FY 07-08 Colorado PIP Validation Report

Childhood Immunization

for

Denver Health Medicaid Choice

March 2008

This report was produced by Health Services Advisory Group, Inc. for the Colorado Department of Health Care Policy & Financing.

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HSAG HEALTH SERVICES ADVISORY GROUP

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for **Denver Health Medicaid Choice**

Overview

The Balanced Budget Act (BBA) of 1997, Public Law 105-33, requires that states conduct an annual evaluation of their managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs) to determine the MCOs' and PIHPs' compliance with federal regulations and quality improvement standards. According to the BBA, the quality of health care delivered to Medicaid members in MCOs and PIHPs must be tracked, analyzed, and reported annually. The Colorado Department of Health Care Policy & Financing (the Department) has contractual requirements with each MCO and behavioral health organization (BHO) to conduct and submit performance improvement projects (PIPs) annually.

As one of the mandatory external quality review activities under the BBA, the Department is required to validate the PIPs. To meet this validation requirement, the Department contracted with Health Services Advisory Group, Inc. (HSAG), as an external quality review organization. The primary objective of the PIP validation is to determine compliance with requirements set forth in the Code of Federal Regulations (CFR), at 42 CFR 438.240(b)(1), including:

- Measurement of performance using objective quality indicators.
- Implementation of system interventions to achieve improvement in quality.
- Evaluation of the effectiveness of the interventions.
- Planning and initiation of activities for increasing or sustaining improvement.

The Centers for Medicare & Medicaid Services (CMS) publication, *Validating Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities*, Final Protocol, Version 1.0, May 1, 2002, was used in the evaluation and validation of the PIPs.

Summary of Study

The study, *Childhood Immunization*, assessed access to, and quality of, care and services to **Denver Health Medicaid Choice** (**DHMC**) members 2 years of age and younger. The study evaluated compliance with the American Academy of Pediatrics (AAP) and Centers for Disease Control and Prevention (CDC) immunization guidelines.

Study Topic

In a 2003 nationwide study by the CDC regarding childhood immunization rates Colorado had the lowest-ranked performance, with just 62.7 percent of children receiving all required immunizations by 2 years of age. Children younger than 2 years of age represent 9 percent of the total **DHMC**

population. Increasing the number of children receiving immunizations will ultimately lead to improved quality of life and outcomes of care. The study topic selected by **DHMC** addressed CMS' requirements related to quality outcomes—specifically, access to care and services.

The study question presented by **DHMC** was: "Interventions taken by the Denver Health program on behalf of members and by providers will increase immunization rates in children during their first two years of life."

Study Methodology

The PIP reviewed the immunization history of 100 percent of the children who turned 2 years of age during the study year and used the results to establish a baseline. **DHMC** used measurements that were based on Healthcare Effectiveness Data and Information Set (HEDIS) standards and national immunization guidelines to develop its nine HEDIS-like study indicators. Baseline 1 results were reevaluated and interpreted as preliminary data due to the regression to the mean that occurred. Baseline 1 results were eliminated from the analysis and Baseline 2 results were considered to be the true baseline values.

In fiscal year (FY) 06–07, **DHMC** retired the original Indicator 7 for Combination 1 and implemented a new Indicator 7 to measure pneumococcal conjugate vaccination rates. A ninth study indicator was added to measure Combination 3 rates. There were no changes to this methodology for the FY 07–08 submission.

DHMC reported the following nine study indicators:

1. "The percentage of eligible children during the measurement period who had four DTP/DtaP vaccines by their second birthday."
2. "The percentage of eligible children during the measurement period who had three IPV vaccines by their second birthday."
3. "The percentage of eligible children during the measurement period who had at least one MMR vaccine by their second birthday."
4. "The percentage of eligible children during the measurement period who had at least three influenza type b vaccines by their second birthday."
5. "The percentage of eligible children during the measurement period who had three hepatitis B vaccines by their second birthday."
6. "The percentage of eligible children during the measurement period who had at least one chicken pox vaccine by their second birthday."
7. "The percentage of eligible children during the measurement period who had the required pneumococcal conjugate vaccines by their second birthday."
8. "The percentage of eligible children during the measurement period who had the required DTP/DtaP, IPV, MMR, Hib, HepB, and VZV vaccines by their second birthday."
9. "The percentage of eligible children during the measurement period who had a record that they received four DTP/DtaPs, three IPV, one MMR, three Hib, three HepB, one VZV, and four pneumococcal conjugate vaccines by their second birthday."

Study Results

DHMC performed data analysis for Baseline 2 (true baseline) for each of the nine study indicators and completed the first remeasurement. As of September 11, 2007, **DHMC** was using the NCQA 90th percentile rates as its goal. Five of the nine study indicators demonstrated improvement from Baseline 2 to the first remeasurement. However, there was no statistical evidence demonstrating that the improvement in the five study indicators was true improvement. Four of the nine study indicators met or exceeded the NCQA 90th percentile goal, including one that was among the four indicators that did not demonstrate improvement. The rate for Study Indicator 8 (Combo 2) did not improve for the first remeasurement but was still above the goal of 83.0 percent. Table 1-1 illustrates the results. The results in bold are indicators that demonstrated improvement.

Table 1-1

Indicator	Baseline 2 Rates	Remeasurement 1	Goals (NCQA 90th Percentile)
1. DTP/DtaP	88.89%	84.78%	89.0%
2. IPV	95.06%	92.39%	95.0%
3. MMR	93.83%	**95.65%**	95.0%
4. Influenza	95.06%	93.48%	95.0%
5. Hepatitis B	92.59%	**93.48%**	95.0%
6. VZV	92.59%	**95.65%**	94.0%
8. Pneumococcal	86.42%	**86.96%**	64.0%
9. Combo 2	85.19%	84.78%	83.0%
10. Combo 3	79.01%	**83.70%**	58.0%

Scoring

HSAG validates a total of 10 activities for each PIP. PIP validation takes place annually and reflects activities that have been completed. A health plan (MCO) may take up to three years to complete all 10 activities. Each activity consists of evaluation elements necessary for the successful completion of a valid PIP. Evaluation elements are the key CMS Protocol components for each activity that reflect the intent of what is being measured and evaluated. Some of the evaluation elements are critical elements and must be scored as *Met* to produce an accurate and reliable PIP. Given the importance of critical elements, any critical element that receives a *Not Met* score results in an overall PIP validation status of *Not Met*. If one or more critical elements are *Partially Met*, but none is *Not Met*, the PIP will be considered valid with low confidence. Revisions and resubmission of the PIP would be required.

Summary of Validation Findings

- For this review, 9 activities with a total of 52 elements were validated. Of this number:
  - 40 evaluation elements were *Met*.

- 2 evaluation elements were *Partially Met.*
- 1 evaluation element was *Not Met*.
- 9 evaluation elements were *Not Applicable (NA).*

- The total number of critical elements that were evaluated equaled 11. Of this number:
  - 9 critical elements were *Met*.
  - 0 critical elements were *Partially Met.*
  - 0 critical elements were *Not Met*.
  - 2 critical elements were *NA.*

The final validation finding of **DHMC's** PIP showed an overall score of 93 percent, a critical element score of 100 percent, and *Met* validation status.

Conclusions

For this FY 07–08 validation cycle, the study successfully addressed access to, and quality of, care to eligible members. Baseline 2 results became the true baseline and first remeasurement data were reported during this validation cycle. The study had not progressed to the point of assessing for sustained improvement. This will be done once baseline data and at least two annual remeasurement periods of data have been reported.

Requirements

There were no requirements identified for this activity during this review.

Recommendations

In Activity II, the study question continued to be stated as a "hypothesis" rather than as a study question. Future submissions of the PIP should make this "hypothesis" the main study question, making sure that the question is in the format: "Does doing X result in Y?" For example, "Will interventions taken by **DHMC** on behalf of members and by providers increase immunization rates in children during their first two years of life?" The three existing baseline questions should be removed or have a strike-through indicating that they are no longer the focus of the study question.

In Activity IX there were two *Partially Met* evaluation elements and one *Not Met* evaluation element. In this activity, rates for five of the nine study indicators demonstrated improvement from Baseline 2 to the first remeasurement, although there was no statistical evidence that this improvement was true improvement. During a conference call on January 16, 2008, HSAG suggested that a second causal/barrier analysis be performed to assess for necessary changes that could be made in order to achieve the desired outcomes for all of the study indicators. Based on the results of the causal/barrier analysis, either existing interventions could be changed or new interventions could be initiated.

Comparison of Years 1 through 3

DHMC completed Activities I through VI during the FY 05–06 validation cycle, receiving a score of 97 percent for evaluation elements *Met*, a score of 100 percent for critical elements *Met*, and a *Met* validation status. In FY 06–07, **DHMC** retired the original Indicator 7 for Combination 1 and implemented a new Indicator 7 to measure pneumococcal conjugate vaccination rates. A ninth study indicator was added to measure Combination 3 rates. **DHMC** progressed through Activity VIII, receiving a score of 100 percent for evaluation elements *Met*, a score of 100 percent for critical elements *Met*, and a *Met* validation status. For FY 07–08, **DHMC** determined that due to the regression to the mean that occurred, the original baseline (Baseline 1) would not be compared to Baseline 2, and results for Baseline 2 would become the true baseline. **DHMC** felt that Baseline 2 results more accurately reflected the activities of the Medicaid population considered eligible for this study. **DHMC** progressed through Activity IX, receiving a score of 93 percent for evaluation elements *Met*, a score of 100 percent for critical elements *Met*, and a *Met* validation status.

Validating PIPs involved a review of the following 10 activities:

- Activity I. Appropriate Study Topic
- Activity II. Clearly Defined, Answerable Study Question
- Activity III. Clearly Defined Study Indicator(s)
- Activity IV. Use a Representative and Generalizable Study Population
- Activity V. Valid Sampling Techniques (If Sampling Was Used)
- Activity VI. Accurate/Complete Data Collection
- Activity VII. Appropriate Improvement Strategies
- Activity VIII. Sufficient Data Analysis and Interpretation
- Activity IX. Real Improvement Achieved
- Activity X. Sustained Improvement Achieved

All PIPs are scored as follows:

Met	(1) All critical elements were *Met* **and** (2) 80 percent to 100 percent of all critical and noncritical elements were *Met*. No action required.
Partially Met	(1) All critical elements were *Met* and 60 percent to 79 percent of all critical and noncritical elements were *Met* **or** (2) One critical element or more was *Partially Met*. Requires revision and resubmission of the PIP.
Not Met	(1) All critical elements were *Met* and less than 60 percent of all critical and noncritical elements were *Met* **or** (2) One critical element or more was *Not Met*. Requires revision and resubmission of the PIP.
NA	Not applicable elements (including critical elements if they were not assessed) were removed from all scoring.

For fiscal year (FY) 07–08, the MCOs were provided the opportunity to resubmit additional information and/or documentation. The health plans were required to take action on any evaluation element receiving a point of clarification or a score of *Partially Met* or *Not Met*. The action could include resubmission of additional PIP documentation prior to final scoring. Future annual PIP submissions should include all information pertinent to the PIP study to achieve a *Met* validation status.

PIP Scores

For this PIP, HSAG reviewed Activities I through IX. Table 2-1 and Table 2-2 show **DHMC's** scores based on HSAG's PIP evaluation of ***Childhood Immunization***. Each activity has been reviewed and scored according to HSAG's validation methodology.

Table 2-1—FY 07-08 Performance Improvement Project Scores *for* Childhood Immunization *for* Denver Health Medicaid Choice

Review Activity	Total Possible Evaluation Elements (Including Critical Elements)	Total *Met*	Total *Partially Met*	Total *Not Met*	Total *NA*	Total Possible Critical Elements	Total Critical Elements *Met*	Total Critical Elements *Partially Met*	Total Critical Elements *Not Met*	Total Critical Elements *NA*
I. Appropriate Study Topic	6	6	0	0	0	1	1	0	0	0
II. Clearly Defined, Answerable Study Question	2	2	0	0	0	1	1	0	0	0
III. Clearly Defined Study Indicator(s)	7	6	0	0	1	3	3	0	0	0
IV. Use a Representative and Generalizable Study Population	3	3	0	0	0	2	2	0	0	0
V. Valid Sampling Techniques	6	0	0	0	6	1	0	0	0	1
VI. Accurate/Complete Data Collection	11	11	0	0	0	1	1	0	0	0
VII. Appropriate Improvement Strategies	4	3	0	0	1	No Critical Elements				
VIII. Sufficient Data Analysis and Interpretation	9	8	0	0	1	2	1	0	0	1
IX. Real Improvement Achieved	4	1	2	1	0	No Critical Elements				
X. Sustained Improvement Achieved	1	Not Assessed				No Critical Elements				
Totals for All Activities	**53**	**40**	**2**	**1**	**9**	**11**	**9**	**0**	**0**	**2**

Table 2-2—FY 07-08 Performance Improvement Project Overall Score *for* Childhood Immunization *for* Denver Health Medicaid Choice

Percentage Score of Evaluation Elements *Met**	**93%**
Percentage Score of Critical Elements *Met* **	**100%**
Validation Status* **	***Met***

* The percentage score is calculated by dividing the total *Met* by the sum of the total *Met*, *Partially Met*, and *Not Met*.
** The percentage score of critical elements *Met* is calculated by dividing the total critical elements *Met* by the sum of the critical elements *Met*, *Partially Met*, and *Not Met*.
*** *Met* equals confidence/high confidence that the PIP was valid.
Partially Met equals low confidence that the PIP was valid.
Not Met equals reported PIP results that were not valid.

Validation and Findings Summary

This section summarizes the evaluation of the activities validated for the PIP. A description of the findings, strengths, requirements, and recommendations is outlined under each activity section. See Appendix B for a complete description of CMS rationale for each activity.

The validation was performed on a clinical PIP by **Denver Health Medicaid Choice (DHMC)**. The PIP evaluated the rate of children 2 years of age and younger who received the appropriate immunizations. Increasing the rate of children receiving the appropriate immunizations in their first two years of life will lead to improved health outcomes for these **DHMC** members.

Activity I. Appropriate Study Topic

Study Topic

DHMC continued its ***Childhood Immunization*** clinical PIP. The study topic was relevant to this population because children younger than 2 years of age represent 9 percent of **DHMC's** population and Colorado had the lowest-ranked performance in a nationwide study, with just 62.7 percent of children receiving the required immunizations by 2 years of age.

Finding(s)

All of the six evaluation elements, including the one critical element, were *Met* for this activity.

Strength(s)

The study topic assessed access to, and the quality of, care and services provided by **DHMC**. The topic had the potential to affect members' health and functional status. The study topic reflected a high-volume service and addressed a broad spectrum of care and services.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity II. Clearly Defined, Answerable Study Question

Study Question(s)

DHMC's study question was: "Interventions taken by the **DHMC** program on behalf of members and by providers will increase immunization rates in children during their first two years of life."

Finding(s)

Both evaluation elements for this activity were *Met*, including the one critical element.

Strength(s)

The study question stated the problem to be studied in simple terms and maintained the focus of the study, which was to evaluate the rate of children receiving immunizations in the **DHMC** Medicaid population.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

The study question continued to be stated as a "hypothesis" rather than as a study question. Future submissions of the PIP should make this "hypothesis" the main study question, making sure that the question is in the format: "Does doing X result in Y?" For example, "Will interventions taken by **DHMC** on behalf of members and by providers increase immunization rates in children during their first two years of life?" The three existing baseline questions should be removed or have a strike-through indicating that they are no longer the focus of the study question.

Activity III. Clearly Defined Study Indicator(s)

Study Indicator(s)

DHMC had nine study indicators for this submission. The study indicators were:

1. "The percentage of eligible children during the measurement period who had four DTP/DtaP vaccines by their second birthday."
2. "The percentage of eligible children during the measurement period who had three IPV vaccines by their second birthday."
3. "The percentage of eligible children during the measurement period who had at least one MMR vaccine by their second birthday."
4. "The percentage of eligible children during the measurement period who had at least three influenza type b vaccines by their second birthday."

5. "The percentage of eligible children during the measurement period who had three hepatitis B vaccines by their second birthday."
6. "The percentage of eligible children during the measurement period who had at least one chicken pox vaccine by their second birthday."
7. "The percentage of eligible children during the measurement period who had the required pneumococcal conjugate vaccines by their second birthday."
8. "The percentage of eligible children during the measurement period who had the required DTP/DtaP, IPV, MMR, Hib, HepB, and VZV vaccines by their second birthday."
9. "The percentage of eligible children during the measurement period who had a record that they received four DTP/DtaPs, three IPV, one MMR, three Hib, three HepB, one VZV, and four pneumococcal conjugate vaccines by their second birthday."

Finding(s)

Six of the seven evaluation elements were *Met* for this activity, including the three critical elements. One element was *Not Applicable* because the study indicators were based on *HEDIS 2006 Technical Specifications* and were not internally developed.

Strength(s)

The study indicators were developed to answer the study question and they measured change in access to, and the quality of, services received. The study indicators were based on *HEDIS 2006 Technical Specifications* and were well-defined and measurable.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity IV. Use a Representative and Generalizable Study Population

Study Population

DHMC's population was defined as 100 percent of eligible **DHMC** children who turned 2 years of age during the measurement year.

Finding(s)

All three of the evaluation elements for this activity, including the two critical elements, were *Met.*

Strength(s)

The study population was completely and accurately defined, included the requirements for length of enrollment, and captured all members to whom the study question applied.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity V. Valid Sampling Techniques

Sampling Technique(s)

DHMC did not use sampling for this PIP. The entire eligible population was used.

Finding(s)

All of the six elements for this activity were scored *Not Applicable*, including the one critical element, based on the use of the entire eligible population.

Strength(s)

The entire eligible population was used for this study, which made the study results generalizable. Using the entire population is in accordance with generally accepted principles of research design and statistical analysis.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity VI. Accurate/Complete Data Collection

Data Collection

DHMC used the hybrid method (administrative data and medical record review) to collect data for the study.

Finding(s)

All 11 evaluation elements for this activity, including the one critical element, were *Met.*

Strength(s)

DHMC identified the data elements and sources used to collect the study data. The study report clearly defined the process for collecting the data, including a description of the manual data collection process and the staff responsible for collecting the data. The timeline for the collection of baseline and remeasurement data was specified. HEDIS methodologies and software were used as part of the data collection process.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity VII. Appropriate Improvement Strategies

Improvement Strategies

DHMC consulted its Quality Assurance Committee to assist in identifying the barriers related to children being immunized. Several programs and processes were developed and implemented to improve immunization rates for Medicaid children in the population.

Finding(s)

Three of the four evaluation elements for this activity were *Met.* One element was *Not Applicable* because standardization of the interventions had not yet taken place.

Strength(s)

The proposed and revised interventions were developed as the result of a causal/barrier analysis and data analysis. The interventions were likely to induce permanent change in the **DHMC** population.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

There were no recommendations identified for this activity during this review.

Activity VIII. Sufficient Data Analysis and Interpretation

Data Analysis and Interpretation

DHMC performed data analysis of Baseline 2 (the true baseline) and the first remeasurement for each of the nine study indicators. As of September 11, 2007, **DHMC** was using the NCQA 90th percentile rates as its goal. Table 3-1 illustrates the results. The results in bold are indicators that demonstrated improvement.

Table3-1

Indicator	Baseline 2 Rates	Remeasurement 1	Goals (NCQA 90th Percentile)
1. DTP/DtaP	88.89%	84.78%	89.0%
2. IPV	95.06%	92.39%	95.0%
3. MMR	93.83%	**95.65%**	95.0%
4. Influenza	95.06%	93.48%	95.0%
5. Hepatitis B	92.59%	**93.48%**	95.0%
6. VZV	92.59%	**95.65%**	94.0%
8. Pneumococcal	86.42%	**86.96%**	64.0%
9. Combo 2	85.19%	84.78%	83.0%
10. Combo 3	79.01%	**83.70%**	58.0%

Finding(s)

Eight of the nine evaluation elements for this activity, including one critical element, were *Met*. One critical evaluation element for this activity was *Not Applicable* because sampling techniques were not used in this PIP.

Strength(s)

The data analysis was conducted according to the analysis plan in the study. The study identified factors that threatened the internal/external validity of the data analysis findings. The data were presented in a clear, easily understood format and included a thorough interpretation of the results. The initial measurement and remeasurement for each study indicator was identified. The study identified statistical differences between Baseline 2 and the first remeasurement.

Requirement(s) (for Critical Elements)

There were no requirements for this activity during this review.

Recommendation(s) (for Noncritical Elements).

There were no recommendations identified for this activity during this review.

Activity IX. Real Improvement Achieved

Real Improvement Achieved

Five of the nine study indicators demonstrated improvement during the first remeasurement and four of the nine study indicators met or exceeded the NCQA 90th percentile goal.

Finding(s)

One of the four evaluation elements for this activity was *Met.* Two of the four evaluation elements in this activity were *Partially Met.* One element was *Not Met*. There were no critical elements in this activity.

Strength(s)

The remeasurement methodology was the same as the methodology for Baseline 2. Five of the nine study indicators demonstrated improvement in the outcomes of care.

Requirement(s) (for Critical Elements)

There were no requirements identified for this activity during this review.

Recommendation(s) (for Noncritical Elements)

Two *Partially Met* evaluation elements and one *Not Met* evaluation element for this activity were discussed on a conference call on January 16, 2008. HSAG suggested that a second causal/barrier analysis be performed to assess for necessary changes that could be made to existing interventions or new interventions that could be initiated in order to achieve the desired outcomes for all study indicators.

Activity X. Sustained Improvement Achieved

Activity X was not assessed for the fiscal year (FY) 07–08 submission of this PIP study. **DHMC** will not be assessed for sustained improvement until the PIP has reported baseline and at least two annual remeasurement periods of data.

Section 4: Colorado FY 07-08 PIP Validation Tool: Childhood Immunization for Denver Health Medicaid Choice

DEMOGRAPHIC INFORMATION			
Health Plan Name:	Denver Health Medicaid Choice		
Study Leader Name:	Mary Pinkney, RN, BS	Title:	Director of Quality Improvement
Phone Number:	(720) 956-2356	E-mail Address:	Mary.Pinkney@dhha.org
Name of Project/Study:	Childhood Immunization		
Type of Study:	Clinical		
Date of Study:	8/1/2004 to 12/31/2008		
Type of Delivery System:	MCO	Number of Medicaid Members in MCO:	35,321
		Number of Medicaid Members in Study:	92
Year 3 Validation:	Resubmission		
Results:	Remeasurement 2		

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
I.	**Appropriate Study Topic: Topics selected for the study should reflect the Medicaid enrollment in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics could also address the need for a specific service. The goal of the project should be to improve processes and outcomes of health care. The topic may be specified by the State Medicaid agency or on the basis of Medicaid member input.**		
	1. Reflects high-volume or high-risk conditions (or was selected by the State). NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study topic reflected a high-volume/high-risk condition and the PIP documentation provided background information that supported the selection of the study topic.
	2. Is selected following collection and analysis of data. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study topic was selected following the collection and analysis of plan-specific data.
	3. Addresses a broad spectrum of care and services (or was selected by the State). The score for this element will be Met or Not Met.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study topic addressed a broad spectrum of care and services over time.
	4. Includes all eligible populations that meet the study criteria. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	All eligible study populations that met the study criteria were included.
	5. Does not exclude members with special health care needs. The score for this element will be Met or Not Met.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	Members with special health care needs were not excluded.
C*	6. Has the potential to affect member health, functional status, or satisfaction. The score for this element will be Met or Not Met.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study topic had the potential to affect member health and functional status.

Results for Activity I				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
1	6	0	0	0

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation		
II. **Clearly Defined, Answerable Study Question: Stating the study question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.**		
1. States the problem to be studied in simple terms. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study question was stated as "hypothesis" and was stated in simple terms and in the correct format to meet CMS Protocols. Point of clarification: The stated "hypothesis" was the main study question and should be stated as the study question. The baseline questions that were listed have been answered and could be removed or have a strikethrough as the study moves forward. Re-review January 2008: After review of the resubmitted PIP documentation, the point of clarification will remain. The hypothesis was unchanged, as well as the existing study questions. Future submissions of the PIP should make the hypothesis the main study question, making sure that the question is in the format: "Does doing X result in Y?". For example, "Will interventions taken by Denver Health Medicaid Choice on behalf of members and by providers increase immunization rates in children during their first two years of life?" The three existing baseline questions should be removed or have a strike-through indicating that they are no longer the focus of the study.

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
II.	**Clearly Defined, Answerable Study Question: Stating the study question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.**		
C*	2. Is answerable. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study question was answerable.

Results for Activity II				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
1	2	0	0	0

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
III.	**Clearly Defined Study Indicator(s): A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last 12 months) or a status (e.g., a member's blood pressure is or is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.**		
C*	1. Are well-defined, objective, and measurable. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study indicators were well-defined, objective, and measurable.
	2. Are based on current, evidence-based practice guidelines, pertinent peer review literature, or consensus expert panels.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The indicators were based on current, evidence-based practice guidelines and sources were cited.
C*	3. Allow for the study question to be answered. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study indicator allowed for the study question to be answered.
	4. Measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study indicators measured changes (outcomes) in member health status.
C*	5. Have available data that can be collected on each indicator. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	There were data available to be collected on each study indicator.
	6. Are nationally recognized measures such as HEDIS specifications, when appropriate. The scoring for this element will be Met or NA.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study indicators were nationally recognized measures.
	7. Includes the basis on which the indicator(s) was adopted, if internally developed.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	The study indicators were not internally developed.

