and achieved all validation criteria.
	3. Intervention Determination	Targeted initiation for April 2019.
	4. Plan-Do-Study-Act (PDSA)	Targeted initiation June 2019, with PDSA cycles continuing through the SMART Aim end date of June 30, 2020.
	5. PIP Conclusions	Targeted for October 2020.
<i>Increasing Mental Healthcare Services After a Positive Depression Screening</i>	1. PIP Initiation	Completed and achieved all validation criteria.*
	2. SMART Aim Data Collection	Completed and achieved all validation criteria.*
	3. Intervention Determination	Targeted initiation for March 2019.
	4. Plan-Do-Study-Act (PDSA)	Targeted initiation June 2019, with PDSA cycles continuing through the SMART Aim end date of June 30, 2020.
	5. PIP Conclusions	Targeted for October 2020.

* **HCI R4** has received a *Conditional Pass* and will need to resubmit Module 1 and Module 2 in October 2019 when 12 months of baseline data allow for the selection of a narrowed focus.

At the time of the FY 2018–2019 PIP validation report, for *Increasing Well Checks for Members 21–64 Years of Age* PIP, **HCI R4** had passed Module 1 and Module 2 and achieved all validation criteria for the two modules, **HCI R4** has progressed to Module 3, with an expected initial submission date in April 2019.

For the *Increasing Mental Healthcare Services After a Positive Depression Screening* PIP, **HCI R4** received a *Conditional Pass* on Module 1 and Module 2. At the PIP initiation, the health plan did not have the 12 months of baseline data required to guide selection of the narrowed focus and to determine the SMART Aim measure goal. The health plan will need to resubmit Module 1 and Module 2 in October 2019 when 12 months of baseline data allow for the selection of a narrowed focus and goal for this PIP. With the *Conditional Pass* on Module 1 and Module 2, the health plan will progress to Module 3, with a targeted submission in April 2019.

Validation Findings

In FY 2018–2019, **HCI R4** completed and submitted Module 1 and Module 2 for validation. Detailed module documentation submitted by the health plan is provided in Appendix A, Module Submission Forms.

The objective of Module 1 is for the health plan to ask and answer the first fundamental question, “What are we trying to accomplish?” In this phase, **HCI R4** determined the narrowed focus, developed its PIP team, established external partnerships, determined the Global Aim and SMART Aim, and developed the key driver diagram.

The objective of Module 2 is for the health plan to ask and answer the question, “How will we know that a change is improvement?” In this phase, **HCI R4** defined how and when it will be evident that improvement is being achieved.

The following section outlines the validation findings for the two modules. Detailed validation criteria, scores, and feedback from HSAG for each module are provided in Appendix B, Validation Tools.

Module 1: PIP Initiation and Module 2: SMART Aim Data Collection

Table 2-1 and Table 2-2 present the FY 2018–2019 validation findings for **HCI R4**’s PIPs.

Table 2-1—Validation Findings for the *Increasing Well Checks for Members 21–64 Years of Age* PIP

Module 1—PIP Initiation	
Narrowed Focus Population	Male members, 21–64 years of age who are attributed to Castillo Primary Care.
SMART Aim Statement	By 6/30/2020, Increase Well Checks for adult male (ages 21–64) members from 32.33 percent to 37.33 percent at Castillo Primary Care.
Module 2—SMART Aim Data Collection	
SMART Aim Measure	Percentage of male members ages 21–64 who received an annual well check at Castillo Primary Care during the rolling 12-month measurement period.
SMART Aim Data Collection Plan	<ul style="list-style-type: none"> • Data Source: Administrative claims. • Data Collection: Monthly based on a rolling 12-month measurement period.

As noted in Table 2-1, **HCI R4** selected a physical health PIP topic focused on increasing the rate of well-check visits among male members 21 through 64 years of age. At the time of the FY 2018–2019 PIP validation report, the health plan had completed and achieved all validation criteria for Modules 1 and 2. The narrowed focus study population, SMART Aim statement, SMART Aim measure

specifications, and data collection methodology had been finalized by the health plan and approved by HSAG. **HCI R4** is expected to submit in April 2019 Module 3, wherein it is required to document the process of determining the interventions for this project using a process map and FMEA table.

