Response to Steering Committee Concerning
NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus
Submitted By: FMQAI on behalf of CMS
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The NQF Endocrine Steering Committee, which met on February 27, 2014, requested a revision to the measure specifications that would account for patients who switched from oral diabetes agents to insulin-only during the measurement period. In addition, FMQAI received a public comment requesting the measure account for patients using incretin mimetics (i.e., exenatide and liraglutide). This document provides results from additional analyses conducted to evaluate these scenarios and recommendations regarding revision to the measure specifications.

1. **What proportion of patients in the denominator use insulin and incretin mimetics?**
   In the 10-state sample, 24.3% (150,774/620,934) of the denominator population had at least one claim for insulin, and 2.85% (17,690/620,934) had at least one claim for incretin mimetics. Since both insulin and incretin mimetics have the indication to be used as the sole medication therapy for diabetes, the impact of medication switching should be evaluated.

2. **What proportion of individuals switched from oral diabetes agents (ODAs) to insulin- or incretin mimetic-only therapy during the measurement period?**
   In the 10 state sample, among individuals who had at least one claim for insulin (n=150,774), 13.1% switched from ODAs to an insulin-only therapy. Among individuals who had at least one claim for incretin mimetics (n=17,690), 8.8% switched from ODAs to an incretin mimetic-only therapy. This suggests that measure rates would be falsely lowered by not accounting for switching in the measure specification.

3. **How are individuals who switched from ODAs to insulin or incretin mimetics identified?**
   Individuals switching to insulin or incretin mimetics are identified by having at least one claim for any type of insulin or incretin mimetic after the end of the days' supply of the last ODA prescription.

4. **How would adherence to ODAs be calculated for individuals who switched to insulin- or incretin mimetics-only during the measurement period?**
   For these individuals, the ODA measurement period is set to the end date of the days' supply of the last ODA prescription during the measurement year. Therefore, adherence is only calculated while the patient is taking ODAs and there is no disincentive for providers to switch their patients to insulin or incretin mimetics-only.

5. **Should the measure specifications also address switching between ODAs?**
   The current measure specifications calculate an individual's adherence to each class of ODAs separately (e.g., biguanides, sulfonylureas, etc.) and the individual would need to achieve a Proportion of Days Covered (PDC) $\geq$0.8 for at least <u>one</u> of the classes to qualify for the numerator. Since individuals might be switched from one ODA to other and it would be difficult to operationalize all the potential switching that would occur, FMQAI proposes a second revision of the specifications that would calculate medication adherence to the whole category of ODAs

regardless of the class. Therefore, as long as the proportion of days covered across all ODAs was at least 0.8, the individual would qualify for the numerator.

6. **What are the impacts from the proposed specification changes on the measure rates and scientific acceptability?**
   On average, the mean measure rate has increased by approximately 1-3% across each level measured and a substantial gap in performance remains with a mean rate of approximately 76% overall (Appendix A). Variation in performance remains approximately 10-14% between the 10th and 90th percentile (Appendix A). Reliability remains adequate across all levels of measurement and convergent validity is improved (Appendix B).

7. **Based on the review, what are the final recommendations and conclusions for the Steering Committee?**
   FMQAI recommends revising the specifications to account for individuals switching to insulin- or incretin mimetic-only therapy and to calculate adherence across all ODA drug classes collectively. Proposed revisions to the specifications are shown below in red.

Revised Specifications

Numerator Statement: Individuals with diabetes mellitus who have at least two claims for ODAs and have a PDC of at least 0.8 for oral diabetes agents.

Numerator Details:
The numerator is defined as individuals with a PDC of 0.8 or greater.

The PDC is calculated as follows:
• PDC Numerator: The PDC numerator is the sum of the days covered by the days' supply of all drug claims in the ODA class. The period covered by the PDC starts on the day the first prescription is filled (index date) and lasts through the end of the measurement period, or death, whichever comes first. For prescriptions with a days' supply that extends beyond the end of the measurement period, count only the days for which the drug was available to the individual during the measurement period. If there are prescriptions for the same drug (generic name) on the same date of service, keep the prescription with the largest days' supply. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
• PDC Denominator*: The PDC denominator is the number of days from the first prescription date through the end of the measurement period, or death date, whichever comes first.

*Individuals switching to insulin or incretin mimetics are identified by having at least one claim for any type of insulin or incretin mimetics after the end of the days' supply of the last ODA prescription. For these individuals, the ODA measurement period is set to the end date of the days' supply of the last ODA prescription during the measurement year.

Denominator Statement: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two claims for oral diabetes agents during the measurement period (12 consecutive months).