Results for Activity III				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
3	6	0	0	1

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
IV.	**Use a representative and generalizable study population: The selected topic should represent the entire eligible Medicaid enrollment population with systemwide measurement and improvement efforts to which the PIP study indicators apply.**		
C*	1. Is accurately and completely defined. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The method for identifying the eligible population was accurately and completely defined.
	2. Includes requirements for the length of a member's enrollment in the health plan.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The method for identifying the eligible population included the required length of member enrollment.
C*	3. Captures all members to whom the study question applies. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The method for identifying the eligible population captured all members to whom the study question applied.

Results for Activity IV				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
2	3	0	0	0

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
V.	**Valid Sampling Techniques: (This activity is only scored if sampling was used.) If sampling is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied.**		
	1. Consider and specify the true or estimated frequency of occurrence.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
	2. Identify the sample size.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
	3. Specify the confidence level.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
	4. Specify the acceptable margin of error.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
C*	5. Ensure a representative sample of the eligible population.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
	6. Are in accordance with generally accepted principles of research design and statistical analysis.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.

Results for Activity V				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
1	0	0	0	6

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
VI.	**Accurate/Complete Data Collection: Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.**		
	1. Clearly defined data elements to be collected. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The data elements to be collected were clearly identified.
	2. Clearly identified sources of data. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The sources for data were specified as administrative data collection, medical record abstraction, and data from the immunization registry.
	3. A clearly defined and systematic process for collecting data that includes how baseline and remeasurement data will be collected. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	A clearly defined and systematic process for collecting baseline and remeasurement data was discussed in the PIP documentation.
	4. A timeline for the collection of baseline and remeasurement data. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	A timeline that included both the collection of baseline and remeasurement data was provided.
	5. Qualified staff and personnel to abstract manual data.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The PIP included documentation on the relevant education, training, experience of all manual data collection staff personnel.
C*	6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	A manual data collection tool that ensured consistent and accurate data collection was provided.
	7. A manual data collection tool that supports interrater reliability.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	A manual data collection tool that supported interrater reliability was included as well as a discussion of the interrater reliability process used by the health plan for manual data collection.
	8. Clear and concise written instructions for completing the manual data collection tool.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	Written instructions on the use of the manual data collection tool were provided with this year's submission.

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
VI.	**Accurate/Complete Data Collection: Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.**		
	9. An overview of the study in written instructions.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	An overview or purpose of the study was not included in the written manual data collection tool instructions. Re-review January 2008: After reviewing the resubmitted PIP documentation, the score for this evaluation element has been changed from Not Met to Met. An overview of the study (purpose for data collection) was included in the HEDIS training documentation.
	10. Administrative data collection algorithms/flow charts that show activities in the production of indicators.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	A description of the administrative data collection process was provided.
	11. An estimated degree of administrative data completeness. Met = 80 - 100% Partially Met = 50 - 79% Not Met = <50% or not provided	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The provided NCQA audit report supports the estimated degree of administrative data completeness. Re-review January 2008: After reviewing the resubmitted PIP documentation, the point of clarification has been removed. The estimated degree of administrative data completeness was reported as 99.9 percent.

Results for Activity VI				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
1	11	0	0	0

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
VII.	**Appropriate Improvement Strategies: Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing systemwide improvements in care. Interventions are designed to change behavior at an institutional, practitioner, or member level.**		
	1. Related to causes/barriers identified through data analysis and quality improvement processes. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The improvement strategies were based on causes/barriers identified through data analysis and quality improvement processes.
	2. System changes that are likely to induce permanent change.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The system changes noted in the PIP were likely to induce permanent change.
	3. Revised if the original interventions were not successful.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	Interventions were revised and additional new interventions developed based on data analysis.
	4. Standardized and monitored if interventions were successful.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Standardization of interventions had not taken place at the time of this review.

Results for Activity VII				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
0	3	0	0	1

** This number is a tally of the total number of critical evaluation elements for this review activity.

	EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
VIII.	**Sufficient Data Analysis and Interpretation: Describe the data analysis process on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used.**		
C*	1. Is conducted according to the data analysis plan in the study design. NA is not applicable to this element for scoring.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The data analysis was conducted according to the plan in the study.
C*	2. Allows for the generalization of results to the study population if a sample was selected. If no sampling was performed, this element is scored NA.	☐ Met ☐ Partially Met ☐ Not Met ☑ NA	Sampling techniques were not used in this PIP.
	3. Identifies factors that threaten internal or external validity of findings.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study identified many factors that threatened the internal and external validity of the findings.
	4. Includes an interpretation of findings.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	An interpretation of the findings was included in the PIP.
	5. Is presented in a way that provides accurate, clear, and easily understood information.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The data analysis findings was presented in a clear and easily understood format.
	6. Identifies initial measurement and remeasurement of study indicators.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The initial measurement and remeasurement for each study indicator was identified.
	7. Identifies statistical differences between initial measurement and remeasurement.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study identified statistical differences between the second baseline (true baseline) and the first remeasurement for each study indicator.
	8. Identifies factors that affect the ability to compare initial measurement with remeasurement.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The study identified factors that could affect the ability to compare baseline measurement with remeasurement periods.
	9. Includes interpretation of the extent to which the study was successful.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	An interpretation of the extent to which the study was successful was provided,

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation		

Results for Activity VIII				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
2	8	0	0	1

* "C" in this column denotes a critical evaluation element.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
IX.	**Real Improvement Achieved: Describe any meaningful change in performance observed and demonstrated during baseline measurement. Discuss any random, year-to-year variation, population changes, and sampling error that may have occurred during the measurement process.**		
	1. Remeasurement methodology is the same as baseline methodology.	☑ Met ☐ Partially Met ☐ Not Met ☐ NA	The remeasurement methodology was the same as the baseline 2 methodology.
	2. There is documented improvement in processes or outcomes of care.	☐ Met ☑ Partially Met ☐ Not Met ☐ NA	There was documentation in the PIP that five of the nine study indicators demonstrated improvement in the outcomes of care. Follow-up conference call January 16, 2008: HSAG held a conference call with DHMC and discussed the score for this evaluation element. HSAG suggested that a second causal/barrier analysis could be performed to assess for necessary changes that could be made to existing interventions or the need for new interventions in order to achieve the desired outcomes for the study indicators.
	3. The improvement appears to be the result of planned intervention(s).	☐ Met ☑ Partially Met ☐ Not Met ☐ NA	The improvement that was noted in five of the nine study indicators appeared to be the result of planned interventions. Follow-up conference call January 16, 2008: HSAG held a conference call with DHMC and discussed the score for this evaluation element. HSAG suggested that a second causal/barrier analysis could be performed to assess for necessary changes that could be made to existing interventions or the need for new interventions in order to achieve the desired outcomes for the study indicators.

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS	SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation		
IX. **Real Improvement Achieved: Describe any meaningful change in performance observed and demonstrated during baseline measurement. Discuss any random, year-to-year variation, population changes, and sampling error that may have occurred during the measurement process.**		
4. There is statistical evidence that observed improvement is true improvement.	☐ Met ☐ Partially Met ☑ Not Met ☐ NA	There was no statistical evidence that demonstrated that any of the improvement noted in five of the nine study indicators was true improvement. Follow-up conference call January 16, 2008: HSAG held a conference call with DHMC and discussed the score for this evaluation element. HSAG suggested that a second causal/barrier analysis could be performed to assess for necessary changes that could be made to existing interventions or the need for new interventions in order to achieve the desired outcomes for the study indicators.

Results for Activity IX				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
0	1	2	1	0

** This number is a tally of the total number of critical evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Performance Improvement Project/Health Care Study Evaluation			
X.	**Sustained Improvement Achieved: Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random, year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.**		
	1. Repeated measurements over comparable time periods demonstrate sustained improvement, or that a decline in improvement is not statistically significant.	☐ Met ☐ Partially Met ☐ Not Met ☐ NA	Not assessed. Activity X is not assessed until the PIP has reported baseline data and at least two annual remeasurement periods of data.

Results for Activity X				
# of Elements				
Critical Elements**	**Met**	**Partially Met**	**Not Met**	**Not Applicable**
0	0	0	0	0

** This number is a tally of the total number of critical evaluation elements for this review activity.

Table 4-1—FY 07-08 PIP Validation Report Scores: Childhood Immunization for Denver Health Medicaid Choice											
Review Activity		**Total Possible Evaluation Elements (Including Critical Elements)**	**Total Met**	**Total Partially Met**	**Total Not Met**	**Total NA**	**Total Possible Critical Elements**	**Total Critical Elements Met**	**Total Critical Elements Partially Met**	**Total Critical Elements Not Met**	**Total Critical Elements NA**
I.	Appropriate Study Topic	6	6	0	0	0	1	1	0	0	0
II.	Clearly Defined, Answerable Study Question	2	2	0	0	0	1	1	0	0	0
III.	Clearly Defined Study Indicator(s)	7	6	0	0	1	3	3	0	0	0
IV.	Use a representative and generalizable study population	3	3	0	0	0	2	2	0	0	0
V.	Valid Sampling Techniques	6	0	0	0	6	1	0	0	0	1
VI.	Accurate/Complete Data Collection	11	11	0	0	0	1	1	0	0	0
VII.	Appropriate Improvement Strategies	4	3	0	0	1	0	No Critical Elements			
VIII.	Sufficient Data Analysis and Interpretation	9	8	0	0	1	2	1	0	0	1
IX.	Real Improvement Achieved	4	1	2	1	0	0	No Critical Elements			
X.	Sustained Improvement Achieved	1		Not Assessed			0	No Critical Elements			
Totals for All Activities		**53**	**40**	**2**	**1**	**9**	**11**	**9**	**0**	**0**	**2**

Table 4-2—FY 07-08 PIP Validation Report Overall Scores: Childhood Immunization for Denver Health Medicaid Choice	
Percentage Score of Evaluation Elements Met*	**93%**
Percentage Score of Critical Elements Met**	**100%**
Validation Status***	***Met***

* The percentage score is calculated by dividing the total Met by the sum of the total Met, Partially Met, and Not Met.

** The percentage score of critical elements Met is calculated by dividing the total critical elements Met by the sum of the critical elements Met, Partially Met, and Not Met.

*** Met equals confidence/high confidence that the PIP was valid.
Partially Met equals low confidence that the PIP was valid.
Not Met equals reported PIP results that were not credible.

EVALUATION OF THE OVERALL VALIDITY AND RELIABILITY OF PIP RESULTS
HSAG assessed the implications of the study's findings on the likely validity and reliability of the results based on CMS Protocols. HSAG also assessed whether the State should have confidence in the reported PIP findings.

***Met* = Confidence/high confidence in reported PIP results**

****Partially Met* = Low confidence in reported PIP results**

*****Not Met* = Reported PIP results not credible**

Summary of Aggregate Validation Findings

*		**		***	
	X *Met*		*Partially Met*		*Not Met*

Summary statement on the validation findings:

Activities I through IX were assessed for this PIP Validation Report. Based on the validation of this PIP, HSAG's assessment determined confidence in the results.

Introduction

The appendices consist of documentation supporting the validation process conducted by HSAG using the CMS Protocol for validating PIPs. Appendix A is the study ***DHMC*** submitted to HSAG for review, Appendix B is the CMS rationale for each activity, and Appendix C includes PIP definitions and explanations.

- Appendix A: **Denver Health Medicaid Choice**'s PIP Study: ***Childhood Immunization***
- Appendix B: CMS Rationale by Activity
- Appendix C: Definitions and Explanations by Activity

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

DEMOGRAPHIC INFORMATION			10/31/07 version
MCO Name and ID:	Denver Health Medicaid Choice (DHMC)		
Study Leader Name:	Mary Pinkney, RN, BS	Title:	Director of QI for DHMC
Telephone Number:	720-956-2356	E-mail Address:	Mary.Pinkney@dhha.org
Name of Project/Study:	*CHILDHOOD IMMUNIZATION*		
Type of Study:	☒ Clinical ☐ Nonclinical		
Dates of Study Period(s):	Aug. 1, 2004 to Jan. 31, 2005 (Baseline 1 is for 6 months), Jan. 1, 2005 to Dec. 31, 2005 (Baseline 2 is for 12 months), January 1, 2006 to December 31, 2006 (Intervention 1- for 12 months), January 1, 2007 to December 31, 2007 (Intervention 2 --for 12 months). January 1, 2008 to December 31, 2008 (Intervention 3 --for 12 months).		

Approx. 14,000 August 1, 2004--#Medicaid Choice members (beginning of Baseline 1 6-month study period) 11,351 June 30, 2005--#Medicaid Choice members (mid-year, for Baseline 2 12-month study period) 9,696 December 31, 2005--#Medicaid Choice members (Baseline 2, end of 12-month study period) 3000 June 30, 2006--#Medicaid Choice members to be 21,819 considered for Project/Study, preliminary count. (Intervention 1--Intervention) 35,321 December 31, 2006--#Medicaid Choice members (Intervention 1- final count).	Section to be completed by HSAG ____ Year 1 Validation ____ Initial Submission ____ Resubmission ____ Year 2 Validation ____ Initial Submission ____ Resubmission _X_ Year 3 Validation _____ Initial Submission _X_ Resubmission
	Section to be completed by HSAG ____ Baseline Assessment _X_ Remeasurement 1 ____ Remeasurement 2 ____ Remeasurement 3

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

√ = changed or updated		Bookmarks	Table of Contents
	Section	Page	Title or Description
	A	4	Activity I: Rationale for Selection of Study Topic. Childhood Immunization.
	B	7	Activity II: The Study Question.
	C	9	Activity III: Selected Study Indicators
	D	14	Activity IV: Identified Study Population.
	E	15	Activity V: Sampling Methods.
√	F	16	Activity VIa: Data Collection Procedures. Summary of Research Steps, Data Entry Staff. IRR. Audit.
√		22	Activity VIb Data Collection and Data Analysis Cycle.
√		23	Activity VIc. Other Pertinent Methodological Features. Population Size. Data Completeness.-Internal/External Validity.
	G	28	Activity VII. Improvement Strategies. Baseline 1 Report.
√		32	Activity VII. Baseline 2 Report. Chronology of Events.
√		34	Activity VII. Intervention Year 1 Report
		35	Chronology of all mailings for PIP
	H	37	Activity VIII. Data analysis and interpretation of study results
√		38	Activity VIII. Notes on Analysis. Baseline 2. Intervention 1
√	I	42	Activity IX. Reported Improvement. Combos 2 & 3 results.
√	J	47	Activity X. Sustained improvement
		49	Graphs. Baseline 1.
		52	Graphs. Baseline 2.
		58	Graphs. Intervention 1
		62	Abbreviations
		63	Proprietary names/trademarked terminology and abbreviations

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

A. Activity I: Choose the study topic. PIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPC codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; local or national data related to Medicaid risk populations; etc. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the State Medicaid agency or CMS and be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

Study Topic: Childhood Immunizations

This Performance Improvement Project [PIP] focuses on all Denver Health Medicaid Choice [MCD] members from birth to two years of age, including children with special health care needs, who received their age-appropriate immunizations based upon HEDIS-like specifications for Childhood Immunizations. The primary goal of this project is to increase the number of children in this age group who receive their entire immunization series by the age of two based on the MCD Childhood Immunization Guidelines.

According to the 2004 NCQA report *The State of Health Care Quality*, immunizations help to protect children from serious childhood diseases and more than twenty percent of the children in the United States are still missing one or more recommended immunizations (1). It is important to ensure that children receive immunizations to prevent a resurgence of diseases that can be prevented by childhood vaccines. Sixteen to twenty doses of vaccine are required by the age of two based on the MCD childhood immunization guidelines. In terms of financial benefits, it is estimated that for every dollar spent for immunizations, the medical system saves two to five dollars per individual in health care costs for infectious disease treatment (1).

In a 2003 study by the Centers for Disease Control regarding childhood immunization rates, Colorado ranked lowest in state performance, with just 62.7 percent of children receiving all the required childhood immunizations by the age of two (2). As of January 21, 2005, the MCD members under the age of 21 represent more than half the population (approx. 8,500 out of 13,900 members, or 61%). Approximately 15% or 1200 members are children under two years of age, and represent 9% of the total MCD population.

This study reviews the immunization history of 100% of the children who turned 2 years of age during the study period and is a baseline two measurement for Denver Health Medicaid Choice. The measurements used for this study are based on HEDIS specifications for the measurement year and national immunization guidelines (4). Documents supporting this method include the immunization guidelines published by the American Academy of Pediatrics and the CDC (3). The following criteria have been defined based on HEDIS measurement criteria (4, see p. 66):

a) Diphtheria, Tetanus and Pertussis (four immunizations, with first on or after 42 days of age);

b) Hepatitis B (at least three, including booster);

c) H. influenza type b (at least three, with first on or after 42 days of age);

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

A. Activity I: Choose the study topic. PIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPC codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; local or national data related to Medicaid risk populations; etc. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the State Medicaid agency or CMS and be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

d) Polio (three IPV immunizations, with first on or after 42 days of age);

e) Measles, Mumps and Rubella (one immunization); and

f) Varicella (Chicken Pox) (one immunization) or evidence of disease,

g) Pneumococcal Conjugate (four immunizations) ADDED TO 2006 PIP, based on HEDIS 2006 changes that now include this antigen.

h) Combination one: the immunization of children by the age of two for all of the above (a through e), excluding (f) Varicella (Chicken Pox), REMOVED FROM 2006 PIP, based on HEDIS 2006 changes that retired this antigen.

i) Combination two: the immunization of children by the age of two fully for all of the above (a through f).

j) Combination three: the immunization of children by the age of two fully for all of the above (a through f). ADDED TO 2006 PIP, based on HEDIS 2006 changes that now include this antigen.

REFERENCES

1. National Committee for Quality Assurance. *The State of Health Care Quality: 2004*. Expanded Edition. National Committee for Quality Assurance, Washington, D.C., 2004. "Childhood Immunization Status," pages 37-38; "What would happen if we stopped immunizations?" Centers for Disease Control, National Immunization Program, accessed 1/25/05 at http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm.

2. Centers for Disease Control. "National, State, and Urban Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2003." MMWR, July 30, 2004 / 53(29);658-661. See also "Childhood Immunization Rates at Record High Levels." *HHS News*, Dated July 29, 2004. US Department of Health and Human Services. Accessed 1/25/05 at http://www.hline.org/cdc072904.pdf; US Department of Health and Human Services. News Release. Childhood Immunization Rates at Record High Levels. For Immediate Release Thursday, July 29, 2004. (2pp). Accessed 1/25/05 at http://www.hhs.gov/news/press/2004pres/20040729.html.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

A. Activity I: Choose the study topic. PIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPC codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; local or national data related to Medicaid risk populations; etc. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the State Medicaid agency or CMS and be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

3. Centers for Disease Control, Department of Health and Human Services. Recommended Childhood and Adolescent Immunization Schedule. United States. 2005. Advisory Committee on Immunization Practices/American Academy of Pediatrics/American Academy of Family Physicians; "Recommended Childhood and Adolescent Immunization Schedule: United States, 2005". Accessed at http://www.aafp.org/x7666.xml on 1/25/05; see also article by same title: Pediatrics, January 2005, Vol. 115(1):182-186. Accessed 3/6/05 at http://pediatrics.aappublications.org/cgi/data/115/1/182/DC1/1.

4. National Committee for Quality Assurance. "Childhood Immunization Status" In HEDIS 2005. Volume 2, pages 65-69. HEDIS 2006, Volume 2, pp 69-73. HEDIS 2007, Volume 2, pp 59-67.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

B. Activity II: The Study Question. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.

Hypothesis: Interventions taken by the Denver Health Medicaid Choice Program on behalf of members and by providers will increase immunization rates in children during their first two years of life.

Study Questions for the Study Period of January 1, 2006 to December 31, 2006 (Contract Years 2005 to 2006, 2006 to 2007):

1. What is the baseline percentage rate for immunization of all children who turned two years of age during the study period, for all of the following combination one requirements?

   Diphtheria. Tetanus and Pertussis? [DTP/DtaP, four vaccines required]
   Hepatitis B? [HepB, at least three vaccines]
   H. influenzae type b? [Hib, three including booster]
   Polio? [IPV, at least three vaccines]
   Measles, Mumps and Rubella? [MMR, at least one vaccine]

   COMBO 1 -- *REMOVED FROM 2006 PIP. (Retired for HEDIS 2006)*

2. What is the baseline percentage rate for immunization of all children who turned two years of age during the study period, for all of the following combination two requirements?

   Diphtheria. Tetanus and Pertussis? [DTP/DtaP, four vaccines required]
   Hepatitis B? [HepB, at least three vaccines]
   H. influenzae type b? [Hib, three including booster]
   Polio? [IPV, at least three vaccines]
   Measles, Mumps and Rubella? [MMR, at least one vaccine]
   Varicella (Chicken Pox)? [VZV, at least one vaccine]

   COMBO 2 -- *Unchanged.*

3. What is the baseline percentage rate for immunization of all children who turned two years of age during the study period, for all of the following combination three requirements?

   Diphtheria. Tetanus and Pertussis? [DTP/DtaP, four vaccines required]
   Hepatitis B? [HepB, at least three vaccines]
   H. influenzae type b? [Hib, three including booster]
   Polio? [IPV, at least three vaccines]
   Measles, Mumps and Rubella? [MMR, at least one vaccine]
   Varicella (Chicken Pox)? [VZV, at least one vaccine]
   Pneumococcal Conjugate? [at least four vaccines]

   COMBO 3 -- *ADDED TO 2006 PIP. (New measurement for HEDIS 2006)*

B. Activity II: The Study Question. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation.

Description of time periods defined for Study Periods [UNCHANGED]:

- Baseline one will use HEDIS like criteria since it will not be based on the HEDIS specifications of continuous enrollment for twelve months prior to the child's second birthday, with no more than a one month gap in coverage. Baseline one will use a 6 month timeframe from August 1, 2004 to January 31, 2005 and any child who turned 2 years of age with enrollment for any period during these dates was included. HEDIS criteria will not apply due to inadequate time to accumulate a significant sample size in this new Medicaid managed care plan. Had discussions with HSAG and Health Care Policy and Financing (HCPF) and confirmed that this is acceptable to have a baseline one and a recommendation was made by HSAG to do a baseline two following HEDIS specifications which we plan to do.
- Baseline two: Full calendar year from 1/1/05-12/31/05 following all HEDIS 2006 specifications. Note there was an overlap of 1 month, January 1 through 31, 2005 between baseline one and baseline two. This was discussed with HSAG and HCPF and since Baseline 1 is a preliminary review this is not an issue (see also ATT 1, graph depicting Monthly changes in Enrollment.)
- Intervention 1: Full Calendar Year from 1/1/06 to 12/31/06, following all HEDIS 2007 specifications. There is no overlap period for this study and previous baseline studies. Completion and review will take place in 2007.
- Intervention 2: Full Calendar Year from 1/1/07 to 12/31/07, following all HEDIS 2008 specifications. There is no overlap period for this study and previous studies. Completion and review will take place in 2008.