Table 2-2—Validation Findings for the *Increasing Mental Healthcare Services After a Positive Depression Screening* PIP

Module 1—PIP Initiation	
Narrowed Focus Population	<i>Not yet determined.</i> In October 2019, when 12 months of baseline data have been collected and analyzed for narrowed focus selection, the health plan will provide the narrowed focus.
SMART Aim Statement	By 6/30/2020 increase the percentage of members AGE Group TBD who receive a mental health services in a physical or mental health care setting within 30 days of a positive depression screening at TBD PROVIDER (from TBD% to TBD%).
Module 2—SMART Aim Data Collection	
SMART Aim Measure	Percentage of members AGE GROUP TBD who received a positive depression screening at PROVIDER TBD and then received a mental health service in a primary care or mental health care setting within 30 days of the positive depression screen during the rolling 12-month measurement period.
SMART Aim Data Collection Plan	<ul style="list-style-type: none"> • Data Source: Administrative claims. • Data Collection: Monthly based on a rolling 12-month measurement period. Denominator events must occur at least 30 days prior to the last day of each measurement period to allow for follow-up within the measurement period.

As noted in Table 2-2, **HCI R4** selected a behavioral health PIP topic focused on increasing behavioral health follow-up visits among members who, in primary care settings, screened positive for depression. At the time of the FY 2018–2019 PIP validation report, the health plan had received a *Conditional Pass* on Module 1 and Module 2. The health plan will determine the narrowed focus, SMART Aim statement, and SMART Aim measure for the project once 12 months of baseline data have been collected and analyzed. Baseline data from a 12-month measurement period are required to determine the narrowed focus population and goal for the project. In October 2019 the health plan will resubmit modules 1 and 2 with a selected narrowed focus and SMART Aim goal, based on 12 months of baseline data. HSAG will conduct a final validation of Module 1 and Module 2 at that time. With the *Conditional Pass* on Module 1 and Module 2, the health plan has progressed to Module 3.

3. Conclusions and Recommendations

Conclusions

The validation findings suggest that for the *Increasing Well Checks for Members 21–64 Years of Age* PIP, **HCI R4** successfully completed Module 1 and Module 2 and developed a methodologically sound project. **HCI R4** was also successful in building internal and external quality improvement teams and developing collaborative partnerships with targeted providers and facilities.

For the *Increasing Mental Healthcare Services After a Positive Depression Screening* PIP, **HCI R4** successfully completed and achieved *Conditional Pass* on Module 1 and Module 2 and designed a methodologically sound project. The narrowed focus population and the SMART Aim goal for the PIP could not be determined due to lack of baseline data. These parameters will be documented and validated in October 2019, once the health plan has collected and analyzed 12 months of baseline data.

Recommendations

- As **HCI R4** moves through the next phase of the PIP to determine interventions to test, it should consider completing process maps for the PIP at both the health plan- and provider-levels.
- For the *Increasing Mental Healthcare Services After a Positive Depression Screening* PIP, **HCI R4** should plan to revisit the Module 3 process map and FMEA after the narrowed focus has been identified.
- As **HCI R4** progresses to testing interventions through a series of incremental PDSA cycles, the health plan's PIP team should ensure clear communication of the rationale for revising intervention strategies and how specified changes will lead to improvement. A common understanding and agreement about the drivers of improvement will allow the health plan's PIP team to properly direct resources and improvement activities toward appropriate change.
- When planning a test of change, **HCI R4** should think proactively (i.e., scaling/ramping up to build confidence in the change and eventually implementing policy to sustain changes).
- When developing the intervention testing methodology, **HCI R4** should determine the best method for identifying the intended effect of an intervention prior to testing. The intended effect of the intervention should be known beforehand to help determine a sound data collection plan for the intervention evaluation measure(s).
- As it tests new interventions, **HCI R4** should ensure making a prediction in each *Plan* step of the PDSA cycle and discussing the basis for the prediction. This will help keep the theory for improvement at the forefront for all involved in the project.
- The key driver diagram for the PIP should be updated regularly to incorporate knowledge gained and lessons learned as **HCI R4** progresses through determining and testing interventions.
- **HCI R4** should contact HSAG if it encounters methodological challenges and/or barriers when determining and testing interventions.

- **HCI R4** should reference the Rapid-Cycle PIP Reference Guide as it progresses through subsequent phases of the PIP and request technical assistance as needed.

Appendix A. Module Submission Forms

Appendix A contains the Module Submission Forms provided by the health plan. The details of these submission forms are too extensive to be included in this report but are available upon request from the Colorado Department of Health Care Policy and Financing.



Appendix B. Module Validation Tools

Appendix B contains the Module Validation Tools provided by HSAG. The details of these validation tools are too extensive to be included in this report but are available upon request from the Colorado Department of Health Care Policy and Financing.