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C. Activity III: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator #1: DTP/DTaP	The percentage of eligible children during the measurement period who had four DTP/DTaP vaccines by the second birthday.
Numerator:	Medicaid Choice children who received an initial DTaP followed by at least three DTP, DTaP, or individual diphtheria and tetanus shots, with at least one diphtheria and tetanus falling on or between the child's first and second birthdays, or who have documented history of the illness or a seropositive test result. Vaccinations administered prior to 42 days after birth cannot be counted.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Baseline Benchmark:	85.8% (90th Percentile); Updated: 88.9% (90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 89% (set at Sept. 11, 2007 Medical Management Committee meeting)
Study Indicator #2: IPV	The percentage of eligible children during the measurement period who had three IPV vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received at least three antigens on or before the second birthday, on different dates of service, or who have documented history of the illness or a seropositive test result. Vaccinations administered prior to 42 days after birth cannot be counted.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	92.8% (90th Percentile); Updated: 94.7%(90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 95% (set at Sept. 11, 2007 Medical Management Committee meeting)

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C. Activity III: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator #3: MMR	The percentage of eligible children during the measurement period who had at least one MMR vaccine by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received at least one measles, mumps and rubella vaccine on and between the first and second birthday, or who have documented history of the illness or a seropositive test result.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	94.10% (90th Percentile); Updated: 95.3% (90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 95% (set at Sept. 11, 2007 Medical Management Committee meeting))
Study Indicator #4: Hib	The percentage of eligible children during the measurement period who had at least three influenza type b vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received at least three antigens on or before the second birthday, with at least one antigen received on or between the first and second birthdays, or who have documented history of the illness or a seropositive test result. Vaccinations administered prior to 42 days after birth cannot be counted.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Baseline Benchmark:	88.3% (90th Percentile); Updated: 95.1%(90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 95% (set at Sept. 11, 2007 Medical Management Committee meeting))

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C. Activity III: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator #5: HepB	The percentage of eligible children during the measurement period who had three hepatitis B vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received at least three antigens on different dates, on or before the second birthday with at least one antigen received on or between six months (180 days) and the second birthday, or who have documented history of the illness or a seropositive test result.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	88.30% (90th Percentile); Updated: 95.2% (90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 95% (set at Sept. 11, 2007 Medical Management Committee meeting)
Study Indicator #6: VZV	The percentage of eligible children during the measurement period who had at least one chicken pox vaccine by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received at least one antigen on or between the first and second birthdays, or who have documented history of the illness or a seropositive test result.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	92.2% (90th Percentile); Updated: 93.8% (90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating.
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 94% (set at Sept. 11, 2007 Medical Management Committee meeting)

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C. Activity III: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator #7: Combo1 RETIRED!	The percentage of eligible children during the measurement period who had the required DTP/DtaP, IPV, MMR, Hib, and HepB vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received four DTP/DtaPs, three IPV, one MMR, three Hib, and three HepB vaccines by the second birthday.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	RETIRED
Source of Benchmark:	RETIRED
Baseline Goal:	RETIRED
Study Indicator #7: Pneumococcal Conjugate	The percentage of eligible children during the measurement period who had the required Pneumococcal Conjugate vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received four Pneumococcal Conjugate vaccines by the second birthday.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First/Current Measurement Period :	January 1, 2005 to December 31, 2005 (Baseline) (12 months)
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	None (baseline year for this measure); Updated: 64.2%990th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating.
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 64% (set at Sept. 11, 2007 Medical Management Committee meeting)

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C. Activity III: Selected Study Indicators. A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator #8: Combo2	The percentage of eligible children during the measurement period who had the required DTP/DtaP, IPV, MMR, Hib, HepB and VZV vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received four DTP/DTaPs, three IPV, one MMR, three Hib, three HepB and one VZV vaccine by the second birthday.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First Measurement Period Dates:	January 1, 2005 to December 31, 2005 [Baseline 2, a 12 mo. study, replaces Baseline 1, a 6 mo study, for this study]
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	75.70% (90th Percentile). Updated : 82.7%(90th Percentile)
Source of Benchmark:	2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 83% (set at Sept. 11, 2007 Medical Management Committee meeting)
Study Indicator #9: Combo3	The percentage of eligible children during the measurement period who had the required DTP/DtaP, IPV, MMR, Hib, HepB, VZV and Pneumococcal Conjugate vaccines by the second birthday.
Numerator:	Medicaid Choice children who had a record that they received four DTP/DTaPs, three IPV, one MMR, three Hib, three HepB, and one VZV and four Pneumococcal Conjugate vaccines by the second birthday.
Denominator:	Medicaid Choice children who turned two years of age during the study period.
First/Current Measurement Period :	January 1, 2005 to December 31, 2005 (Baseline) (12 months)
Current Measurement Period :	January 1, 2006 to December 31, 2006 (Intervention 1) (12 months)
Benchmark:	None (baseline year for this measure); Updated: 57.8%(90th Percentile)
Source of Benchmark:	NEW MEASURE IN 2005 (2006 Review); 2006 HEDIS Percentile Rating
Baseline Goal:	90% (set at Sept. 12, 2006 QAC meeting) Updated: 58% (set at Sept. 11, 2007 Medical Management Committee meeting)

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D. Activity IV: Use a representative and generalizable study population. The selected topic should represent the entire Medicaid enrolled population, with system wide measurement and improvement efforts to which the study indicators apply. Once the population is identified, a decision must be made whether to review data for the entire population or a sample of that population. The length of a member's enrollment needs to be defined in order to meet the study population criteria.

Identified Study Population (see ATT 1, ATT 14, p. 1 figure):

Baseline 1 Measurement (UNEDITED): 100 percent of eligible Denver Health Medicaid Choice children identified based on HEDIS-like criteria. HEDIS criteria requires all children with at least 11 months (12 months with one 30-day gap of enrollment) of continuous enrollment in the health plan be included in the study. This study will only require a 6 month enrollment period and will not use HEDIS eligibility criteria, based on Denver Health Medicaid Choice being a new MCO effective May 1, 2004. Baseline one will use a 6 month timeframe from August 1, 2004 to January 31, 2005 and any child who turned 2 years of age with enrollment for any period during these dates was included.

Initial membership for this study was approximately 1200 in May of 2004. By August 2004, this membership grew to approximately 14,000 members, providing us with a sufficient sample size to study. Since August 2004, the population has been decreasing and as of September 2005 was around 10,000.

Baseline 2 measurement period (1/1/05 to 12/31/05) (NEW): In 2005, Medicaid Choice population decreased on a monthly basis due to changes in the enrollment process related to state computer problems and the automatic enrollment process. This resulted in reenrollment of members and assignment of PCPs as part of a fee-for-service program. This portion of the reenrollment process was corrected around the end of 2005. At the time of the Baseline 2 part of this study, 9,696 members were enrolled in the Medicaid Choice program. This eligible population is based on Diamond enrollment data, and includes all children born on or between August 1, 2002 and January 31, 2003.

Intervention 1 measurement period (1/1/06 to 12/31/06): As of May 1, 2006, Medicaid Choice enrollment increased in size due to changes in the Medicaid Program. New members were enrolled based on Passive Enrollment procedures. Through the end of 2006, monthly enrollment rates are expected to average approximately 4000 to 5000 members per month.

Enrollment in 2006 indicates that total population changes can dilute outcomes; however, current study shows no significant changes. These possible changes won't show any drastic outcomes in a yearly basis as they will over multiple year periods.

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E. Activity V: Use sound sampling methods. If sampling is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied.

Measure	Sample Size	Population	Method for Determining Size (*describe*)	Sampling Method (*describe*)
Baseline 1 (8/1/04 to 1/31/05) and Baseline 2 (1/1/06 to 12/31/06)	No sampling is done; 100% of the population was used.	All Children turning 2 y/o in 2005. Baseline 2 also requires HEDIS eligibility.	100% of entire population was used for the 2005 and 2006 PIP.	NA
Intervention 1 (2007)	**No sampling is done; 100% of the population was used because eligible population was 81.**	**All Children turning 2 y/o between in 2006; requires HEDIS eligibility (see Step 6)**	**432 members are selected by TierMed; 411 is typical for HEDIS studies; HEDIS 2007 specifications will be used.**	**Sampling done by TierMed in accordance with HEDIS standards.**

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F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

[X] Clear identification of the data to be collected **[for BASELINE 2 Study Period]**

100% of Medicaid Choice children who turned two years old during the study period and who for BASELINE 1, met *HEDIS-like criteria* for the 2004-2005 population studied in 2005; for BASELINE 2 met *HEDIS criteria* for 2005 population study carried out in 2006.

[X] Identification of the data sources and how and when the baseline and repeat indicator data will be collected [see Step 6b for process]

Major Data entry methodology changes from 2005 to 2006. *In 2005,* data entry processes were carried out using an internal Access database with data entry forms and IRR/validation forms produced by the QI Analyst at Denver Health. The list of members for this study was provided by HEDIS Help, an NCQA-certified vendor for conducting HEDIS studies. For the first phase of the Baseline 1 activity, data was extracted from internal VaxTrax and Medical Records Imagery [MRI] databases and the statewide CDPHE-operated CIIS database (each described in the last submission), and entered manually into an Access database. After an IRR and internal data validation process were completed, this datasets was then exported in an Excel worksheet form and forwarded to HEDIS Help for final analysis and review. *In 2006*, a new software vendor was contracted—TierMed—enabling most the manual data entry and IRR/validation processes to be automated. These TierMed processes replace the manual data entry procedure required for database development in 2005 (see ATT 3). In March 2006, Guardian Angel Consulting, Inc. became responsible for staff training on performing HEDIS measures.

****NOTE: These HEDIS 2006 data entry and review processes were unchanged and repeated for HEDIS 2007 and related PIP review.**

Population Data Sources and Processing for the 2006 HEDIS. For the Baseline 2 study (1/1/05 to 12/31/05), TierMed utilized NCQA certified HEDIS software and methods to identify eligible members eligible for this study. ATTACHMENT 1 provides an overview of the population eligible for this study according to demographic statistics pulled for eligible membership as of December 31, 2005.

Data Collection Chronology (see also CHRONOLOGY section at end of PIP): Schedule of events—BASELINE 2 study: December 2005 preliminary data review; March 2006 data collection training by Guardian Angel Consulting, Inc., April 2006 medical records review, May 15 -Interrater Reliability review (IRR), June 15, 2006 data submission and analysis of baseline data, July to August 2006 - QAC review of PIP. October 2006 - final PIP submission to state for Baseline 2 study. Intervention 1 study: January 2007 – reinitiate data review for 2007 HEDIS. **April 2007 – HEDIS data collection, May 15, 2007 – IRR, June 15, 2007, data submission and analysis, July-August 2007 – Med Mgmt Comm. review. Nov. 2007- Submit PIP.**

Summary of Research Steps for BASELINE 2 Study Period (10/2005 to 6/2006)

October 1 to December 31, 2005: development of the initial Administrative database: all of the member, enrollment, provider, and claims data was collected and sent to Tiermed where it was processed as HEDIS data using NCQA-certified software. This resulted in a dataset listing eligible members, each with a unique identifier, DOB and some immunization dates populated from claims. The remaining database was then forwarded to QI Analysts, who entered the initial immunization extracted from VaxTrax and MRI. The resulting database was then submitted back to TierMed in Excel form for review. Following a reconciliation process, this final dataset was imported and entered into the final TierMed Access database, via an ftp serve, for use in the final data entry process to be carried out using the TierMed Compass Navigator data entry tool (ATT 3a-h *replaced by* ATT 3a-d).

January 1, 2006 – April 30, 2006. QI staff entered the remaining hybrid data into the Childhood Immunization HEDIS database using the Compass Navigator Tool provided by TierMed (ATT 3d). For each member on the list, Member ID, DOB, and Plan ID were re-verified, followed by entry of any remaining immunization dates uncovered by the team that were not found in this database. Some of this data was obtained from VaxTrax (ATT 4a-c),

F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

CIIS (ATT 5) and Medical Records Imagery (ATT 6). As in the Baseline 1 study, Diamond/Perot Systems were used to verify member id and/or provider address when no immunization dates could be located.

May 2006. Interrater Reliability Review: throughout the hybrid data entry process, audits were performed internally as well as by an outside agency. During the first stage of the hybrid data entry process in 2006, all of the records entered were audited by Guardian Angel Consulting, Inc. (ATT 7), an agency contracted to train and oversee QI analysts' activities throughout the data entry processes. Following the initial audit, weekly audits were performed of 10% of the remaining data entries. Throughout this process, the standard for Interrater Reliability (IRR) accuracy remained 95% (ATT 7).

The completed database of eligible members was submitted to HEDIS for review and summarization in May 2006 (see ATT 3a flowchart; ATT 10). The results of this review and summary were returned and reviewed by QI Director. Following approval of these results by the Director, they were entered into the PIP.

The end results of the data entry are viewable using the TierMed Compass Viewer tool, an extension of Compass Navigator. These data and/or results were reported to NCQA, HCPF, and HSAG by June 2006, and discussed with the Quality Assurance Committee and Operations Management Team in September in order to determine possible barriers and develop effective interventions (ATT 11). For other PIP-related analyses, immunization tables were extracted from the Access database and then copied into Excel for further analysis and production of final graphs and figures (ATT 9).

The final PIP was submitted for review by HSAG in June 2006 (see Step 7 discussion).

These steps will be repeated for each study period, with the addition of intervention procedures discussion in the 2006 study (2007 report).

In September 2006, these results were presented to the Quality Assurance Committee for a review of possible barriers and to determine if any changes or additions to the intervention process are needed.

Following QAC approval, the final PIP is completed and submitted to HSAG for review by October 15th (ATT 10).

For the Intervention 1 study (1/1/05 to 12/31/05), data collection will begin in December 2006 (see Updated Chronology attachment).

(NEW) 2007: For the 2007 HEDIS, IRR was performed internally, with 95%+ accuracy maintained throughout the data entry process. All remaining processes for HEDIS and the PIP remain unchanged.

Data Collection and Entry Processes.

(*UNEDITED*). 2004-2005 Immunization Data Collection and Entry (see ATT 3-5). Any children with evidence of receiving an immunization based on claims will have a date populated on the spreadsheet by TierMed. DH will obtain the remaining immunization data from VaxTrax, CIIS or from a medical record on antigens without a date. This immunization data is collected and entered from the following information sources (in descending order): Denver Health's (DH's) VaxTrax database, Colorado Immunization Information System (CIIS), DH's Medical Records Imagery (MRI), and DH's Diamond. An Access database linked to TierMed's Compass Navigator tool will be used for all data entry and review processes. The following process is used for data search and entry on the HEDIS list:

1) Administrative data is extracted primarily from the VaxTrax (Denver Health immunization registry) (see ATT 3, 4a-c)

F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

2) The entire database is queried and members with missing data searched in *Colorado Immunization Information System (ATT 5)*.
3) Members still missing immunization data will be searched for individually in the Medical Records using the Medical Records Imaging [MRI] system, a Denver Health electronic medical record provided by Denver Health (see ATT 3, 6). These records provide information on immunizations which are repeated following enrollments in Denver Health by members lacking the documentation required to demonstrate their required immunization history or their history of a disease.
4) Members lacking an entire series or most of a series of one or more immunizations will be reviewed in the Medical Records to confirm missing data and assessed for contraindications by the use of Medical Records and VaxTrax.

(NEW.) 2005 PIP Study/2006 Data Collection and Entry. For the Baseline 2 study period (1/1/05 to 12/31/05), data was gathered and summarized by TierMed utilizing their NCQA certified software program. TierMed also produced the final data collection tools and final analyses of data. TierMed data was transferred to Excel spreadsheets for comparison with goals and previous Baseline 1 results and presentation to QAC in order to establish new goals. Aside from processes involving TierMed, all other steps in this Data Collection and Analytic processes remain unchanged. <Back to Table of Contents>

Interrater Reliability (NEW): Once all the data is entered into an Access database (and all the necessary steps noted above carried out), Interrater reliability is performed using a TierMed Report Form and review processes discussed earlier carried out by Guardian Angel Consulting, Inc. (ATT 7 (REVISED)). This IRR review is used to verify that all immunization date entries are accurate and complete with medical records. For all steps in this review process, a goal of 95% accuracy is maintained. <Back to Table of Contents>

Data Submission and Processing. 2005, Baseline 1 process (***UNEDITED***): Once the data entry, assessment and reconciliation steps are completed, this data is queried to produce an Access database that matches the details of the submission worksheet built by HEDIS HELP, which is designed to interface with their HYBRID HELP software in order to calculate rates (see ATT 1 -- Hybrid Help 2005 User Manual). The method of importing this data into the HEDIS HELP is described in ATT 8. Once results are obtained from QMark, they will be reviewed and, if necessary, a reconciliation between the HEDIS HELP dataset and any Excel and Access databases developed during this research process carried out to ensure the count is accurate.

2006, BASELINE 2 Process : The above steps are carried out, with HEDIS HELP replaced by TierMed and the Hybrid Help Software replaced by the TierMed program and Compass Navigator Tool. To ensure the accuracy of this new data entry process by TierMed, a review of the previous year's data and statistical results were carried out in October 2005 (see 3a flowchart). An assessment and reconciliation process were then carried out, consisting of several steps to ensure accuracy in reporting and statistical analysis by TierMed in agreement with DH QI Director and DH HEDIS IS. This process and its results are summarized in the ATT 3a flowchart.

2007, INTERVENTION 1 (NEW). Data Submission and Processing steps remain UNCHANGED for HEDIS 2007.

Data Processing Audit: 2005 (**UNCHANGED**): DH collected HEDIS 2005 data and successfully completed a 2005 NCQA HEDIS audit for the commercial

F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

line of business. Our processes for Medicaid Choice have minimal differences compared to our commercial plan. The differences are related to the processing of the member files (see ATT 1e-- BAT Section 5 Member Data Processing for details and documentation of Medicaid Choice Daily Enrollment Files).

2006 (NEW): Following an internal IRR and an external data reviews by Guardian Angel Consulting, Inc., a 2006 NCQA HEDIS audit for the Medicaid line of business was performed and successfully passed prior to submission of the final HEDIS 2006 data results (ATT 8).

2007, INTERVENTION 1 (NEW). Data Processing steps remain UNCHANGED for HEDIS 2007. Guardian Angel Consulting, Inc. training and review was done by internal staff under the direction of QI RN, Carol Martinez, She developed the training materials and trained staff and was responsible for Interrater Reliability.[HEDIS TRAINING and IRR ATT 7].

[X] Specification of who will collect the data <Back to Table of Contents>

Ivette Villalobos	Information Management Dept.	Experienced Diamond Data analyst x7 years, responsible for HEDIS data management for Managed Care in 2005, HEDIS Help & TierMed trained.
Melissa Cook	**Database development**	**Experienced Database technician x3 years with DH training including Medical Records Imaging, VaxTrax, Diamond, Tier Med and CIIS trained.**
Jennifer Kikla MSPH	**Intervention Manager**	**Experienced researcher x4 years with DH training including Medical Records Imaging, VaxTrax, Diamond, and CIIS trained.**
Carol Martinez, RN	IRR auditor/Data entry.	Experienced HEDIS Medical Record training and auditing x5 yrs. Quality Improvement Coordinator (16 years). DH training includes Medical Records Imaging, VaxTrax, Diamond and TierMed trained.
Cindy Ashley	**HEDIS Project Manager**	**16 years Managed Care experience. Experienced project manager with 4 years of HEDIS/CAHPS experience. DH training includes Medical Records Imaging, Diamond training and Peradigm training. Tiermed training includes the use of the 2007 Compass Navigator Tool and the Data Collection Tool.**

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

		These tools are used for analysis, auditing and qualtiy control functions
Mary Pinkney RN, BS	Inter-reliability/database auditor	Experienced project manager, 9+ years HEDIS experience, DH training including Medical Records Imaging, VaxTrax, CIIS, and Diamond, with HEDIS Help trained on the use of the 2005 Hybrid Help tool and auditing functions. Tier Med training
No longer within Denver Health:		
Brian Altonen MS, MPH	**Database Development**	**Experienced spatial epidemiologist 22 yr; researcher 20yrs; DH training including Medical Records Imaging, VaxTrax, CIIS, and Diamond, with HEDIS Help trained on the use of the 2005 Hybrid Help tool and auditing functions. Tier Med training**

[X] Identification of instruments used to collect the data **[UNCHANGED]**
Excel spreadsheets and/or Access Database with a Data Entry Form--see ATTs #2, 4, 9.
For HEDIS 2006, a new NCQA-certified software vendor, TierMed, was contracted (see ATT 3).

[X] Medical/treatment records: **[UNCHANGED]**
Medical Record Imaging-electronic records (EDM)

[X] Administrative data: **[UNCHANGED]**
Claims
VaxTrax
Colorado Immunization Information Systems (CIIS)

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F. Activity VIa: Data Collection Procedures. Data collection must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. ***[Note, some sections modified to properly describe 2005 research period.]***

[X] Claims/encounter data [ ] Complaints [ ] Appeals [ ] Telephone service data [ ] Appointment/access data

[X] Hybrid (medical/treatment records and administrative)
Occasional use of medical records available through Medical Records Imaging at Denver Health to verify disease and immunization history, or administration of immunizations due to lack of adequate documentation of immunization history.

[ ] Pharmacy data

[ ] Survey data (attach the survey tool and the complete survey protocol)

[X] Other (list and describe):

Denver Health's VaxTrax--an immunization registry report of a immunizations given to two year olds was used by TierMed to obtain immunization dates for all eligible members in this study (see: ATT 4 --VaxTrax immunization registry training tool). CIIS is used to provide additional and supporting documentation for immunizations (see ATT 5). **[NOTE: ATT 4, 5 and 6 not included in this version of the PIP.]**

NOTE: ALL PARTS REMAIN UNCHANGED FOR THE FOLLOWING SECTIONS

If medical/treatment records, check below:	If administrative, check all that apply:
[X] Medical/treatment record abstraction	[X] Programmed pull from claims/encounter files of all eligible members
If survey, check all that apply:	[ ] Programmed pull from claims/encounter files of a sample of members
[ ] Personal interview	[ ] Complaint/appeal data by reason codes
[ ] Mail	[ ] Pharmacy data
[ ] Phone with CATI script	[ ] Delegated entity data
[ ] Phone with IVR	[ ] Vendor file
[ ] Internet	[ ] Automated response time file from call center
[ ] Incentive provided	[ ] Appointment/access data
[ ] Other (list and describe):	[ ] Other (list and describe):

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F. Activity VIb: Determine the Collection Cycle.	Determine the Data Analysis Cycle.
[X] Once a year (for all years of study once baseline is established) [ ] Twice a year (for first twelve month period of study) [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Once a week [ ] Once a day [ ] Continuous [ ] Other (list and describe):	[X] Once a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Continuous [ ] Other (list and describe):

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

F. Activity VIc. Other Pertinent Methodological Features. [Note, some sections modified to describe 2005 research period.]

POPULATION SIZE. BASELINE 1 **[UNCHANGED]**: The initial baseline measurement data was gathered for the study period of 8/1/04 to 1/31/05. Since then, all study periods extend from January 1st to December 31th for the measurement year. The initial membership population was approximately 1200 in May 2004. By August 2004, the membership increased to approximately 14,000 members, providing a sufficient sample size to study. From August 2004 to September 2005, the population decreased to approximately 10,000 members.

BASELINE 2 **[UNCHANGED]:** On January 6, 2006, the size of the Medicaid Choice population was 9,696, with 273 children between 0 and 2 years of age. Beginning April 2006, only 81 members who turned two years of age in 2005 were considered eligible for the 2006 HEDIS study and thereby reviewed.

Intervention 1 [UNCHANGED]: As of June 2006, the Medicaid Choice population increased to 21,819 (a 125% increase); this was due to changes in the Enrollment processes. (see p. 11, D. Step 4 section). Approximately 3200 (14.7%) of these members are 0 to 2 years of age, with about 1000 of these children (5% of the total population) born in 2004 making them potentially eligible for the HEDIS 2006 review in 2007. The actual **number and percentage of members to be reviewed** for the Intervention 1 year (2006) study will be determined in December 2006.

[NEW] December 2006 Report. As of December 2006 the Medicaid Choice population increased to 35,321 members, with 6,370 (18%) of the members between the ages of 0 to 2. For Intervention 1 a total of 2.072 members (6%) turned 2 during 2006 and reviewed for this study period. Please see attachment 1 for a breakdown of the population demographics.

DATA COMPLETENESS. [UNCHANGED]: BASELINE 1 (Aug 2004-Jan 2005) (UNCHANGED): Several steps are taken to minimize threats to data completeness, accuracy and reliability. First, this study uses the entire membership that meets the criteria defined for this study based on HEDIS like criteria. Second, to identify members for this study, a list is developed by Information Management staff approximately 5 months (150 days) after the last date of the study period. This reduces the impact of claims lags of 60 to 90 days. Third, a reconciliation process takes place with the goal of verifying members on all datasets produced by QMark and our QI team. This includes reviews of the early datasets provided in Excel by an NCQA-certified software vendor (QMark), data submissions material (in Access form) for import into the Hybrid Help tool, and a review of our results produced by QMark to make sure we have an accurate count and the correct members identified. Fourth, once we have received the final rates from our NCQA-certified software vendor QMark, we verify that the denominator, numerator, and exclusions are correct, and undergo the necessary reconciliation processes for documenting members excluded from the study (no exclusions were found for Baseline 1 according to Coding entries noted in ATT 2a–HEDIS 2005, Childhood Immunization Status, p 8: Table E1-B). Finally, additional steps are taken to ensure data completeness, including the use of Interrater Reliability (IRR) tools and the IRR related reconciliation process explained earlier (this PIP, pp 9-10).

Since the greatest risk to data completeness is missing data (data not found), the possibility for name/id search failures and/or missing medical records is reviewed. This includes a thorough review for medical records possibly filed as external documents (e.g. outpatient visit and referrals), rather than as typical internal documents researched with Medical Records Imaging. Also, searches for members with missing data also focus on possible name changes (i.e. post-marital surname change, changed surname spelling, paternal-related name change, hyphenated multiple surname transpositions), using other data sources and identifiers including the DH immunization database (which has a section for alternative names and spelling).

BASELINE 2 (Jan 2005-Dec 2005): Beginning January 1, 2005, the childhood immunization (Denver Health's VaxTrax Immunization Registry) data was provided

F. Activity VIc. Other Pertinent Methodological Features. [Note, some sections modified to describe 2005 research period.]

electronically by Denver Health to TierMed; this data is then entered into as administrative data into TierMed's NCQA-certified software. The data submitted to TierMed for this study is the immunization data for all Medicaid Choice children turning tow years old in 2005. TierMed then determines eligibility for these members based on HEDIS specifications.

To validate the accuracy and validity of the resulting database produced by TierMed, at least 1 in 10 of the members are reviewed by QI staff using previously described methodologies (ATT 7); this process involves a review of the VaxTrax database, Medical Records Imagery and the CIIS database. In addition, missing data is re-researched using VaxTrax, Medical Records Imagery, and CIIS to confirm there is no date for a given immunization. As part of the final review process, members without a VZV date are reviewed in the Medical Records Imagery for documentation of a possible history of the disease.

INTERNAL VALIDITY. BASELINE 1 (Aug 2004-Jan 2005) [UNCHANGED]: No factors have been identified that influence the internal validity of these research and analytic processes. Selection bias is avoided by the inclusion of all members into this study based solely on their enrollment period, regardless of ethnicity, race, Hispanic background, disability history, or income status. Due to population size (n=217) and age-related features for members of this study (0-2 years of age), experimental mortality is not a major concern. Some variation in results is expected due to changes in membership, for which reason research population are interpreted as unique sets that change membership from year to year, with the likelihood that some members may qualify for one measurement period but not another due to changes in eligibility for baseline 2 only. For further studies, the population will be different from year to year based on the criteria of turning 2 years old during the measurement year. No changes are foreseen for any future instrumentation of this study.

BASELINE 2 (Jan 2005 –Dec 2005): Procedural Change: The data development and submission process for this study changed from a manual process of data entry using an access database (which is then exported into Excel format and submitted to QMark), to an entirely electronic submission process utilizing the internal administrative data source, VaxTrax. This reduces the possibility of errors being generated through the manual data entry process previously used. As with the 2004/5 data entry process, a review of medical records is then carried out upon completion of this work, with the goal of eliminating missing data and/or verifying absent or missing records and/or immunization dates.

Study Design and Engagement: For the most part, the internal validity issues for these processes remain unchanged. As anticipated, a *Regression to the Means was observed* following completion of Baseline 2 due to the changes in eligibility requirements for the study population and improvements in our ability to obtain complete datasets (see Step 7, Improvement Strategies, p. 23-Baseline 1 and p 24-Baseline 2 "Regression to the Mean" discussions). Future changes in these research methodology-related processes are not expected.

Intervention 1 (Jan. 2006 to Dec. 2006) [NEW]:

While changes in immunization rates may be due to our efforts, without a control group we are unable to link a direct cause and effect relationship. Other possible explanations that could have affected our immunization rates include: Changes in clinic sites with the LaMariposa FP Clinic and Kids Care relocating to the new Webb building on our Main campus. This new facility has lab, pharmacy and offers services for pediatrics, Family Medicine and Internal Medicine.

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F. Activity VIc. Other Pertinent Methodological Features. **[Note, some sections modified to describe 2005 research period.]**

Emphasis on providing immunizations at every visit in the Denver Health clinics and reminders generated from Vax Trax to children who are in need of immunizations. All these factors could have had an affect our childhood immunization rates.

Intervention 2 (Jan. 2007 to Dec. 2007) [NEW]: .Analyze 08

EXTERNAL VALIDITY

BASELINE 1 (Aug 2004-Jan 2005) (UNCHANGED): Regional demographic differences may impact one's ability to relate our results to similar studies in other institutions, regions or populations. According to a recent HSAG meeting (August 4, 2005), rural settings contain a significantly different percentage of certain age and income groups than urban settings. Since this study engages families who reside in a fairly urban/suburban setting, the applicability of our results at the state level may be limited. On the other hand, this impact of population differences may also be inconsequential, based on following HEDIS specifications to produce interventions, making them broadly applicable. Finally, it is important to note that education-related efforts to improve childhood immunization rates could be deterred by member address changes, validity, and/or frequent moves by members of this population.

BASELINE 2 (Jan 2005 to Dec 2005) (NEW): The increase in the study period from six months to twelve months for Baseline 2 produced a more accurate and reliable measures of the Denver Health program. The overall impact of these outcomes on external validity remains unchanged.

Intervention 1 (Jan 2006 to Dec 2006): The significant increase in Medicaid Choice enrollment in 2006 has the potential of increasing the similarity of this study population regionally, if not Statewide. For the most part, any differences noted to exist earlier between local urban settings and more peripheral, suburban to rural settings remain unchanged. Likewise, in-migration/out-migration patterns for the Denver urban setting remain an important factor with the potential of differentiating this Denver Health population from other populations in Colorado.

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F. Activity VIc. Other Pertinent Methodological Features. [Note, some sections modified to describe 2005 research period.]

ATTACHMENTS – F. Data Collection Process/Methodology

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BASELINE 1

➢ Qmark Data Requirements. HYBRIDHelp 2005. Version 1.33. Dec. 7, 2004.	ATT #1a [UNCHANGED]
➢ Description of Claims or Encounter Submission Process; Claims quarterly audit for the 4th Quarter of 2004; Data completeness correspondence.	ATT #1b [UNCHANGED]
➢ Qmark HEDIS. Data Extracts.	ATT #1c [UNCHANGED]
➢ Data Assessment Notes and Correspondence	ATT #1d [UNCHANGED]
➢ BAT Section 8-Control Procedures to Ensure HEDIS Data Integrity	ATT #1e* [UNCHANGED, managed by TierMed]
➢ BAT Section 5- Membership Data Processing	ATT #1f [UNCHANGED, managed by TierMed]
➢ Documentation regarding Medicaid Choice Daily Enrollment Files	ATT #1g [UNCHANGED]
➢ Data Extract Reconciliation and Completeness of Claims/Encounters	ATT #1h [UNCHANGED]
➢ HEDIS 2005, Vol. 2. Technical Specifications. "Childhood Immunization Status"	ATT #2a [UNCHANGED, UPDATED for 2006/7]
➢ 2005 Hybrid Help User Manual. Feb. 28, 2005. "Childhood Immunization Status"	ATT #2b [UNCHANGED, replaced by TierMed documents, see ATT 3]
➢ Qmark HYBRIDHelp. The Data Entry and Evaluation Process . . . (for PIP)	**ATT #3a** [UNCHANGED, replaced by TierMed documents, see ATT 3]
➢ Vax Trax View Only Training Manual	ATT #4a [UNCHANGED]
➢ Vax Trax Clinic Training Manual	ATT #4b [UNCHANGED]
➢ Worksheet for reviewing VaxTrax Childhood Immunization records	ATT #4c [UNCHANGED]
➢ VaxTrax Correspondence (memos on updates, changes, etc.)	ATT #4d [UNCHANGED]
➢ Getting Started. Colorado Immunization Information System (CIIS)	ATT #5 [UNCHANGED]
➢ Evaluation of Medical Records Imaging Data Worksheet (3pp)	ATT #6 [UNCHANGED]
➢ DH Inter Rater Reliability Tool, Score Sheet generated, and QI Audit results (3 pp)	ATT #7 [for 2006 IRR, see 7b, 7c]
➢ Preparing the Childhood Immunization Dataset for Submission to QMark	**ATT #8a** [REMOVED from submission Process, see 8b]
➢ Excel Spreadsheet for use in Calculating Chi-Squared	ATT #9 [UNCHANGED]
➢ Final immunization rates	ATT #10a [UPDATED to 10b]

10-1-06 NOTE: Qmark attachments 1a through 1h were removed in 2006 and replaced by TierMed (see ATT 3).

New ATT 1 topic: Demography.

BASELINE 2. (Attachments for this PIP include only those with changes from the above list)

➢ Demography of Study Population	ATT #1	[NEW]
➢ HEDIS 2005, Vol. 2. Technical Specifications. "Childhood Immunization Status"	ATT #2	[UPDATED]
➢ Evaluation of TierMed Data/IRR Process (Flowchart)	ATT #3a	[NEW]
➢ TierMed Training Workbook, Methodology, Compass Navigator, Compass Viewer manuals	ATT #3b-e	[Methodology changes from 2005]
➢ Data Assessment Notes and Correspondence with TierMed	ATT #3f	[Methodology Change/Updates]
➢ DH Inter Rater Reliability	ATT #7 repl. By #7b	[Methodology Change]
➢ Guardian Angel Consulting, Inc. HEDIS Date Entry Training and Audit activities	ATT #7c	[NEW]
➢ Preparing the Childhood Immunization Dataset for Submission to TierMed	ATT #8 repl. By #8b	[Methodology Change]
➢ Final immunization rates	ATT #10 repl. By #10b	[Methodology Change]
➢ QAC Meeting Minutes	ATT #11	[UPDATED]

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F. Activity VIc. Other Pertinent Methodological Features. **[Note, some sections modified to describe 2005 research period.]**		
➢ Intervention Activities Flowcharts	ATT #13	[UPDATED]
➢ PIP Intervention Activities	ATT #14	[UPDATED]
➢ Denver Health System-related Intervention Activities	ATT #15	[UPDATED]

ATTACHMENTS – F. Data Collection Process/Methodology (continued)

Intervention 1. (NOTE: Attachments for this PIP include only those from the above two lists which underwent changes during the last study period)

➢ **Demography of Study Population**	**ATT #1**	**[Replaces Previous Report]**
➢ **HEDIS 2007, Vol. 2. Technical Specifications. "Childhood Immunization Status"**	**ATT #2**	**UNCHANGED**
➢ **TIERMED - Chronology of Tiermed Data Submission**	**ATT #3a**	**[UPDATED]**
➢ **HEDIS 2007 Abstraction and Collection Process**	**ATT #3e**	**[UPDATED]**
➢ **HEDIS TRAINING ACTIVITIES**	**ATT #7a**	**[New Process described; replaces previous 7a]**
➢ **SUMMARY OF INTERRATER RELIABILITY**	**ATT #7b**	**[UPDATED]**
➢ **HEDIS Audit Report; 2007 HEDIS Review**	**ATT #8**	**[UPDATED]**
➢ **Excel Spreadsheet for use in Calculating Chi-Squared**	**ATT #9**	**[UPDATED]**
➢ **Final immunization rates**	**ATT #10**	**[Replaces Previous Report]**
➢ **2006 QAC/2007 Medical Management Committee Meeting Minutes**	**ATT #11**	**[UPDATED]**
➢ **PIP Intervention Activities**	**ATT #14**	**[UPDATED]**
➢ **Well visit Insert-related Activities**	**ATT#14**	**[NEW]**

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

BASELINE 1 Report. What are the barriers to children getting immunized? *[Not edited or modified, 8/2006; Baseline 2 begins on p. 24; Intervention 1 Report begins on p. 29]*

Discussion of this topic at the Quality Assurance Committee [QAC] meeting (ATT 11a. QAC Meeting Minutes) led to the identification of the following activities already ongoing for the childhood immunization program:

- immunization records are provided for review during each visit;
- cards developed with the Denver Health VaxTrax registry are routinely sent out by clinics to children deficient in vaccinations;
- program awards are presented to clinics for immunization of toddlers.

In addition, a new Care Management outreach process has been designed by Denver Health Managed Care to reduce the number of children not coming in for their regular EPSDT well visits for Denver Health Medicaid Choice [DHMC] members (ATT 14a). Other ongoing activities noted at this and previous QAC meetings include:

- mailing EPSDT material as part of the Welcome packet for new members (ATT 14b);
- the development of Provider Education Sessions conducted by Denver Health Product Line Manager for DH Medicaid Choice physicians regarding EPSDT services and billing;
- the design of two electronic mailings for PCPs on EPSDT visits in January 2005 (ATT 15e);
- the design of EPSDT screen savers to be placed on all computers within the Denver Health system including the Family Health clinics (work in progress); and ongoing maintenance activities for Denver Health Immunization Registry—VaxTrax (ATT 4d).

Three barriers to Childhood Immunization were also identified at the Sept. 13, 2005 QAC meeting (ATT 11b):

1) Well Visits are often not coded as such due to inclusion of these activities with another type of primary care visit, suggesting that recorded PCP visits may be an inaccurate representation of well visit activity;
2) Children who lack primary care provider (PCP) visits also tend to lack participation in the immunization program, and
3) For various reasons, some children have no prior record of their immunization history available to their Denver Health PCPs.

Since all three of these barriers pertain to Well Visit activities involving PCPs, it is hoped that by increasing the percentage and number of children who complete all of the recommended Well Visits, that the number of children receiving all the recommended childhood immunizations will increase as well.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

Supporting Documentation. BASELINE 1. A preliminary review of Baseline 1 data supports the premise that a successful completion of the childhood immunization process may be related to the completion of all recommended childhood Well Visits (ATT 12a-d). Baseline 1 data demonstrated that the average number of immunizations a child receives increases in proportion to the number of Well Visits accomplished (R^2 = 0.8831) (see ATT 12e Average Number of Vaccines in Relation to Well Visits). Moreover, a review of members who underwent all of their recommended Well Visits (for which n = 74) shows that the numbers of immunizations received per member averaged 5.97 (ideal result/PIP Goal = 7.00 for full immunizations) and that the percentage of members completing their immunization process for a given number of visits is highest (97.37%) for the 'All Visits' (7 visits) group (see ATT 12f Percent Members Completing Their Immunizations in relation to the Number of Well Visits).

The Intervention Process. Along with continuing to provide PCPs with education sessions on EPSDT and documentation about EPSDT and childhood immunization activities, a series of intervention activities were designed to improve member participation in both the Well Visit and immunization programs. The Intervention Process for this PIP targeting members is the implementation of a combined EPSDT-Reminder Letter Mailing procedure designed to increase the number of well visits and in turn the number of immunizations provided to each child (ATT 13a-b). This intervention process combines a number of ongoing programs, including the Colorado EPSDT program (ATT 13c), Denver Health Managed Care's Care Management program (ATT 14a), and VaxTrax–Denver Health's Childhood Immunization registry program (ATT 4). For each individual involved in the ESPDT program, an EPSDT intervention packet is sent (Attachments 14a-c), followed by a reminder letter for immunization (Attachment 14e), followed by a well visit (documented in Diamond), followed by the entry of immunizations in the VaxTrax registry. Two groups of members are involved in this intervention process: a) families with children <1y/o who are eligible for EPSDT (EPSDT children are <6 y/o); b) children > 1 y/o who will turn two during the study year. Both mailings, although similar, serve different purposes. The mailing to children <1y/o is designed to be proactive, reducing the number of children who miss well visits and do not become part of the DH VaxTrax intervention process in the form of reminder letters sent from VaxTrax (see ATT 13c). The mailing to children who turn 2 y/o during the study period serves to increase the percent of members who successfully catch-up with their immunizations by the age of two during the study period.

Description of Mailings (see ATT 14a-f)

The first mailing—the EPSDT letter–is for all members under six years of age (ATT 14a). This population includes those who turn 2 y/o between 1/1/06 and 12/31/06 (all eligible members with birthdates between 1/1/04 and 12/31/04) and who are therefore eligible for the Baseline 1 PIP study.

Baseline 2. The second mailing—a targeted immunization letter–is planned for members who turn two during the study period (ATT 14e,f) and/or who did not undergo the recommended well visits (based on "no PCP visits" report provided by Information Management Dept, ATT

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

14d).

For the Baseline 2 study period, the first mailing was sent to members in April 2005 (see ATT 14a-c.). This packet informed them of the EPSDT program, including the opportunities provided by Well Visits and the related immunization program at Denver Health. The second mailing (ATT 14e,f), sent in October 2005, targets members with a history of no PCP visits. This letter and the attached information card reminds them of the goals of the immunization program and the role of Well Visits in improving their health.

In sum, by encouraging member participation in the form of PCP visits, it is hoped that more children will complete their immunizations and be entered into Vax Trax during the current study year. By including them in the registry, it is hoped that the reminder mailings sent the members due to the immunization history in VaxTrax will increase their participation in this program.

Counts of Letters Mailed (ATT 14a-f)

For the first year of this intervention (results for the Baseline 2 study), the first letter (ESPDT letter, ATT 14a) was mailed in April to approximately 900 members who had no PCP visits entered into the Diamond records for Denver Health (ATT 14d. EPSDT stats). These mailings targeted special needs children who had only Specialty Encounters and no Well Visits (n=97 for ages 0-6 y/o) and Special Needs children who had no encounters (n=127 for ages 0-6 y/o). No letters were reported as returned.

The second mailing for 2005, the letter on immunizations and well visits mailed in October 2005 (see ATT14e,f. Letter 2), targeted all members <2 y/o who to date lacked PCP visits (approximately 74 members). No letters were returned.

This intervention process will be repeated around the end of the year (December 2005), when a listing of members eligible for the first Re-measurement study period will be generated by Information Management based on the Diamond records. Those members eligible for the PIP will be sent a reminder letter regarding well visit and immunization recommendations by the age of 2.

Limitations

Four limitations are noted for this study. First, the results of the second mailing in October 2005 are limited by the fact that they may impact just three months of activity by members with regarding to reaching the Well Visits and immunizations goals (October 2005 through December 2005). Therefore, these letters have the potential of impacting a small percentage of the Baseline 2 population (less than 25%). In contrast, the earlier mailing of the same packet between December 2005 and January 2006 has the potential of producing a more noticeable impact on the population, providing up to a full year of Well Visits activity for completing any immunization activities. Second, it is important to note that depending on changes in eligibility status in 2006, some members may be eliminated from this PIP study, making any impact produced by the

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

December-January mailing immeasurable. Third, members who turn two years of age between January and February of 2006 are less likely to benefit from this mailing due to the reduced time they have to make up for their Well Visits and immunizations. Fourth, any new members added to the 2006 PIP study eligibility list between November 2005 and January 2006 (3 months time), should they have a history of immunizations and Well Visits not generated by Denver Health Medicaid Choice, still have the potential of impacting our final ratings should their activities and medical history prior to DHMC coverage be limited or non-compliant.

Validity

The population included in the study for a given year is defined by HEDIS eligibility requirements. Beginning with the Baseline 2 study, members included in this study are required to be enrolled for the full year (January 1, 2005 to December 31, 2005), with no more than one 30-day (one month) gap in enrollment.

The intervention process is detailed in the attached chronology and flowchart (ATT 13a-b). Intervention letters are mailed to all members who meet the eligibility requirements for the year of the mailing. For this reason, it is expected that some letters will be mailed to members considered eligible for the study at the time of the mailing, but who later become ineligible due to changes in Medicaid coverage. For this reason, those who re-enroll for DHMC (Year 1) but subsequently disenroll (end of Year 1, beginning Year 2) may be missed for the second intervention depending on when these enrollment lists are produced for this intervention mailing (see ATT 3b). Letters mailed to members under one year of age and who meet eligibility requirements are more likely to be impacted by this effect. Letters mailed to members eligible for the review during the present research year are less likely to be impacted by this sequence of events.

Also impacting the eligible population is the enrollment of new members >6 months of age. During the first six months of age, four of the seven well visits reviewed for this research should have taken place; this represents four of the six visits accomplished by 15 months of age during which all of the immunizations should have been given. This means any members lacking complete immunization after 6 months of age have a greatly reduced likelihood of meeting all the immunization recommendations by 15, 18 or 24 months of age. Should such a member with no history of wellness visits by >6 months year of age become enrolled in Denver Health by 12 to 13 months of age, the lack of immunization due to previous health care activities will have a noticeable impact on the final results for the entire Denver Health Medicaid Choice. Such results are due to enrollment practices rather than member- or member-clinic-related activities.

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

Regression to the Mean. *(Italics added, 6/2006)*

In theory, any changes in immunization rates for the two Baseline Periods may be related to the mailing of letters. However, since the Baseline 2 measurement period is significantly longer than Baseline 1, the population of Medicaid Choice members in this PIP should also be more representative of the total PIP population for a 12 month study. This suggests that any improvements noted may in fact be linked to a Type 1 error scenario—2005 Baseline 2 rates can reflect the results of a more stable study population study that the 2004-2005 Baseline 1 study, resulting in regression toward the true mean for the Denver Health Medicaid Choice population (probability increases).

Opting Out vs. Exclusion from the PIP.

Finally, it is important to note that a small number of families may opt out (parent refuses) of immunization altogether, or opt out of the use of particular forms of immunization. These members are not excluded from the study, however, and therefore still impact overall results. It is equally important to note that these members are not always noted as "opt outs" in the Denver Health medical records or Denver Health and CIIS Immunization registries. Should such members be identified, they remain in the study and their potential impact on the overall results discussed in the conclusion (for Study Results, see Step 9; for Discussion of these Results, Actions taken and Conclusion, see Step 10; Opt out issues are reviewed in ATT 16).

BASELINE 2 Report (NEW). What are the barriers to children getting immunized? (Report for 1/1/05 to 12/31/05 period). <TOC>

Events for Baseline 2 and Intervention 1 Activities (2005 – 2006) (as of 10/1/06). <Back to Table of Contents>

1. Completion of the second annual *EPSDT mailing* (July 2005).
2. Completion of Baseline 1 study and submission (October 2005)
3. Information Systems (IS) Request: List of members eligible for PIP study produced by Information Systems (IS) (December 2005)
4. Development, production and mailing of *Intervention Letter* to populations eligible for review in 2006 and 2007. (December 2005)
5. Completion of *EPSDT mailing* and statistical review (January 2006)
6. Mailing of Intervention letter with card to members in January 2006.
7. Development of *New Incentives Package* for members with Children < 2 y/o (January/February 2006).
8. February/March 2006. Design of new booklet to be added to the next mailing scheduled for June 2006. This booklet will be discussed with staff persons engaged in CHP- and MCD-related activities. It will then be presented to QAC in March or April for final approval. [*Booklet activity replaced by New Incentives Package, August 2006*]
9. Final list of members eligible for PIP study produced by TierMed/IS (February 2006)
10. HEDIS Submission of Childhood Immunization data for 2005 (March 2006)
11. Review of Well Visits data in Medical Records Imagery (tentative date – April/May 2006)

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

12. Return of HEDIS results; review of final results by PIP Researchers (April/May 2006).
13. IS Request: list of members eligible for 2006 review of immunizations and well visits. Sent out new packet and booklet to these members (May 2006).
14. QAC presentation on HEDIS results (May/June/July 2006)
15. Report to QAC on status of PIP (July/Aug/Sept 2006).
16. Completion of the second annual *EPSDT mailing* (July 1, 2006).
17. Review of statistics related to *EPSDT mailings* for year by IS (August 2006)
18. Implementation of *New Incentives Package* for member regarding completion of Childhood Immunization/Well Visits activities (August/September 2006). [8 returns as of 9/1/06, 6 with immunizations completed].
19. Completion of PIP—Baseline 2 version for submission in October 2006*; presentation to QAC (September 12, 2006)*
20. Prepare PIP for review by QAC in September 2006.
21. Submission of PIP for final review (October 2006)
22. Begin developing database with TierMed for 2007 HEDIS: VaxTrax data form and quality to be reviewed (Oct/Nov 2006).
23. Develop new eligible members list using TierMed dataset; mail new Intervention letters (Dec 2006/Jan 2007).

NOTE: For updated versions of the above activities, see ATTs 11 (QAC minutes), 13 (flowcharts) and 14 (letters and results). A new version of ATT 12 was not produced for the 2005 activities summarized in this 2006 PIP update.

Intervention activities for Baseline 2 **(See chronological listing at end of this section, p. 28)**

Impact of Population Change on Research and Analysis Methodology. In 2005 and 2006 the Medicaid Choice population size underwent a substantial change in size (see p. 18, Population Size). Such shifts should not impact statistical results for any related intervention studies. One of the more important outcomes of an increase in population pertains to research methodology: the Baseline 2 study reviewed the entire eligible population; the methodology used for next study (Intervention 1) will be a population sampling technique based on HEDIS methodologies.

Validity and reliability. Between November and December of 2005, the possibility for changes in validity (data truthfulness and accuracy) of the study had to be considered due to changes in the contracting agencies for this project in 2006 (from QMark for the 2005 PIP, to TierMed for the 2006 PIP). For this reason, data production, handling, storage and analysis techniques were reviewed with the newly contracted agency (TierMed) from December 2005 to January 2006. This assessment was followed by a review of the validity, reliability and reproducibility through a second running of the same dataset used for Baseline 1 study. (The results of this review are summarized in ATTACHMENT 7.)

Upon completion of this validation process and acceptance of Tiermed's results, the collection of data for Baseline 2 began in late January 2006. Due to the automation of many of the initial data collection processes, some improvements in our HEDIS results were expected. However, other activities

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

engaged in as part of the manual (Hybrid) portion of the data entry process remain unchanged. In theory, the final outcomes expected for these changes include better reporting and the production of truer results by the Baseline 2 study. In actuality, a methodology-related error, predicted in the 2005 PIP submission, took place as well: a *regression to the mean* occurred due to changes in the study period (from 6 months in 2005 to 12 months in 2006) (for more, see Step 8, p. 29).

Attachments for SYSTEM-RELATED INTERVENTION ACTIVITIES. Baseline 2. (2005 Activities)

A number of system-related activities are worth noting due to their potential impact on other member activities related to well visits and immunization practices. Each of the following may be provided to Medicaid Choice members at any time during the visit encounters, examples of which include (see ATT 15):

Activity	*Presented as part of*
➢ Intervention Postcard mailed by DH clinics	(BASELINE 1)
➢ EPSDT Activities for 6-2005 to 9-2006 (continuing into 2006/7).	(BASELINE 1)
➢ Reminder letters mailed by DH, based on VaxTrax entries	(BASELINE 2)
➢ Best Babies program information	(BASELINE 2)
➢ CHP+ activities information	(BASELINE 2)
➢ WIC information	(BASELINE 2)
➢ "Milestones" booklet	(BASELINE 2)

INTERVENTION YEAR 1 REPORT. <Back to TOC> **[NEW]**

Changes on Well visits activities and performance (i.e. coding, billing, scope of performance including improve provider and member education on well visits and immunizations). Newsletter Insert and developing a Newborn Database (in process). SYSTEM ACTIVITY.

INTERVENTION YEAR 2 REPORT. <Back to TOC>

To be completed in 2008.

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

Chronology of All Mailings for this PIP (ATT 14)

- BASELINE 1. 2005. Letter 1 (ATT 14a-d), July/August 2005--EPSDT packet and letter for 'No PCP Visits' for Special Needs Children. This mailing included letters mailed to members in the age range eligible for this study (0-2 y/o); no returns were reported. (see ATT 14, p. 7-10, p. 11 for results--424/902 visits; 12 immunizations received.)
- BASELINE 1. 2005. Letter 2 (ATT 14e-f; ATT 14, p. 12-16), September, October 2005. Combined Well Visit/Immunization Letter sent: *a)* to all members between 0 and 2 y/o regarding immunization recommendations, *b)* to all members ≤2 y/o lacking well visits. Based on an October 1, 2005 query of MCD membership. A total of 74 letters were sent to children ≤2 years of age considered eligible for the 2005 Baseline 2 study. Twelve of these letters targeted new children eligible for the PIP study who were between 1 and 2 years of age and considered possibly eligible for the upcoming HEDIS. No returns are noted.
- BASELINE 2. 2006. Letter 3. (ATT 14g; ATT 14, p. 18), December 2005. Baseline 1, Letter 2 revised, printed in tricolor form; sent regarding immunizations and well visits to be completed by the Age of 2. Mailing list based on a November 2005 query of MCD membership for children <=2 years of age, all of which were considered eligible for the 2005 Baseline 2 study. Packet included blue Benefits card. No returns noted.
- BASELINE 2. 2006. Letter 4 ['No PCP Visit' letter, June 2006]. (ATT 14 pp. 27-31 (stats), 33-34 (letter)), June & July 2006 activities. BASELINE 2 mailing, targeting INTERVENTION 1 population. This new letter with well visit information (3 pp) was sent to all members <2 yo in July 2006. This letter targets by mothers/guardians with regard to well visits, anticipatory guidance actions taken by the PCP, and any related immunization or immunization update activities. Three returns noted.
- BASELINE 2. 2006. Letter 5. (ATT 14, pp, 35-39), June & July 2006 activities. BASELINE 2, Letter 3 revised, printed in **tricolor** form, and sent in July 2006 regarding immunizations and well visits to be completed by the Age of 2. Mailing list based on a query of MCD membership for children <=2 years of age and who may be considered eligible for the Intervention 1 study. Packet included a form filled out by the parent/guardian for a Coupon awarded upon completion of the childhood immunization series (including 4 Pneumococcal conjugate or PCV7 vaccines). No returns noted. (See pp. 43-47 for coupon responses).
- **INTERVENTION 1, Letter 6. December 2006. Reminder letter (same form as above) on value of immunizations and well visits for children who will turn two in 2007 and who have not yet received all of their immunizations.**

G. Activity VII. Improvement Strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or beneficiary level.

Chronology of All Mailings for this PIP (ATT 14) (continued)

- **INTERVENTION 2, Letter 7. June/July 2007. Tricolor Letter re-dated; sent regarding immunizations and well visits to be completed by the Age of 2. Mailing list based on a query of MCD membership for children <=2 years of age requested June 2007.**
- **INTERVENTION 2, Newsletter Mailing insert. June/July 2007. 'Well Visit' letter (see June 2006 notes, ATT 14 (letter)). A letter with well visit information was sent to all members <2 yo in July 2007. This letter targets by mothers/guardians with regard to well visits, anticipatory guidance actions taken by the PCP, and any related immunization or immunization update activities.**
- **INTERVENTION 2, NEWSLETTER INSERT. June/July 2007. "Well Visit" newsletter insert (see June 2007 notes, ATT 14 (newsletter insert)). This newsletter insert targets mothers/guardians and provides information on the importance of well visits, number of well visits, anticipatory guidance, and required immunizations by age 2.**
- **INTERVENTION 2, Letter 9. Planned for December 2007. Tricolor Letter re-dated; sent regarding immunizations and well visits to be completed by the Age of 2. Reminder letter (same form as above) on value of immunizations and well visits for children who will turn two in 2007 and who have not yet received all of their immunizations.**

H. Activity VIII. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

BASELINE 1 (Unedited). To monitor the success of our mailings, numbers of returned letters are recorded. Letters that are not returned are assumed to have reached the target address and planned recipient. A successful mailing of 90% is the goal of this project. This number and percentage of success will be graphed and reported as part of our trends analysis.

In addition, each immunization result documented as measurements 1 through 8 in the PIP is graphed. The Chi-Squared equation will be used to compare results from one study period to the next (see Step 8). The two sequential Baseline measurements will be kept as separate measures and not combined. Chronological and comparative bar charts will be used for immunizations and their combinations (see Step 10—Graphs). If necessary, the outcomes for different clinics will be compared to see if significant differences in performance or performance improvement exist at a clinic level.

Although discussed in a review of Baseline 1 results, it is important to note that Well Visits are part of our EPSDT-related activities but not part of the reported data. Reviews of the Well Visit data may be graphed as a part of this study, and will be regularly included in any discussion of results.

BASELINE 2 (Unedited). Overall methodology remains unchanged.

For Baseline 2 activities, mailings were carried out according to above chronology (see pp. 25, 27, 28 and attached Chronology).

As anticipated during the preliminary review of Baseline 1 results in 2005 (see previous page), a *Regression to the Mean* occurred in 2006 and is partly responsible for the significant changes noted in the Baseline 2 study. This means that the Baseline 2 results more accurately reflect the activities of a Medicaid Choice population considered eligible for this study according to HEDIS standards. Two primary reasons for these improvements are worth noting: 1) for Baseline 1, by extracting a study population from a large population of members without regard to HEDIS requirements (one full year's worth of eligibility, with just one month lapse in membership), the likelihood that less active members might be included in the study group increases, i.e. members who do not engage in immunization-related well visit activities with their physicians (resulting in reductions in VaxTrax database entries), and 2) for Baseline 2, by increasing the period of study from six months to twelve months, the amount of time allowed for members to fully participate in the appropriate well visit activities is increased, thereby increasing the opportunity for completion of immunization sequences.

Due to regression to the means, results following Baseline 2 will not be compared to Baseline 1 results. Baseline 1 results are excluded from any subsequent analysis and Baseline 2 will be used as the true Baseline measure for reviewing Intervention 1 results.

H. Activity VIII. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

Notes on Analysis (Unedited)

No Odds Ratio (Chi-squared test) was performed to compare Baseline 1 and Baseline 2 results since a *Regression to the Mean* was observed.

Chi square methods will be used to compare the Baseline 2 (2005 activities) results evaluated for HEDIS 2006 with the Intervention 1 (2006 activities) results evaluated for HEDIS 2007 (see ATT 9—UNCHANGED).

Measures will be based on p = 0.05, unless otherwise noted.

Results are trended and graphed to demonstrate ongoing change and/or improvement in the childhood immunization rates (see Step 10. 'Graphs' section).

RESULTS

BASELINE 1 [UNEDITED].

In April 2005 a letter and EPSDT packet was sent to 902 members who had no visits with their provider, reminding them of the importance of well visits (ATT14a-c, for schedule, see ATT 13d). According to administrative data extracted from Diamond, there were 424 well visits and 12 immunization visits following the mailing of this letter (ATT 14d). The impact of this letter/packet can be evaluated by comparing it with the Baseline 1 measurement period (August 1, 2004 to Jan. 31, 2005), which preceded this EPSDT mailing.

In October 2005, a second letter was sent to all eligible members describing the immunizations provided to them through the well visits program. This letter may be repeated depending upon whether or not new members are included on the updated lists to be produced for the MCD population <2 y/o.

BASELINE 2. <Back to Table of Contents>

The first intervention-related mailing for mid-January 2006 is nearly identical in content to the Immunizations-Well Visits letter mailed in October 2005. It was a tricolor version of the previous letter, sent as a two-sided copy with English on one side and Spanish on the other, and included information on submitting a completed immunization record based on Combo 3 in order to receive **a grocery store certificate.** This mailing was sent to 176 members who were <2 y/o and considered potentially eligible for the next PIP study of childhood immunization. This mailing will be repeated for each re-measurement year.

H. Activity VIII. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

The second letter, dated December 2005, targeted members under the age of 2 y/o who were expected to undergo immunizations and/or Well Visits between January 1, 2006 and December 31, 2006. This letter encourages the parent/guardian to make an appointment and make sure all of the immunizations required by the child are completed by the child's second birthday. *This letter relates primarily to the 2006 PIP study.* This mailing will be repeated for each re-measurement year.

INTERVENTION 1. **The previous mailing was updated in form and content and mailed in July 2006 to members eligible for the Intervention 1 review (2006 activities studied in 2007). As above, this letter included form to be filled for a grocery store coupon, which is rewarded to all members who complete their immunizations by 2 yo (see ATT 14, pp. 35-38). removed**

Returned Mail.

Three returned for Well Visits notification as of July 30, 2006.

DISCUSSION OF RESULTS.

BASELINE 1 to BASELINE 2. Following review of a Baseline 2 data, Baseline 1 results were re-evaluated and interpreted as preliminary data due to *Regression to the Means*-based error (as previously discussed, p. 26). For this reason, Baseline 1 results are eliminated from any future analyses. Baseline 2 results are considered true baseline values.

BASELINE 2 to INTERVENTION 1.

Baseline 2 results demonstrate a considerably high percentage of completed immunization sequences except Pneumococcal Conjugate (new for HEDIS 2006). For this reason, the following two measures most likely provide the best opportunity to demonstrate sustained improvement:

a) completion of four Pneumococcal conjugate vaccines (PCVs) by the age of two years,

b) completion of the entire series of immunizations for DTP/DtaP (3 immunizations by 2 y/o), IPV/IPoV (4), Hep B (3), HIB (3), MMR (1), VZV (1, or history of Chicken Pox), and PCV7 (4).

Since all results were well above the Colorado mean for Medicaid, the following outcomes are needed to reach these goals:

1) Maintain the high percentage of completion for Combo 2 and all immunization sequences included in the Combo 2 measure.

2) Focus on intervention activities that result in the completion of all four PCV immunizations by the age of two years.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

H. Activity VIII. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

Events favoring this approach: The rates for completion of PCV7 are considerably less than the immunizations measured for previous childhood immunization studies. Since this is a first year study, popularization of the PCV7 sequence will not only improve both public and PCP

performances but also increase awareness of this part of the immunization program, thereby increasing rates of reporting and engagement in PCV7-related immunization activities such as well visits.

Events possibly confounding the related 2007 research results: new goals for immunizations in 2006 may not be valid for upcoming years due to the changes in membership.

At the September 12, 2005 QAC Meeting, it was decided that the Goals for all immunizations would be set at 90%, the institutional goals set for the same for all Denver Health childhood immunization intervention activities. This was due in part to concerns that significant changes in population size as of 2006, have a considerable impact on final childhood immunization percentages. The goals for all immunization rates, including the new pneumococcal conjugate and combination 3 rates are therefore 90%.

Baseline 2 Related Materials

QAC Meeting minutes (include Guideline and Goals discussions)
Childhood Immunization Guidelines–Update regarding Pneumococcal Conjugate and Combo 3.
Intervention Letters
EPSDT Mailings (July 2005, January 2006, July 2006)
New Incentives Package (August 2006)
HEDIS/ TierMed results for 2006

H. Activity VIII. Data analysis and interpretation of study results: Describe the data analysis process on the selected clinical or non-clinical study indicators. Include the statistical analysis techniques utilized.

INTERVENTION 1. Results.

A chi-square analysis and graphing of Baseline 2 and Intervention 1 results performed in July of 2007, following validation of HEDIS data from Tiermed, successful completion of the HEDIS audit, and submission of HEDIS 2007 to NCQA.

At the September 11, 2007 MMC Meeting, it was decided that the Goals for all immunizations would be set to be NCQA 90th percentile and the same for all Denver Health childhood immunization intervention activities. This was due in part to concerns that significant changes in population size as of 2007 have a considerable impact on final childhood immunization percentages. The goals forl immunization rates are as follows: DTP (89%), IPV, MMR, Hib, and HepB(95%); VZV(94%), Pneumococcal(64%), Combo 2(83%) and Combo 3(58%).

Intervention 1 Related Materials

MMC Meeting minutes (include Guideline and Goals discussions)
Childhood Immunization Guidelines–Update regarding Pneumococcal Conjugate and Combo 3.
Intervention Letters
EPSDT Mailings (July 2005, July 2007)
HEDIS/ TierMed results for 2007

INTERVENTION 2. Results

Pending the 2008 HEDIS review.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

I. Activity IX. Reported Improvement: Describe any meaningful change in performance observed between baseline measurement(s) and remeasurement(s).

#1 Quantifiable Measure: DTP/DtaP Immunization (Goal = 80.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance* (NOTE: Chi-Sq test performed for all measures comparing baseline 2 to remeasurement 1 $p = 0.05$)
					2005 NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	137	217	63.13%	75.7% *(2004 50th%ile]*	57.7%	Chi-Sq: Not Significant P value = 0.42
1/1/05 to 12/31/05	**Baseline 2:**	72	81	88.89%	85.8% (2005 90th%ile]	66.3%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**78**	**92**	**84.78%**	**88.9% (2006 90th%ile]**	**Not available**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

#2 Quantifiable Measure: IPV Immunization (Goal = 85.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	161	217	74.19%	88.4% *(2004 50th%ile]*	66.2%	Chi-Sq: Not Significant P value = 0.35
1/1/05 to 12/31/05	**Baseline 2:**	77	81	95.06%	92.8% (2005 90th%ile]	75.0%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**85**	**92**	**92.39%**	**94.70% (2006 90th%ile]**	**Not available**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

I. Activity IX. Reported Improvement: Describe any meaningful change in performance observed between baseline measurement(s) and remeasurement(s).

#3 Quantifiable Measure: MMR Immunization (Goal = 82.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	148	217	68.20%	88.3% *(2004 50th%ile]*	72.5%	Chi-Sq: Not Significant P value = 0.42
1/1/05 to 12/31/05	**Baseline 2:**	76	81	93.83%	94.1% (2005 90th*%ile]*	79.5%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**88**	**92**	**95.65%**	**95.3% (2006 90th*%ile]***	**Not available**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

#4 Quantifiable Measure: Haemophilus influenza type b Immunization (Goal = 79.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	139	217	64.06%	80.3% *(2004 50th%ile]*	60.8%	Chi-Sq: Not Significant P value = 0.46
1/1/05 to 12/31/05	**Baseline 2:**	77	81	95.06%	88.3% (2005 90th*%ile]*	77.8%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**86**	**92**	**93.48%**	**95.1% (2006 90th*%ile]***	**Not available**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

I. Activity IX. Reported Improvement: Describe any meaningful change in performance observed between baseline measurement(s) and remeasurement(s).

#5 Quantifiable Measure: Hepatitis B Immunization (Goal = 80.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	154	217	70.97%	82.7% *(2004 50th%ile]*	63.2%	Chi-Sq: Not Significant P value = 0.82
1/1/05 to 12/31/05	**Baseline 2:**	75	81	92.59%	91.2% (2005 90th%ile]	73.9%	
1/1/06 to 12/31/06	**Remeasurement 1:**	86	92	93.48%	95.2 % (2006 90th%ile]	Not available	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

#6 Quantifiable Measure: VZV (Chicken Pox) Immunization (Goal = 83.0%)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	142	217	65.44%	84.2% *(2004 50th%ile]*	69.7%	Chi-Sq: Not Significant P value = 0.30
1/1/05 to 12/31/05	**Baseline 2:**	75	81	92.59%	92.2% (2005 90th%ile]	77.5%	
1/1/06 to 12/31/06	**Remeasurement 1:**	88	92	95.65%	93.8% (2006 90th%ile]	Not available	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

I. Activity IX. Reported Improvement: Describe any meaningful change in performance observed between baseline measurement(s) and remeasurement(s).

#7 Quantifiable Measure: Combo 1 Immunization (DTP, IPV, MMR, Hep B, Hib) (Goal = 70.5%) *REMOVED FROM PIP as of 2006.*

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	123	217	56.68%	65.0%	47.1%	RETIRED
1/1/05 to 12/31/05	**Baseline 2:**		RETIRED		RETIRED	----	
1/1/06 to 12/31/06	**Remeasurement 1:**						
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

#8 Quantifiable Measure: Pneumococcal Conjugate Immunization (Goal = tbd)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***						
1/1/05 to 12/31/05	**Baseline 2 (NEW):**	70	81	86.42%	NEW	34.6%	Chi-Sq Not Significant P value = 0.92
1/1/06 to 12/31/06	**Remeasurement 1:**	**80**	**92**	**86.96%**	**64.2%** **(2006 90th *%ile]***	**Not available**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

I. Activity IX. Reported Improvement: Describe any meaningful change in performance observed between baseline measurement(s) and remeasurement(s).

#9 Quantifiable Measure: Combo 2 Immunization (completion of DTP, IPV, MMR, Hep B, Hib and VZV) (Goal = 70.0%) <Back to Table of Contents>

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***	123	217	56.68%	65.0% *(2004 50th%ile]*	47.1%	Chi-Sq Not Significant P value = 0.92
1/1/05 to 12/31/05	**Baseline 2:**	69	81	85.19%	75.7% (2005 90th%ile]	58.2%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**78**	**92**	**84.78%**	**82.7% (2006 90th%ile]**	**69.54%**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

#10 Quantifiable Measure: Combo 3 Immunization (all of Combo 2 plus VZV) (Goal = tbd)

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Benchmarks		Statistical Test and Significance*
					NCQA 90th %ile for Medicaid	HEDIS Colorado Medicaid	
8/1/04 to 1/31/05	***Baseline 1:***						Chi-Sq: Not Significant P value = 0.43
1/1/05 to 12/31/05	**Baseline 2 (NEW):**	64	81	79.01%	NEW	30.3%	
1/1/06 to 12/31/06	**Remeasurement 1:**	**77**	**92**	**83.70%**	**57.8% (2006 90th%ile]**	**64.48%**	
1/1/07 to 12/31/07	**Remeasurement 2:**						
1/1/08 to 12/31/08	**Remeasurement 3:**						
1/1/09 to 12/31/09	**Remeasurement 4:**						

*If used, specify the test, p value, and specific measurements (e.g., baseline 1 to baseline #2, remeasurement #1 to remeasurement #2, etc., or baseline to final remeasurement) included in the calculations.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

J. Activity X. Sustained improvement: Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random, year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.

BASELINE 1. The Baseline 1 measurement for August 1, 2004 to January 31, 2005 was completed in July 2005. The BASELINE 2 measurement period is 1/1/05 to 12/31/05. The Remeasurement 1 period is 1/1/06 to 12/31/06.

Content of Letters (ATT 14 a-f):

a) The first intervention is a letter mailed to members regarding well visit activities for EPSDT. For example, the EPSDT mailing sent in April 2005 contained: a cover letter (Att 14a), a pamphlet or similar educational materials (Att 14b), and a card detailing Medicaid Choice benefits (Att 14c). Subsequent mailings will include a cover letter (14e) and a card (3' x 5' light blue in 2005) detailing Medicaid Choice benefits and informing members of immunizations and well visits and steps to take for obtaining or changing a PCP (see attached card, Att 14e). In future years, this mailing would take place around June.

b) Welcome calls (not evaluated or monitored for this PIP) will be performed in the usual fashion for each new members; if needed, materials similar to the EPSDT packet will be mailed to each individual contacted. These contacts have no specific schedule and these activities are not evaluated for this PIP. (see Att 15b-c)

c) The second intervention letter targeting members eligible for the PIP study for the year will be mailed around December and is not expected to change. This mailing will be performed as close to the months of December-January as possible, and any variations in this process will be noted for each year of performance (Att 14e-f).

d) The third intervention packet mailed in June 2006 consists of the improved tricolor second intervention letter and a booklet designed in February and March 2006 and approved by all staff members involved and QAC by April 2006.

Year to year variations in intervention activities are anticipated with regard to the date for mailing the intervention packet of materials. Moreover, due to changes in finances and coverage of expenditures, the types of packets mailed from year to year may vary slightly in their contents. For the first Intervention letter (EPSDT information) mailed in 2005, pamphlets were already printed and provided by the Colorado Department of Health Care Policy & Financing. In the future, mailings may also be changed or limited due to changes in availability and/or costs of the information mailed. For such cases, similar information will be delivered to members, through the use of similar if not identical educational information or materials.

Regarding the Study Population for the Baseline 1 study:

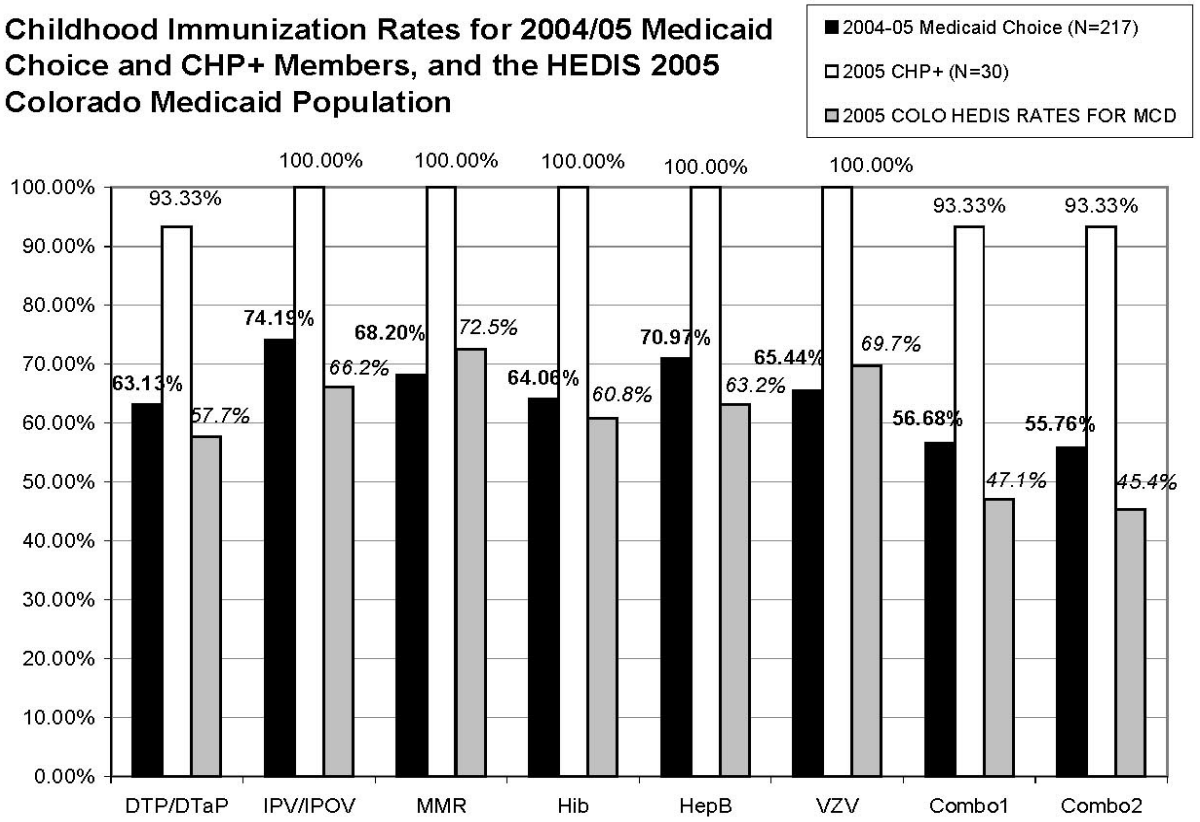
a. The entire population eligible for this study according to HEDIS guidelines will be used; no sampling will be done.
b. Random year-to-year variations in population size and content are anticipated for this PIP.
c. With the exception of the January 2005 overlap for the periods reviewed for Baselines 1 and 2, members eligible for one study year are never eligible for any other study year.

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

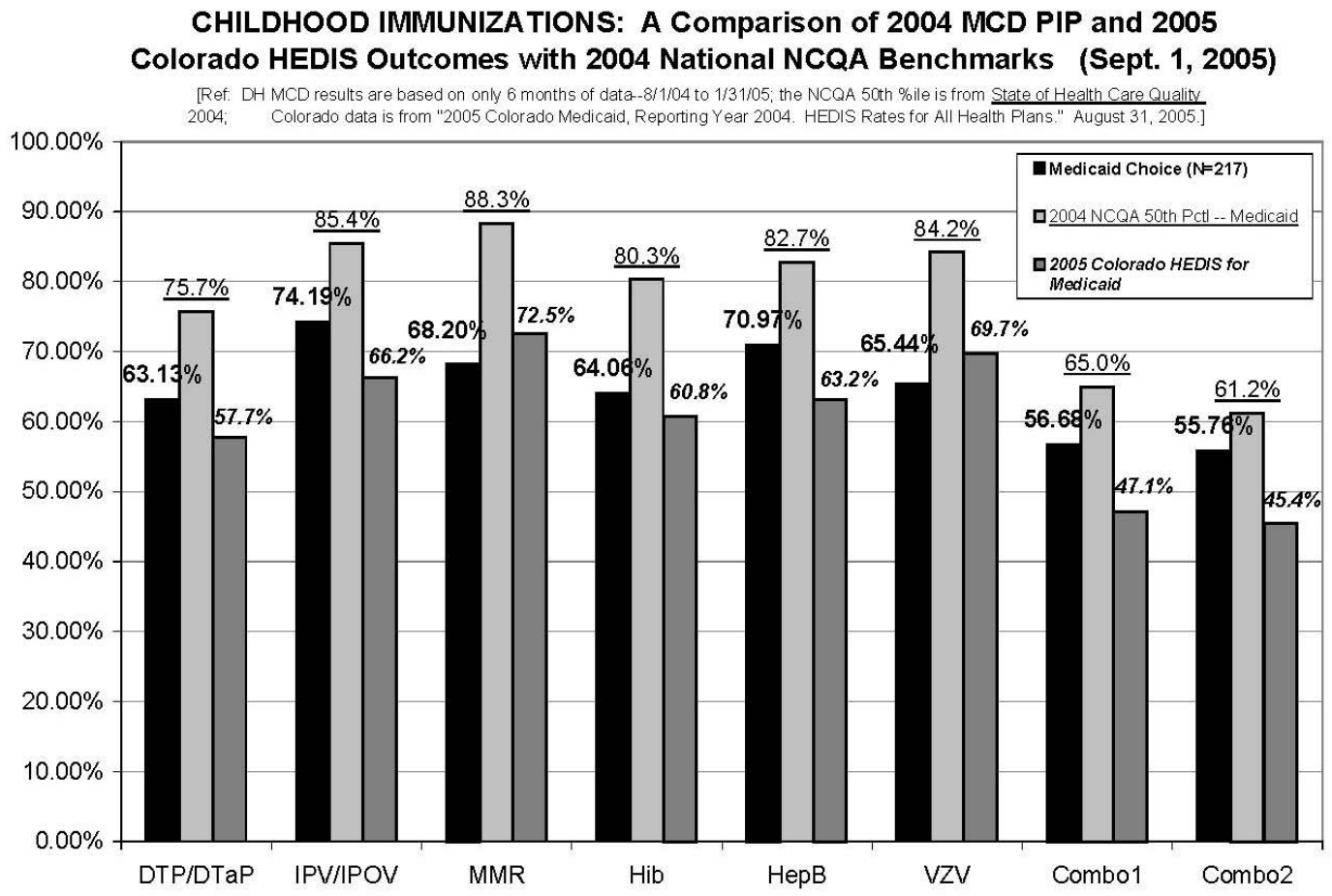
J. Activity X. Sustained improvement: Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random, year-to-year variation, population changes, and sampling error that may have occurred during the remeasurement process.
BASELINE 2 (NEW). Note changes in study population (p. 12). Evidence for <u>*sustained improvement*</u> will begin with a review of results from the first Intervention year (review not expected until July 2008 when HEDIS 2008 completed).
INTERVENTION 1. Assessment of Intervention 1 is completed. Note changes in study population (p.12). The following is based on the Childhood Immunizations results in the 2006-2007 External Quality Review Technical Report for Colorado Medicaid Managed Care published by HSAG for Quality Performance by Colorado Medicaid Health Plans and PCPP in 2007. DHMC had the highest rates for Comobo 2 & 3 compared to the other plans. **<u>DHMC:</u>** **Combo 2 - 84.78% and Combo 3 - 83.70%** **<u>RMHP</u> :** **Combo 2 – 74.46% and Combo 3 – 68.01%** **<u>PCPP:</u>** **Combo 2 – 49.39% and Combo 3 – 41.72%** **Additional rate improvements in HEDIS 2007 for Combo 2 and Combo 3 compared to the HEDIS 2006 90th percentile results are the following::** **Combo 2- 84.78% (82.7% 90th Percentile)** **Combo 3- 83.70% (57.80% 90th Percentile)** **DHMC was above the HEDIS 2006 90th Percentile ratings for both Combo 2 & 3.**
INTERVENTION 2. Assessment of Intervention 2 to be completed in 2008. ***<u>sustained improvement</u>***

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

Baseline 1 – GRAPHS <Back to Table of Contents>

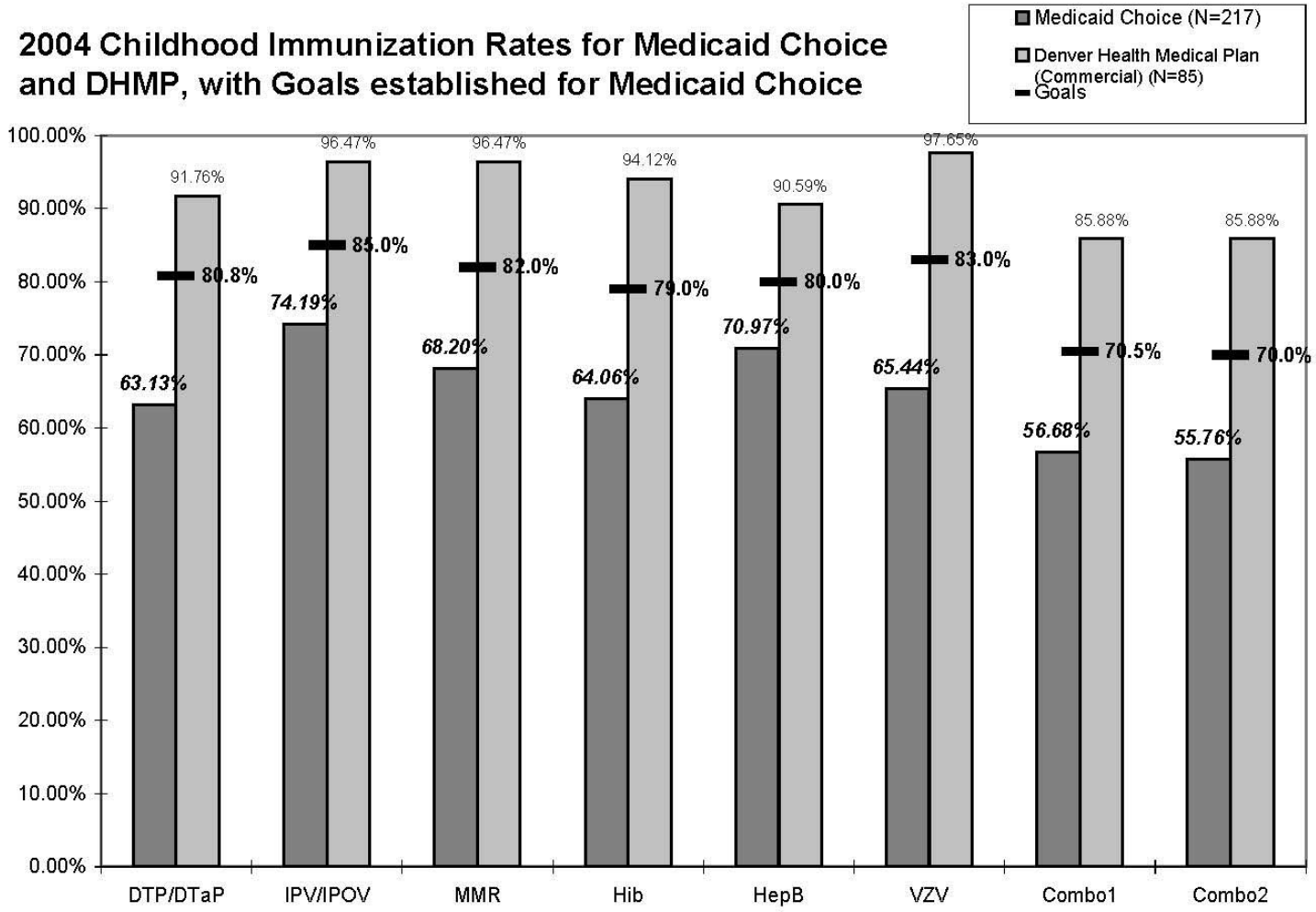


Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice



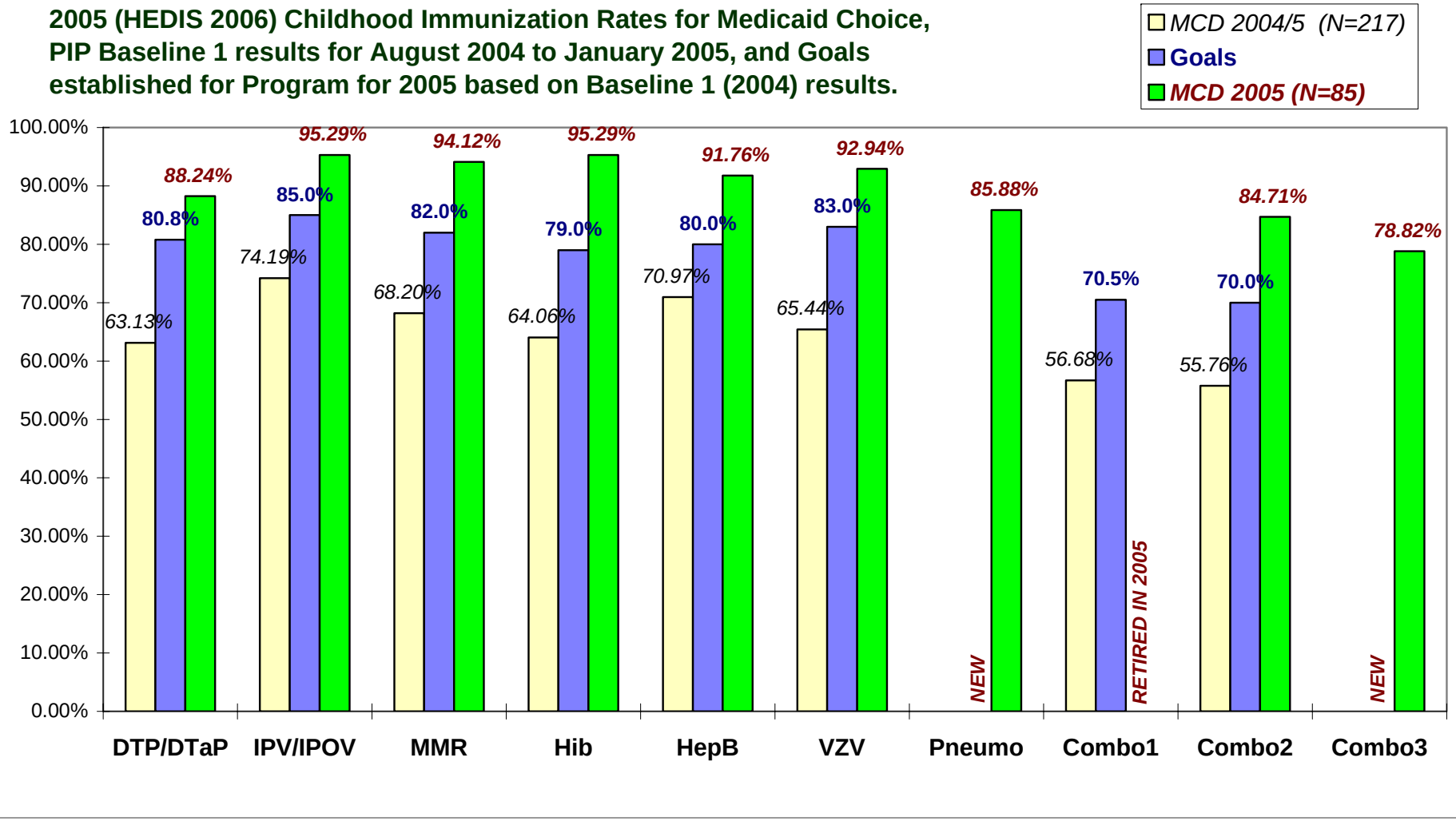
Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

2004 Childhood Immunization PIP



BASELINE 2 -- GRAPHS <Back to Table of Contents>

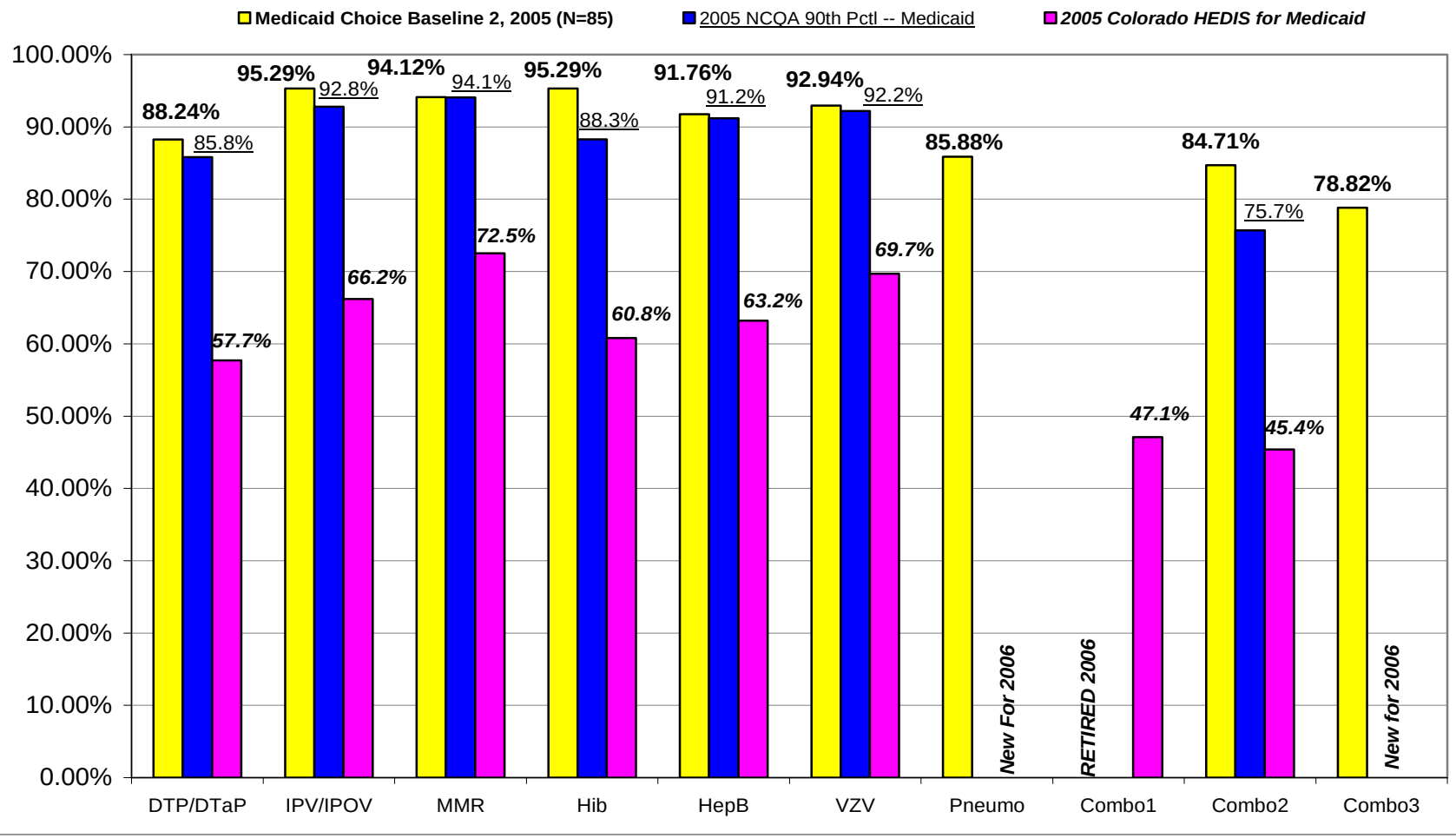
2005 (HEDIS 2006) Childhood Immunization Rates for Medicaid Choice, PIP Baseline 1 results for August 2004 to January 2005, and Goals established for Program for 2005 based on Baseline 1 (2004) results.



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

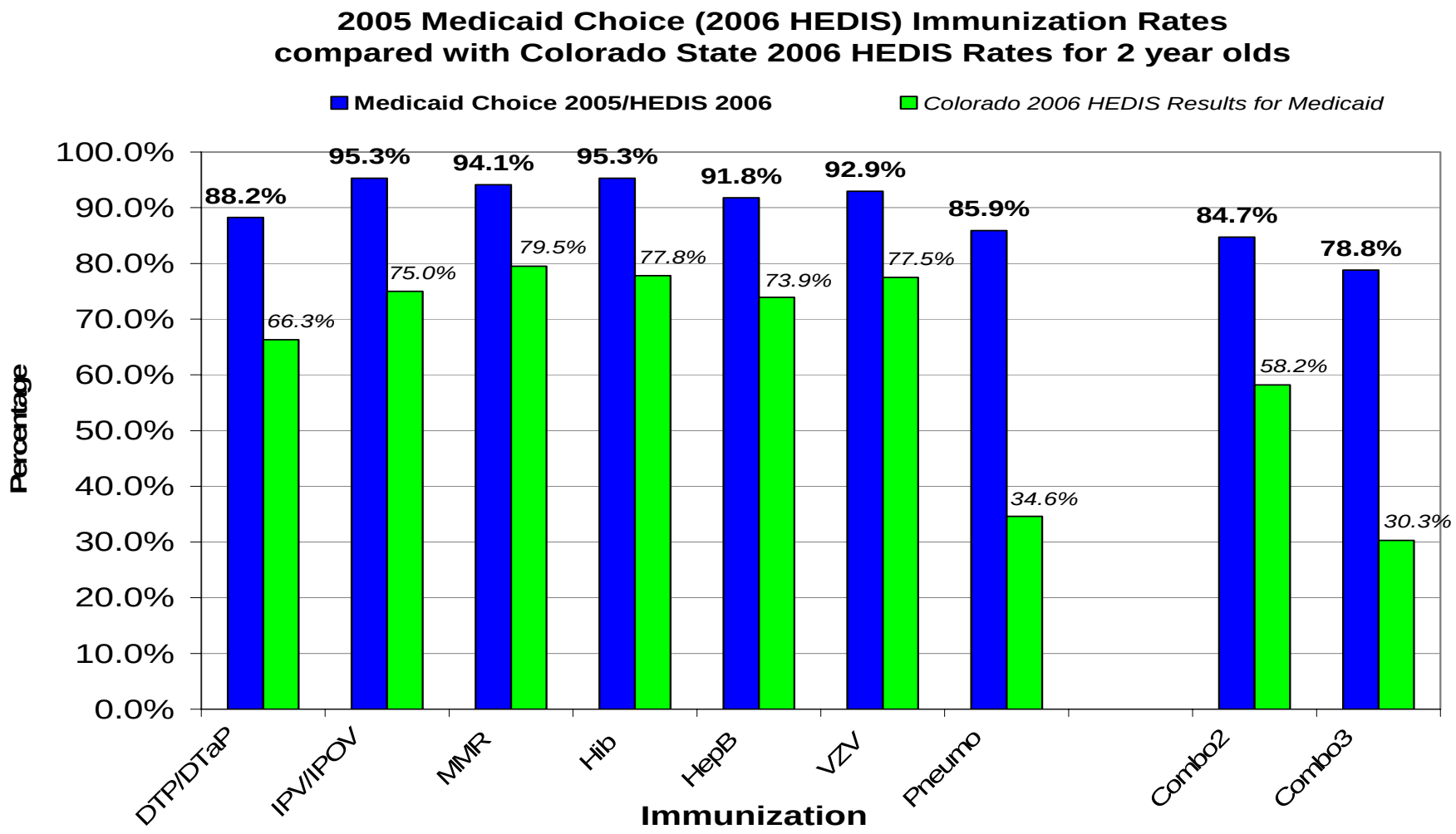
CHILDHOOD IMMUNIZATIONS: A Comparison of 2005 MCD PIP (2006 HEDIS) and 2005 Colorado HEDIS Outcomes with 2005 National NCQA Benchmarks (8/17/06)

[Ref: DH MCD results are based on the 2005 HEDIS results; the NCQA 50th %ile is from State of Health Care Quality 2004; Colorado data is from "2005 Colorado Medicaid, Reporting Year 2004. HEDIS Rates for All Health Plans." August 31, 2005.]

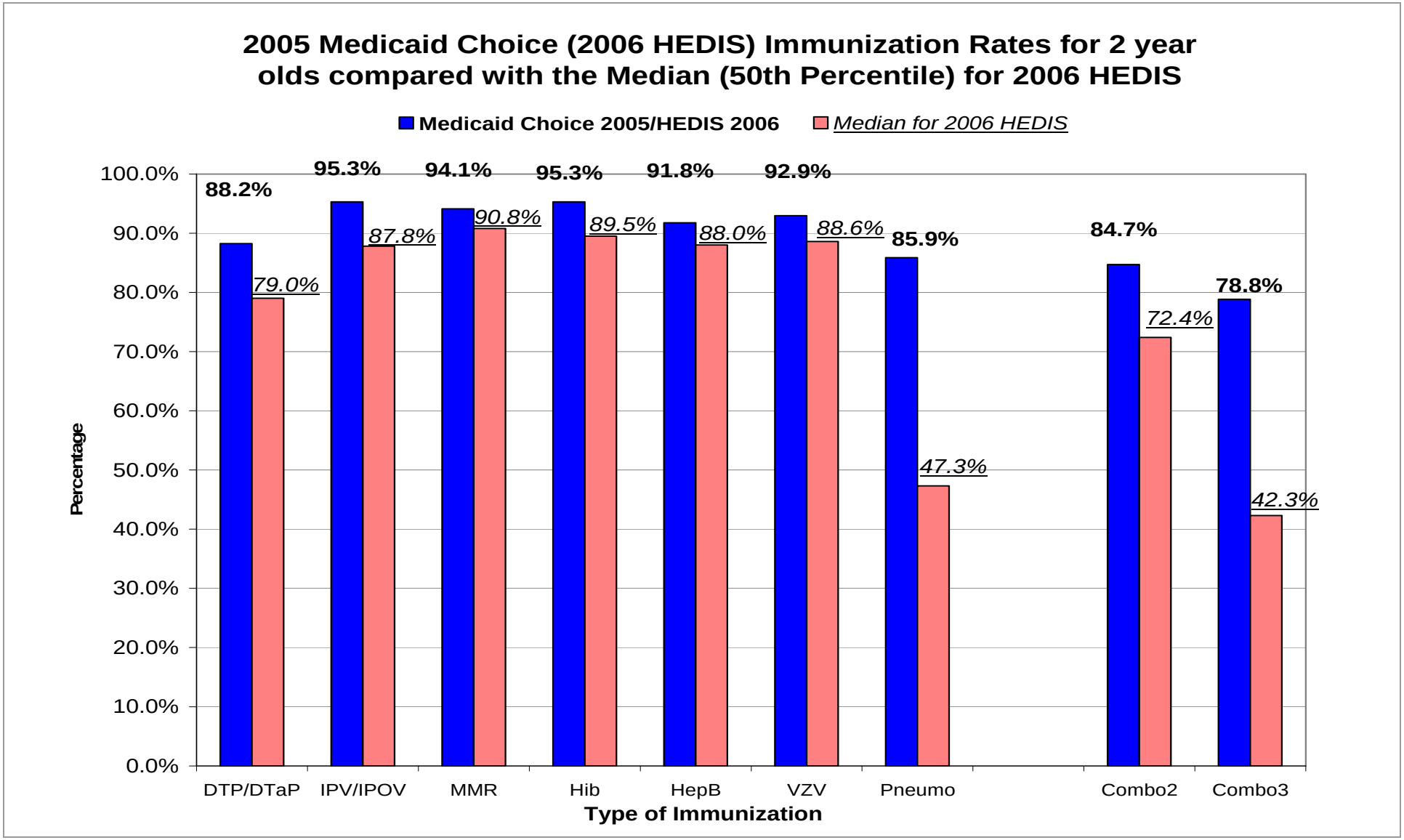


Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

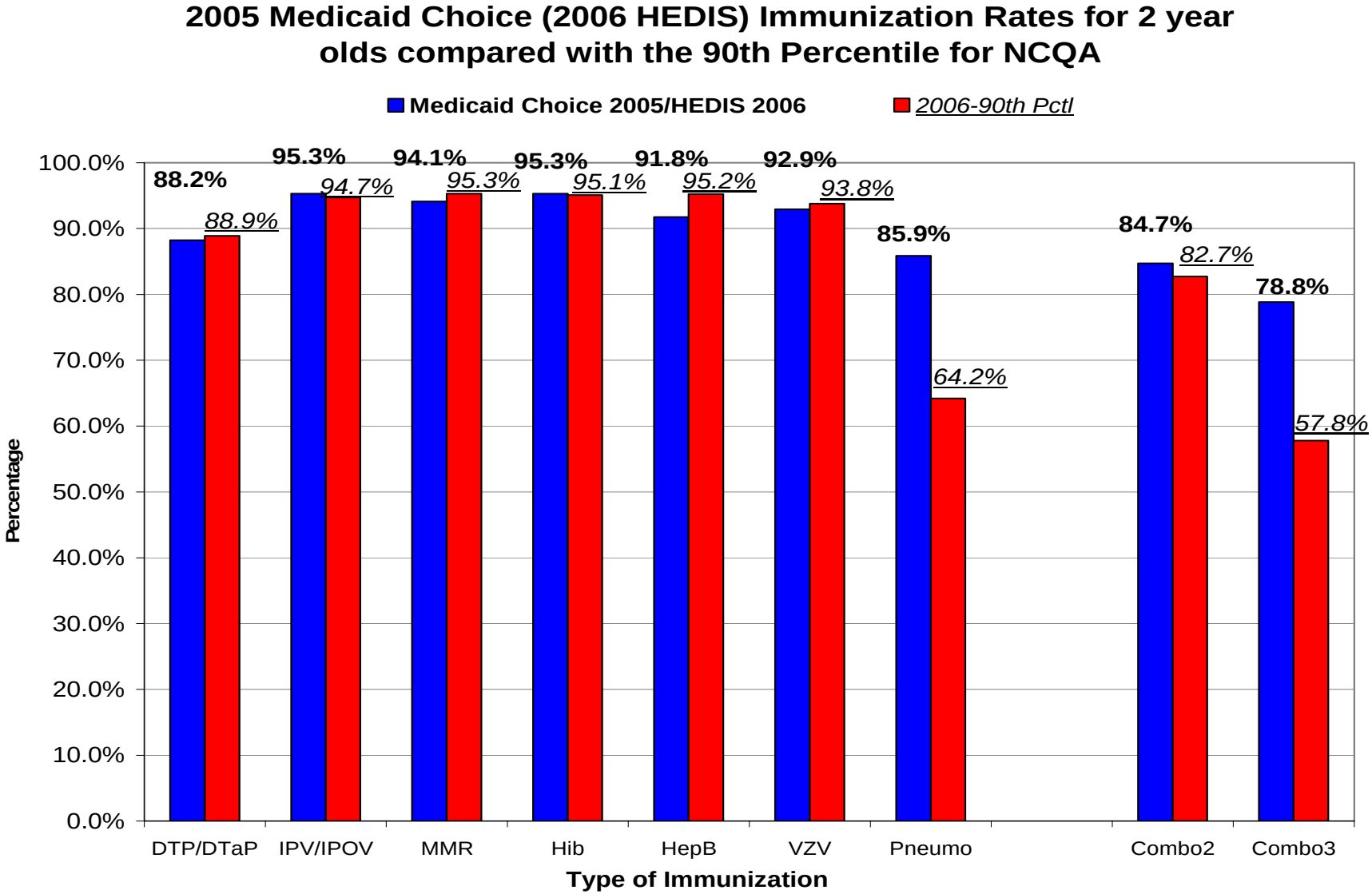
UPDATED GRAPHS USED FOR MAY 2006 PRESENTATION
(with updated COLORADO and NCQA Stats)



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

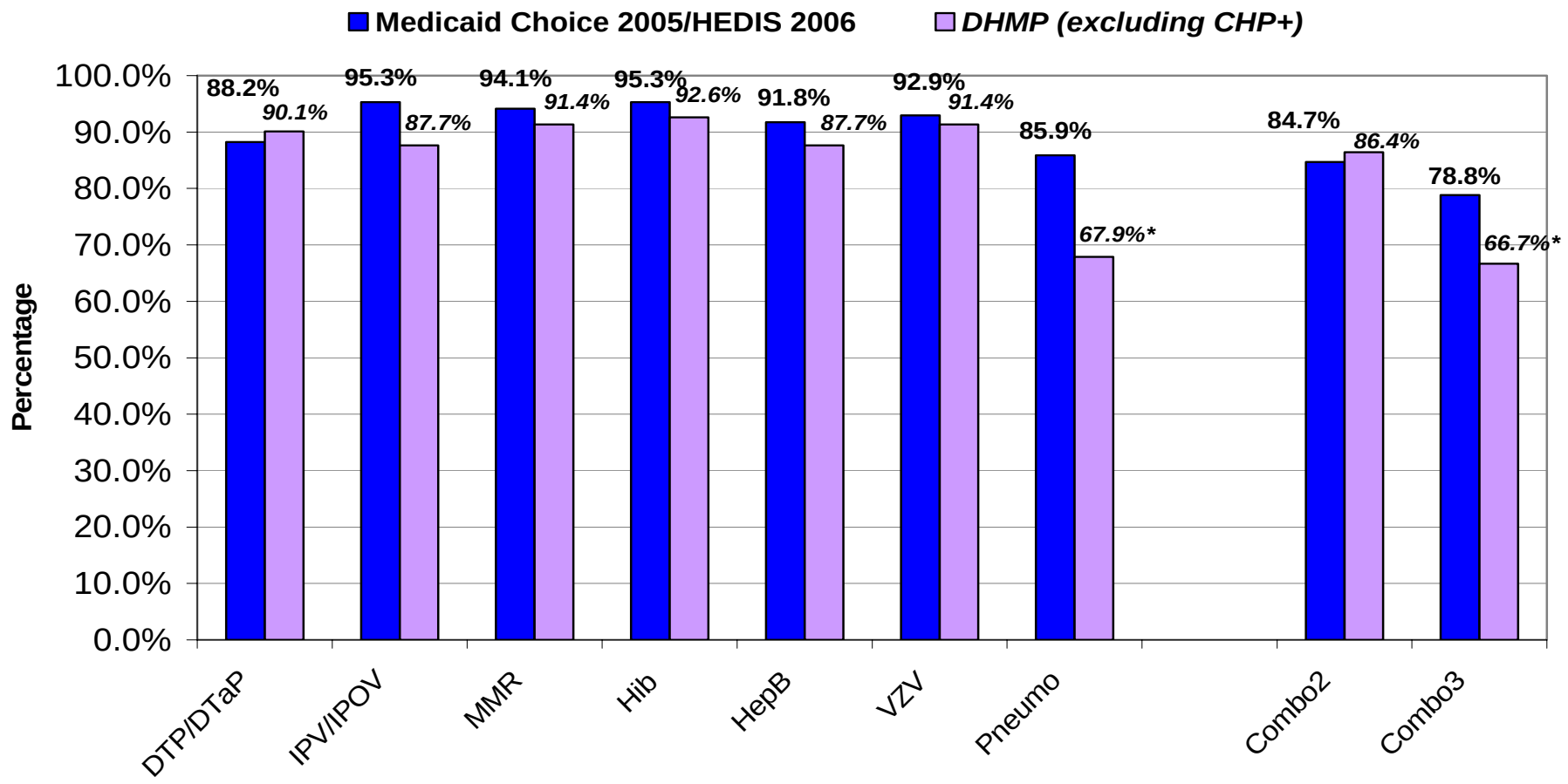


Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

2005 Medicaid Choice (2006 HEDIS) Immunization Rates for 2 year olds (N = 85) compared with 2005 Immunization Rates for DHMP members (N =81)



***NOTES:**

Pneumo
Chi-sq = 7.59, significantly different for $p = 0.05$.

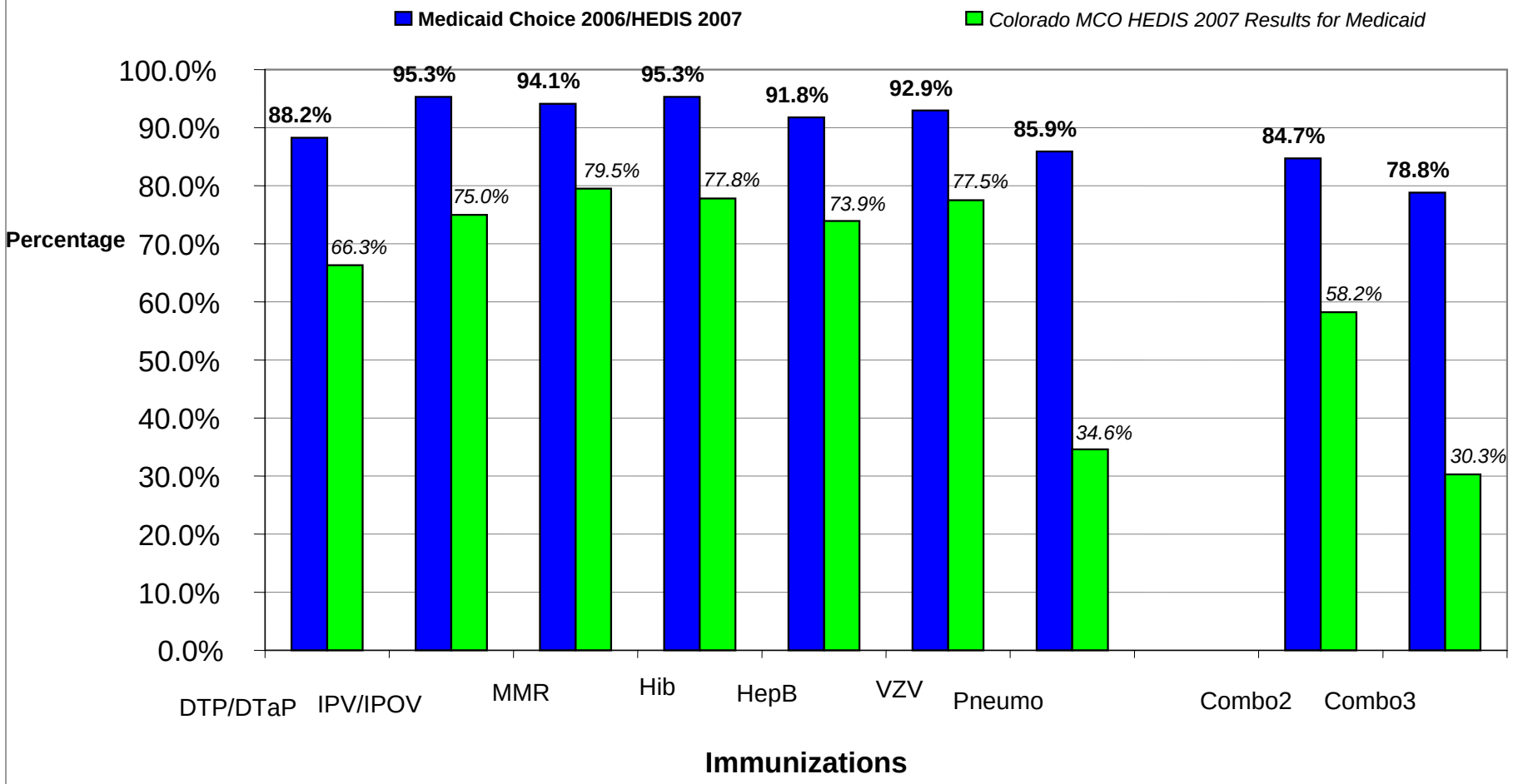
Combo 3
Chi-sq = 3.1, signif. diff. for $p = 0.1$

Remaining immunizations
No significant difference documented.

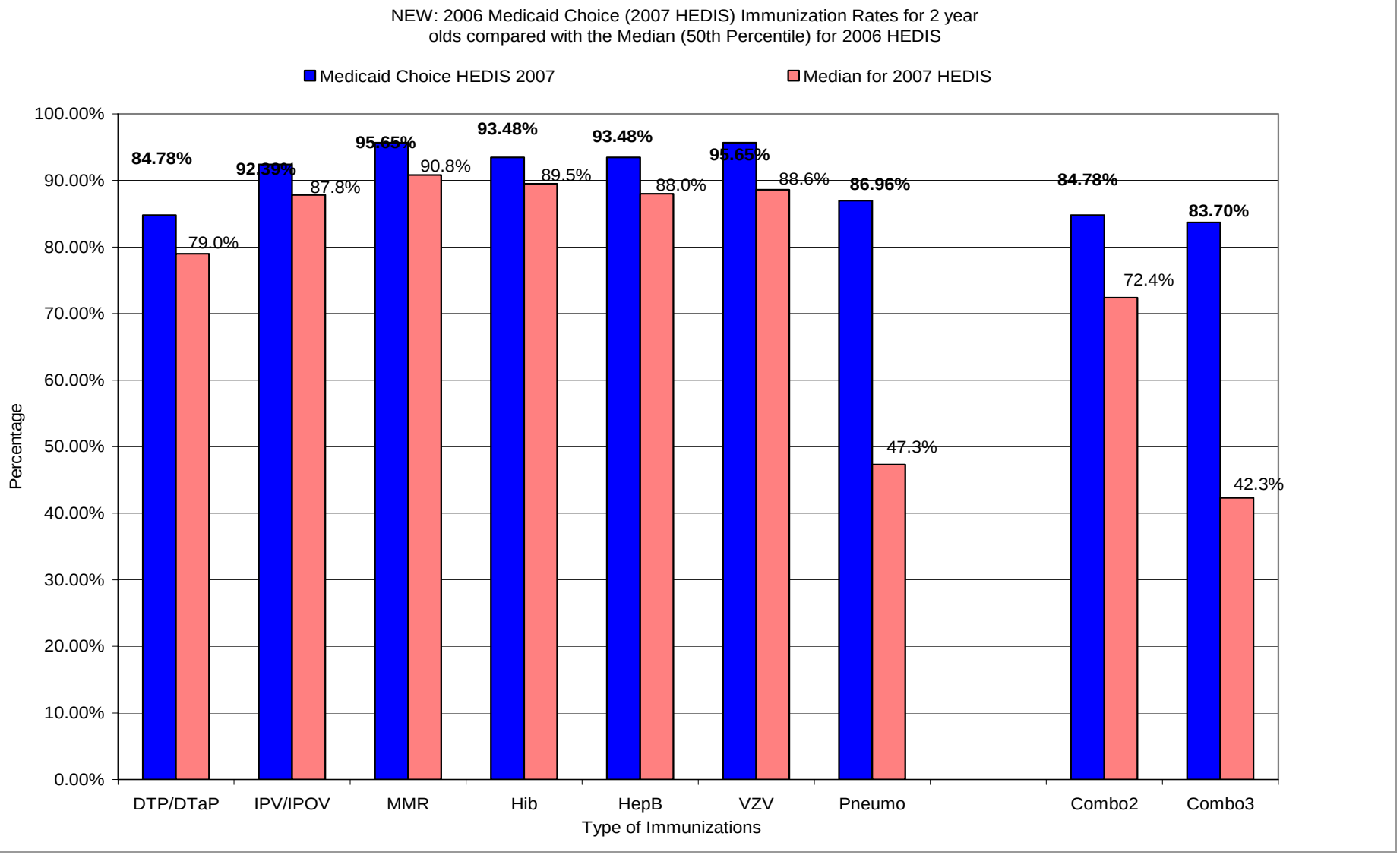
Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

NEW : INTERVENTION 1. GRAPHS (HEDIS 2007 RESULTS- 2006 DATA)

(2007 HEDIS) DHMC Immunization Rates compared with 2007 HEDIS Medicaid Rates

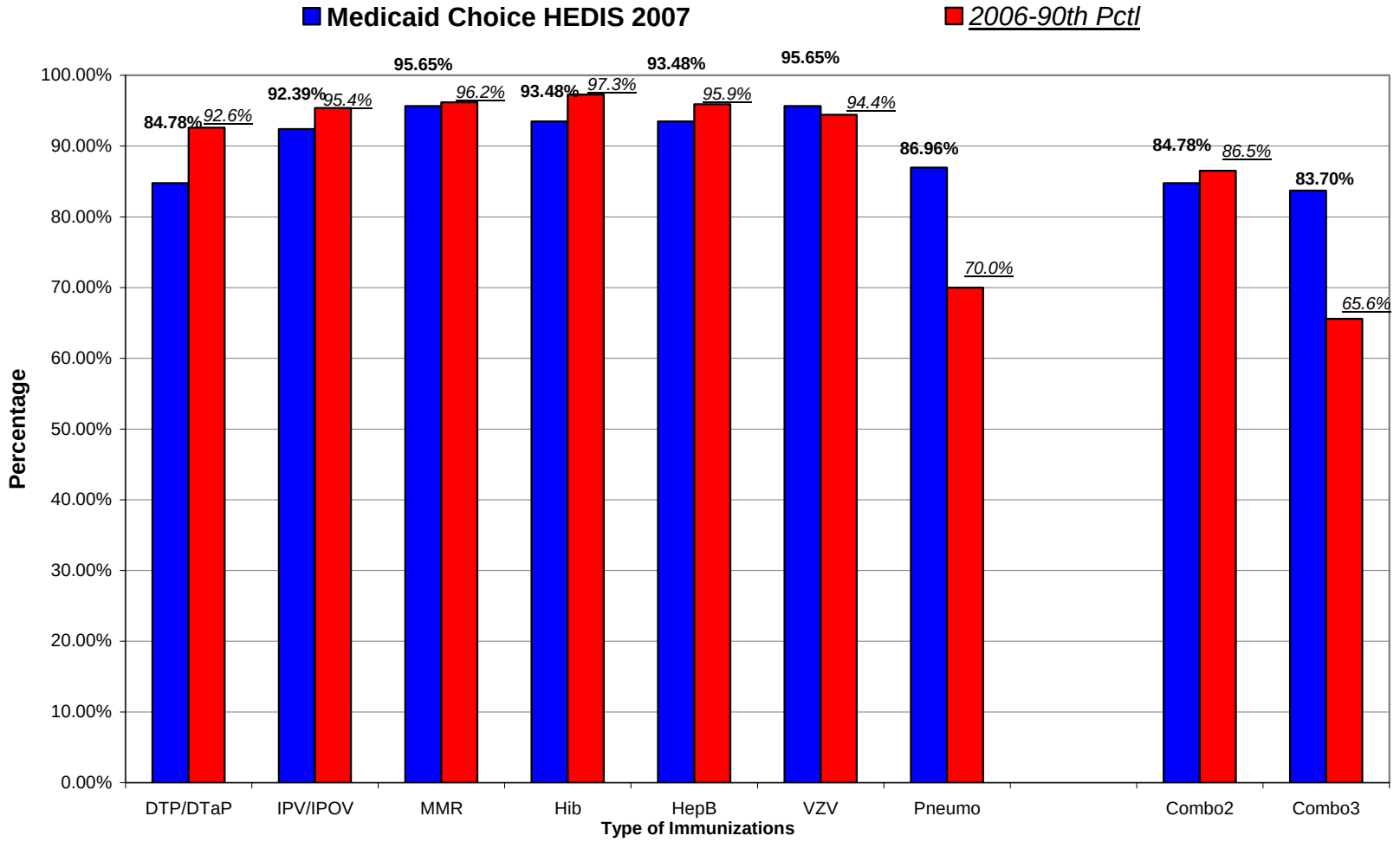


Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

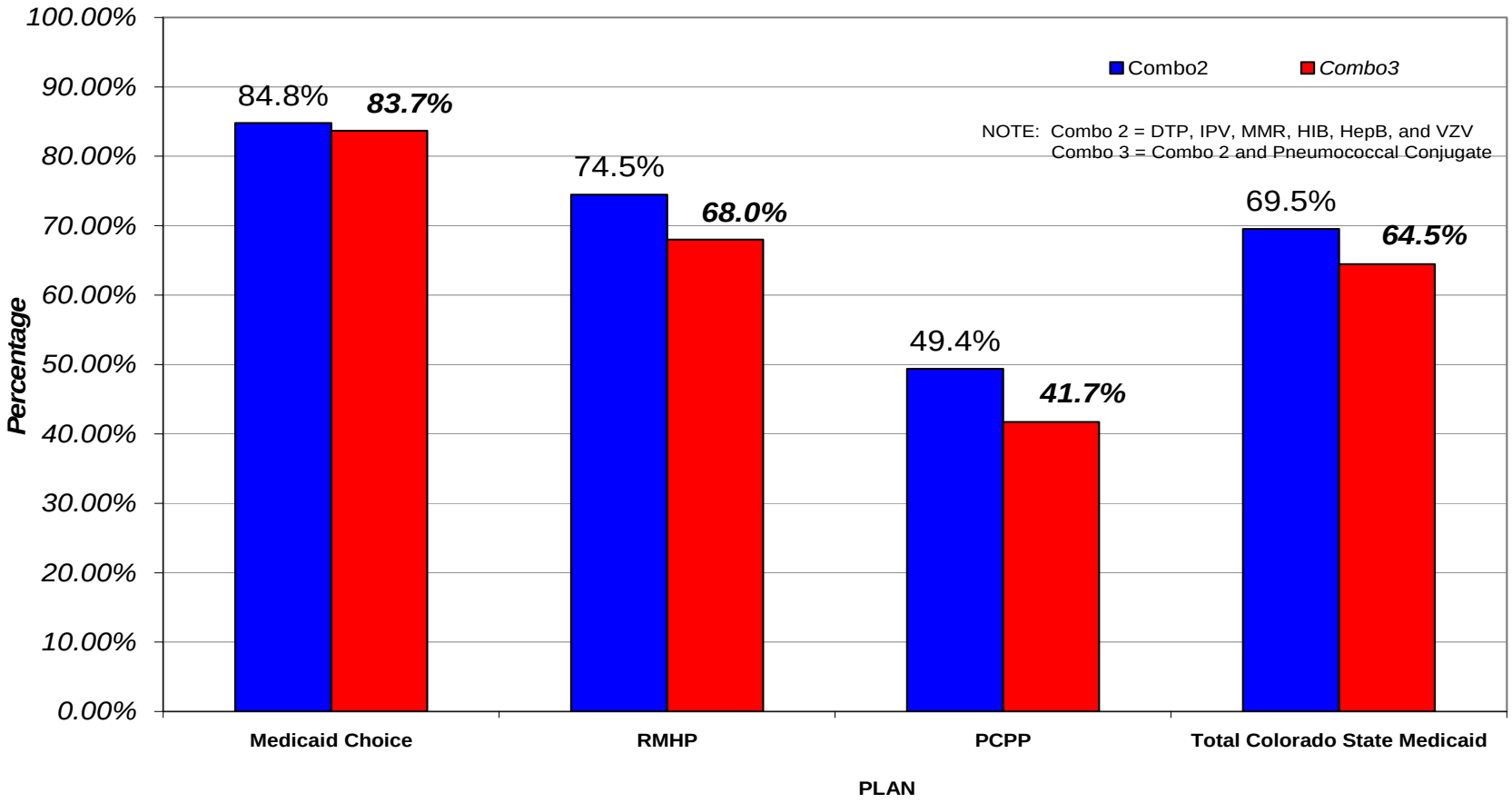
NEW: 2007 HEDIS(2006 Data) Immunization Rates for 2 year olds compared with the NCQA Medicaid 90th Percentile



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

NEW: Comparison of Results between Colorado Medicaid Health Plans for the Immunization of Children turning 2 yo in 2006

Source: HSAG 2006-2007 External Quality Review Technical Report for Colrado Mediacid Managed Care Reported September 2007.



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

Abbreviations in Use for PIP

ATT or **Att**	Attachment (refers to supplementary attachments for PIP)
CIS	NCQA abbreviation for HEDIS topics called Childhood Immunizations Study.
CP	Chicken Pox; related abbrev. CPV = Chicken Pox Vaccine
DH	Denver Health, *i.e. DH MCD = Denver Health Medicaid Choice*
DTP or **DTaP**	**DTP** is colloquial reference to Diphtheria-Tetanus-Pertussis immunization/vaccine; from **DTaP** for Diphtheria and Tetanus Toxoids and Acellular Pertussis.
HepB	Hepatitis B immunization/vaccine
HIB or **Hib**	*Haemophilus influenzae* type B immunization/vaccine
IM	Information management
IPV	Inactivated Polio Virus immunization/vaccine
IRR	Interrater Reliability Review
IS	Information Systems (internal DH department)
LCR	Lifetime Clinical Records (clinically-accessed internal/DH medical records registry)
MCD	Medicaid Choice *(not to be interpreted as a referral to the general or statewide Medicaid program(s)).*
MMC	**Medical Management Committee (for DHMC program implememted on January 2007)**
MMR	Measles-Mumps-Rubella immunization/vaccine
MRI	Medical Records Imagery (Denver Health's Adobe *.pdf-based electronic library of patients' medical records)
NA or **N/A**	Not Applicable
PCP	Primary Care Provider
pctl	percentile
PCV7	generally used to refer to all Pneumococcal Conjugate shots or vaccines; more specifically: Pneumococcal Conjugate 7-Valent immunization/vaccine, i.e. Prevnar/TM
PCV	Pneumococcal Conjugate Vaccine
PIP	Performance Improvement Project
QA	Quality Assurance (primary use). Also: Quality Assessment; Qualitative Analysis.
QAC	Quality Assurance Committee (for DHMC program replaced by MMC on January 2007)
QI	Quality Improvement
QIA	Quality Improvement Activity
/TM	Trademark
TOC	Table of Contents (p.2 of PIP)
VZV	Varicella-zostera virus (refers to immunization/vaccine)
y/o, yo	year[s] old

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

Proprietary Names / Terminology in PIP

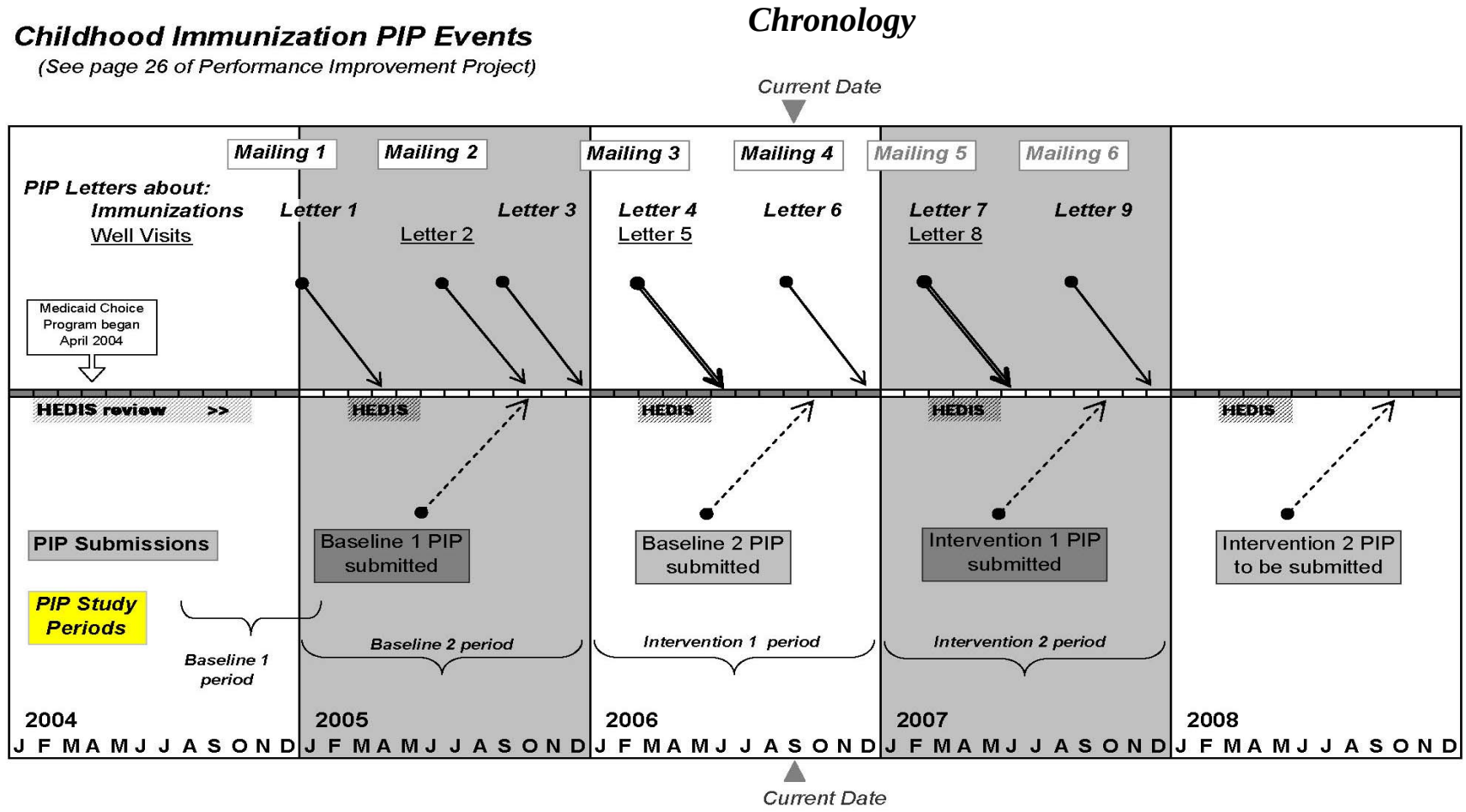
AAP	American Academy of Pediatrics, Inc.
ACIP	Advisory Committee for Immunization Practices, Inc.
AHRQ	Agency for HealthCare Research and Quality, Federal agency/npo (see www.ahrq.gov/about/budgtix.htm).
CAHPS	Consumer Assessment of Healthcare Providers and Systems, refers to a standardized survey administered to members, by AHRQ
CDC	Centers for Disease Control and Prevention
CDPHE	Colorado Department of Public Health and Environment; source for CIIS database.
CDHCPF	Colorado Dept of Health Care Policy and Financing (a Colorado State program)
CHP or **CHP+**	Child Health Plan or Child Health Plan Plus (a Colorado state program)
CIIS	Colorado Immunization Information Systems (statewide CDPHE database)
Compass Navigator	TierMed's HEDIS interface for data entry related to HEDIS studies; a data entry tool.
Compass Viewer	TierMed final report viewing tool; used to review HEDIS reports and outcomes.
DHHA	Denver Health and Hospital Authority
DHMC	Denver Health Medicaid Choice (internal DH program)
DHMP	Denver Health Medical Plan, Inc.; employees' health care program.
Diamond	Perot Systems/TM electronic data interchange platform; primary source for DH members data (see www.perotsystems.com).
EPSDT	Early and Periodic Screening Diagnosis and Treatment [statewide Medicaid-sponsored program]
FFS	Fee-For-Service, referring to related Medicaid program compared to DHMC
HCPF	Health Care Policy & Financing (agency)/Colorado Dept of Health Care Policy and Financing.
HEDIS	Health Employer Data Information Set (database); NCQA program.
HEDIS Help	QMark, Inc. program for Quality Assessment work (database tool)
HSAG	Health Services Advisory Group; special interest group in HCPF
Hybrid Help	QMark Software tool for Quality Assessment work (database tool used for data entry for Hybrid studies) [trademark name]; NCQA-certified.
NCQA	National Committee for Quality Assurance (agency/npo)
PCPP	Primary Care Physician Program (a Colorado Medicaid program compared to DHMC)
QMark	QMark Research and Polling; NCQA-certified company contracted for the 2004 and 2005 HEDIS studies for DHMC, results of which were used for Baseline 1 PIP report.
TierMed	TierMed Systems, LLC; NCQA-certified company contracted for the 2006 and 2007 HEDIS studies for DHMC, results of which were used for the 2005 to 2007 activities associated with Baseline 2 and Intervention PIP studies.
VaxTrax	A Denver Health Immunization Registry used to track Immunization and infectious disease history for individual members.
WIC	Special Supplemental Nutrition Program for Women, Infants and Children (USDA/CDPHE program)

Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

List of Attachments and Other Documents Submitted October 2007

(NOTE: Documents submitted in Oct. 2006 with previous PIP are not included in this report, unless attachment is deemed necessary)

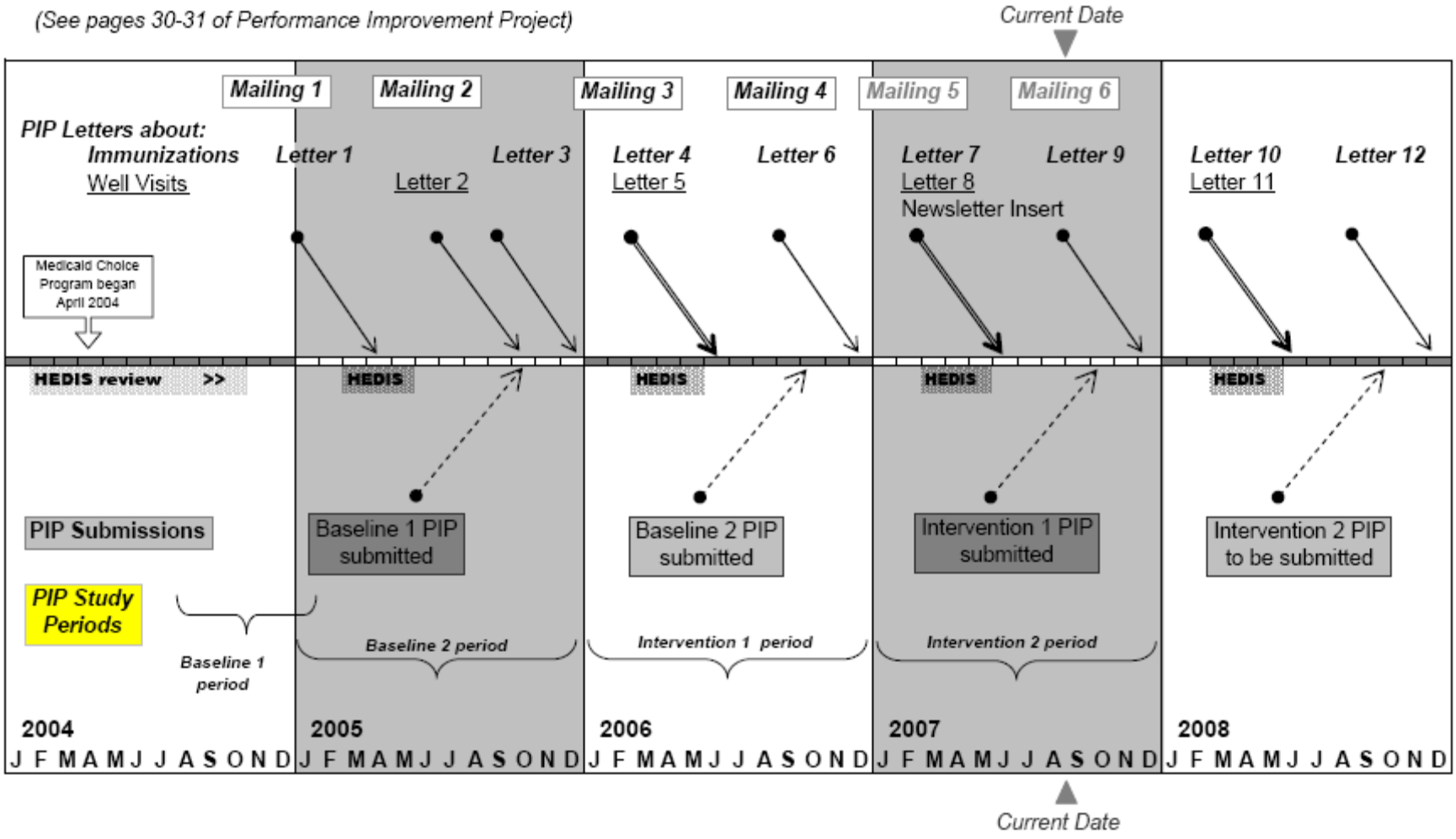
Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice



Appendix A: PIP Summary Form: Childhood Immunization *for* Denver Health Medical Choice

Childhood Immunization PIP Events - 2 (September 2007)

(See pages 30-31 of Performance Improvement Project)



PIPs provide a structured method of assessing and improving the processes, and thereby the outcomes, of care for the population that an MCO serves. This structure facilitates the documentation and evaluation of improvements in care or service. PIPs are conducted by the MCOs to assess and improve the quality of clinical and nonclinical health care services received by members.

The PIP evaluation is based on CMS guidelines as outlined in the CMS publication, *Validating Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities*, Final Protocol, Version 1.0, May 1, 2002 (CMS PIP Protocol).

This document highlights the rationale for each activity as established by CMS. The protocols for conducting PIPs can assist the MCOs in complying with requirements.

CMS Rationale

Activity I. Appropriate Study Topic

All PIPs should target improvement in relevant areas of clinical care and nonclinical services. Topics selected for study by Medicaid managed care organizations must reflect the MCO's Medicaid enrollment in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease (CMS PIP Protocol, page 2).

Activity II. Clearly Defined, Answerable Study Question

It is important for the MCO to clearly state, in writing, the question(s) the study is designed to answer. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis, and interpretation (CMS PIP Protocol, page 5).

Activity III. Clearly Defined Study Indicator(s)

A study indicator is a quantitative or qualitative characteristic (variable) reflecting a discrete event (e.g., an older adult has/has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured.

Each project should have one or more quality indicators for use in tracking performance and improvement over time. All indicators must be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. In addition, all indicators must be capable of objectively measuring either member outcomes, such as health status, functional status, or member satisfaction, or valid proxies of these outcomes.

Indicators can be few and simple, many and complex, or any combination thereof, depending on the study question(s), the complexity of existing practice guidelines for a clinical condition, and the availability of data and resources to gather the data.

Indicator criteria are the set of rules by which the data collector or reviewer determines whether an indicator has been met. Pilot or field testing is helpful in the development of effective indicator criteria. Such testing allows the opportunity to add criteria that might not have been anticipated in the design phase. In addition, criteria are often refined over time based on results of previous studies. However, if criteria are changed significantly, the method for calculating an indicator will not be consistent and performance on indicators will not be comparable over time.

It is important, therefore, for indicator criteria to be developed as fully as possible during the design and field testing of data collection instruments (CMS PIP Protocol, page 5).

Activity IV. Use a Representative and Generalizable Study Population

Once a topic has been selected, measurement and improvement efforts must be systemwide (i.e., each project must represent the entire Medicaid-enrolled population to which the study indicators apply). Once that population is identified, the MCO must decide whether to review data for that entire population or use a sample of that population. Sampling is acceptable as long as the samples are representative of the identified population (CMS PIP Protocol, page 8). (See Activity V. Valid Sampling Techniques.)

Activity V. Valid Sampling Techniques

If the MCO uses a sample to select members for the study, proper sampling techniques are necessary to provide valid and reliable (and, therefore, generalizable) information on the quality of care provided. When conducting a study designed to estimate the rates at which certain events occur, the sample size has a large impact on the level of statistical confidence in the study estimates. Statistical confidence is a numerical statement of the probable degree of certainty or accuracy of an estimate. In some situations, it expresses the probability that a difference could be due to chance alone. In other applications, it expresses the probability of the accuracy of the estimate. For example, a study may report that a disease is estimated to be present in 35 percent of the population. This estimate might have a 95 percent level of confidence, plus or minus 5 percentage points, implying a 95 percent certainty that between 30 percent and 40 percent of the population has the disease.

The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied. In such situations, the most prudent course of action is to assume that a maximum sample size is needed to establish a statistically valid baseline for the project indicators (CMS PIP Protocol, page 9).

Activity VI. Accurate/Complete Data Collection

Procedures used by the MCO to collect data for its PIP must ensure that the data collected on the study indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. The MCO should employ a data collection plan that includes:

- Clear identification of the data to be collected.
- Identification of the data sources and how and when the baseline and repeat indicator data will be collected.
- Specification of who will collect the data.
- Identification of instruments used to collect the data.

When data are collected from automated data systems, development of specifications for automated retrieval of the data should be devised. When data are obtained from visual inspection of medical records or other primary source documents, several steps should be taken to ensure the data are consistently extracted and recorded:

1. The key to successful manual data collection is in the selection of the data collection staff. Appropriately qualified personnel with conceptual and organizational skills should be used to abstract the data. However, their specific skills should vary depending on the nature of the data collected and the degree of professional judgment required. For example, if data collection involves searching throughout the medical record to find and abstract information or judge whether clinical criteria were met, experienced clinical staff members, such as registered nurses, should collect the data. However, if the abstraction involves verifying the presence of a diagnostic test report, trained medical assistants or medical records clerks may be used.
2. Clear guidelines for obtaining and recording data should be established, especially if multiple reviewers are used to perform this activity. The MCO should determine the necessary qualifications of the data collection staff before finalizing the data collection instrument. An abstractor would need fewer clinical skills if the data elements within the data source are more clearly defined. Defining a glossary of terms for each project should be part of the training of abstractors to ensure consistent interpretation among project staff members.
3. The number of data collection staff members used for a given project affects the reliability of the data. A smaller number of staff members promote interrater reliability; however, it may also increase the amount of time it takes to complete this task. Intrarater reliability (i.e., reproducibility of judgments by the same abstractor at a different time) should also be considered (CMS PIP Protocol, page 12).

Activity VII. Appropriate Improvement Strategies

Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance and developing and implementing systemwide improvements in care. Actual improvements in care depend far more on thorough analysis and implementation of appropriate solutions than on any other steps in the process.

An improvement strategy is defined as an intervention designed to change behavior at an institutional, practitioner, or member level. The effectiveness of the intervention activity or activities can be determined by measuring the MCO's change in performance according to predefined quality indicators. Interventions are key to an improvement project's ability to bring about improved health care outcomes. The MCO must identify and develop appropriate interventions for each PIP to ensure the likelihood of measurable change.

If repeated measurements of quality improvement (QI) indicate that QI actions were not successful (i.e., the QI actions did not achieve significant improvement), the problem-solving process begins again with data analysis to identify possible causes, propose and implement solutions, and so forth. If QI actions were successful, the new processes should be standardized and monitored (CMS PIP Protocol, page 16).

Activity VIII. Sufficient Data Analysis and Interpretation

Review of MCO data analysis begins with examining the MCO's calculated plan performance on the selected clinical or nonclinical indicators. The review examines the appropriateness of, and the MCO's adherence to, the statistical analysis techniques defined in the data analysis plan (CMS PIP Protocol, page 17).

Activity IX. Real Improvement Achieved

When an MCO reports a change in its performance, it is important to know whether the reported change represents real change, is an artifact of a short-term event unrelated to the intervention, or is due to random chance. The external quality review organization (EQRO) will need to assess the probability that reported improvement is actually true improvement. This probability can be assessed in several ways, but is most confidently assessed by calculating the degree to which an intervention is statistically significant. While the protocol for this activity does not specify a level of statistical significance that a reported change in performance must meet, it does require that EQROs assess the extent to which any performance changes reported by an MCO can be found to be statistically significant. States may choose to establish their own numerical thresholds for the significance of reported improvements (CMS PIP Protocol, page 18).

Activity X. Sustained Improvement Achieved

Real change results from changes in the fundamental processes of health care delivery. Such changes should result in sustained improvements. In contrast, a spurious, one-time improvement can result from unplanned, accidental occurrences or random chance. If real change has occurred, the MCO should be able to document sustained improvement (CMS PIP Protocol, page 19).

Appendix C. Definitions and Explanations by Activity for Denver Health Medicaid Choice

This document was developed by HSAG as a resource to assist MCOs in understanding the broad concepts in each activity related to PIPs. The specific concept is delineated in the left column, and the explanations and examples are provided in the right column.

Concepts	Definitions and Explanations
Activity I. Appropriate Study Topic	
Broad spectrum of care	◆ Clinical focus areas: Includes prevention and care of acute and chronic conditions and high-volume/high-risk services. High-risk procedures may also be targeted (e.g., care received from specialized centers). ◆ Nonclinical areas: Continuity or coordination of care addressed in a manner in which care is provided from multiple providers and across multiple episodes of care (e.g., disease-specific or condition-specific care).
Eligible population	◆ May be defined as members who meet the study population parameters.
Selected by the State	◆ If the study topic was selected by the state Medicaid agency, this information is included as part of the description under Activity I: "Choose the Selected Study Topic" in the PIP Summary Form.
Activity II. Clearly Defined, Answerable Study Question	
Study question	◆ The question(s) directs and maintains the focus of the PIP and sets the framework for data collection, analysis, and interpretation. The question(s) must be measurable and clearly defined. ◆ Examples: 1. Does educational outreach about immunizations increase the rates of immunizations for children 0–2 years of age? 2. Does increasing flu immunizations for members with chronic asthma impact overall health status? 3. Will increased planning and attention to follow-up after inpatient discharge improve the rate of mental health follow-up services?

Concepts	Definitions and Explanations
Activity III. Clearly Defined Study Indicator(s)	
Study indicator	◆ A quantitative or qualitative characteristic reflecting a discrete event or status that is to be measured. Indicators are used to track performance and improvement over time. ◆ Example: The percentage of enrolled members who were 12–21 years of age who had at least one comprehensive well-care visit with a primary care practitioner or an obstetrician-gynecologist during the measurement year.
Sources identified	◆ Documentation/background information that supports the rationale for the study topic, study question, and indicators. ◆ Examples: HEDIS®[1] measures, medical community practice guidelines, evidence-based practices, or provider agreements. ◆ Practice guideline examples: American Academy of Pediatrics and American Diabetes Association.
Activity IV. Use a Representative and Generalizable Study Population	
Eligible population	◆ Refers to members who are included in the study. ◆ Includes age, conditions, enrollment criteria, and measurement periods. ◆ Example: The eligible population includes all children 0–2 years of age as of December 31 of the measurement period, with continuous enrollment and no more than one enrollment gap of 30 days or less.
Activity V. Valid Sampling Techniques	
True or estimated frequency of occurrence	◆ This may not be known the first time a topic is studied. In this case, the MCO should assume the need for a maximum sample size to establish a statistically valid baseline for the study. HSAG will review whether the MCO defined the impact the topic has on the population or the number of eligible members in the population.
Sample size	◆ Indicates the size of the sample to be used.
Representative sample	◆ Refers to the sample reflecting the entire population.
Confidence level	◆ Statistical confidence is a numerical statement of the probable degree of certainty or accuracy of an estimate (e.g., 95 percent level of confidence with a 5 percent margin of error).

[1] **HEDIS®** is a registered trademark of the National Committee for Quality Assurance (NCQA).

Concepts	Definitions and Explanations
Activity VI. Accurate/Complete Data Collection	
Data elements	◆ Identification of data elements includes unambiguous definitions of data that will be collected (e.g., the numerator/denominator, laboratory values).
Interrater reliability (IRR)	◆ The HSAG review team evaluates if there is a tool, policy, and/or process in place to verify the accuracy of the data abstracted. Is there an over-read (IRR) process for the review of a minimum percentage of records? ◆ Examples: A policy that includes how IRR is tested, documentation of training, and instruments and tools used.
Algorithms	◆ The development of any systematic process that consists of an ordered sequence of steps. Each step depends on the outcome of the previous step. ◆ The HSAG review team expects the MCO to describe the process used in data collection. What are the criteria (e.g., what Current Procedural Terminology and/or source codes were used)?
Data completeness	◆ For the purposes of PIP scoring, data completeness refers to the degree of complete administrative data (e.g., encounter data or claims data). MCOs that compensate their providers on a fee-for-service basis require a submission of claims for reimbursement. However, providers generally have several months before they must submit the claim for reimbursement, and processing claims by the health plan may take several additional months, creating a claims lag. Providers paid on a capitated or salaried basis do not need to submit a claim to be paid, but should provide encounter data for the visit. In this type of arrangement, some encounter data may not be submitted. ◆ PIPs that use administrative data need to ensure that the data has a high degree of completeness prior to its use. Evidence of data completeness levels may include claim processing lag reports, trending of provider submission rates, policies and procedures regarding timeliness requirements for claims and encounter data submission, encounter data submission studies, and comparison reports of claims/encounter data versus medical record review. Discussion in the PIP should focus on evidence at the time the data was collected for use in identifying the population, sampling, and/or calculation of the study indicators. Statements such as, "Data completeness at the time of the data pull was estimated to be 97.8 percent based on claims lag reports (see attached Incurred But Not Reported report)," along with the attachment mentioned, usually (but not always) are sufficient evidence to demonstrate data completeness.

Concepts	Definitions and Explanations
Activity VII. Appropriate Improvement Strategies	
Causes and barriers	◆ Interventions for improvement are identified through evaluation or barrier analysis. If there is no improvement, what problem-solving processes are put in place to identify possible causes and proposed changes to implement solutions? ◆ It is expected that interventions associated with improvement of quality indicators will be system interventions.
Standardized	◆ If the interventions result in successful outcomes, the interventions should continue and the MCO should monitor them to ensure that the outcomes remain. ◆ Examples: If an intervention is the use of practice guidelines, then the MCO continues to use them. If mailers are a successful intervention, then the MCO continues the mailings and monitors the outcomes.
Activity VIII. Sufficient Data Analysis and Interpretation	
Analysis plan	◆ Each study should have a plan for how data analysis will occur. ◆ The HSAG review team will ensure that this plan was followed.
Generalization to the study population	◆ Study results can be applied to the general population with the premise that comparable results will occur.
Factors that threaten internal and external validity	◆ Did the analysis identify any factors (internal or external) that would threaten the validity of study results? ◆ Example: There was a change in record extraction (e.g., a vendor was hired or there were changes in HEDIS methodology).
Presentation of the data analysis	◆ Results should be presented in tables or graphs with measurement periods, results, and benchmarks clearly identified.
Identification of initial measurement and remeasurement of study indicators	◆ Clearly identify in the report which measurement period the indicator results reflect.
Statistical differences between initial measurement and remeasurement periods	◆ The HSAG review team looks for evidence of a statistical test (e.g., a t-test or chi-square test).
Identification of the extent to which the study was successful	◆ The HSAG review team looks for improvement over several measurement periods. ◆ Both interpretation and analysis should be based on continuous improvement philosophies, with the MCO documenting data results and the follow-up steps that will be taken for improvement.

Concepts	Definitions and Explanations
Activity IX. Real Improvement Achieved	
Remeasurement methodology is the same as baseline	◆ The HSAG review team looks to see that the study methodology remains the same for the entire study.
Documented improvement in processes or outcomes of care	◆ The study should document how interventions were successful in impacting system processes or outcomes. ◆ Examples: There was a change in data collection or a rate increase or decrease demonstrated in graphs/tables.
Activity X. Sustained Improvement Achieved	
Sustained improvement	◆ The HSAG review team looks to see if study improvements have been sustained over the course of the study. This needs to be demonstrated over a period of several (more than two) remeasurement periods.