Appendix A – Meaningful Differences in Performance

Table A1. Summary of State Level Performance

	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
Original Measure	10	73.9%	75.2%	67.7%	80.8%	4.0%	5.7%	68.2%	70.3%	75.2%	76.0%	78.4%
Revised Measure	10	76.6%	77.9%	70.2%	83.2%	3.9%	5.2%	70.9%	73.3%	77.9%	78.5%	81.0%

Based on the revised measure, four of the 10 states (40.0%) had scores statistically significantly lower than the mean and six states (60.0%) had scores significantly higher than the mean. Measure rates ranged from 70.2% in Mississippi to 83.2% in Iowa, indicating suboptimal performance across all 10 states.

Table A2. Summary of Plan Level Performance

	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
Original Measure	40	74.2%	75.0%	60.7%	83.6%	5.7%	6.8%	66.0%	71.2%	75.0%	78.0%	80.8%
Revised Measure	40	76.7%	77.5%	63.2%	86.3%	5.4%	6.4%	69.2%	73.9%	77.5%	80.4%	82.1%

Based on the revised measure at the plan level, 27.5% of providers were statistically significantly lower than the mean, and 50.0% of providers were statistically significantly higher than the mean. For those plans with at least 175 eligible individuals, high- (90th percentile) and low- (10th percentile) performing plans were 12.9% apart, indicating suboptimal performance across all plans and variation between high- and low-performing plans.

Table A3. Summary of Physician Group Level Performance

	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
Original Measure	543	72.6%	73.4%	43.6%	88.7%	6.3%	7.6%	64.8%	69.6%	73.4%	77.2%	79.6%
Revised Measure	464	75.9%	76.6%	50.5%	90.5%	5.8%	7.3%	68.2%	72.6%	76.6%	79.9%	82.3%

Based on the revised measure at the physician group level, 20.3% of providers were statistically significantly lower than the mean, and 23.9% of providers were statistically significantly higher than the mean, indicating a wide range of scores. For those physician groups with at least 175 eligible individuals, high- (90th percentile) and low- (10th percentile) performing physician groups were 14.1% apart. The results indicate ample room for improvement and meaningful differences in quality of care between the highest and lowest performing physician groups.

Table A4. Summary of ACO Level Performance

	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
Original Measure	31	74.6%	74.9%	67.5%	82.5%	3.9%	5.6%	69.0%	71.9%	74.9%	77.5%	79.5%
Revised Measure	31	75.9%	76.5%	69.1%	83.4%	3.9%	5.8%	70.3%	72.6%	76.5%	78.4%	80.8%

Based on the revised measure at the ACO level, 29.0% of providers were statistically significantly lower than the mean, and 38.7% of providers were statistically significantly higher than the mean. Among all 31 ACOs, high- (90th percentile) and low- (10th percentile) performing ACOs were 10.5% apart, indicating suboptimal performance across all ACOs and variation between high- and low-performing ACOs.

Interpretation of the Results

The results indicate that overall performance, calculated using the revised measure, is suboptimal with variation in performance across states, plans, ACOs, and physician groups. Statistically significant differences were identified at the state, plan, ACO, and physician group level when compared to the overall mean.

Appendix B –Reliability and Validity

Table B1. 2011-2012 State Level Measure Rates and Reliability Assessments

State	Original Measure				Revised Measure			
	Num	Denom	Rate	Reliability	Num	Denom	Rate	Reliability
Overall	449,843	620,934	72.5%	--	469,476	623,987	75.2%	--
AZ	19,533	27,773	70.3%	0.994	20,494	27,946	73.3%	0.995
DE	7,706	10,233	75.3%	0.986	8,007	10,286	77.8%	0.988
FL	105,256	144,262	73.0%	0.999	109,918	145,033	75.8%	0.999
IA	30,625	37,915	80.8%	0.997	31,630	38,012	83.2%	0.997
IN	47,862	63,664	75.2%	0.998	49,860	63,946	78.0%	0.998
MO	46,197	60,955	75.8%	0.998	47,976	61,184	78.4%	0.998
MS	32,702	48,289	67.7%	0.996	34,048	48,472	70.2%	0.997
RI	6,146	8,082	76.1%	0.982	6,365	8,107	78.5%	0.985
TX	123,050	179,316	68.6%	0.999	129,167	180,416	71.6%	0.999
WA	30,766	40,445	76.1%	0.996	32,011	40,585	78.9%	0.997

Based on the revised measure, we concluded that the reliability test was adequate, since all state-level reliability scores were greater than 0.7, indicating that the measure would produce reliable scores at the state level.

Table B2. 2011-2012 Plan Level Measure Rates and Reliability Assessments

	Min Denominator	# of Plans	Mean Rate	Reliability Score
Original Measure	150	40	74.2%	0.695
Revised Measure	175	40	76.7%	0.717

Based on the revised measure and using the method of mean denominator and volume categories, a minimum denominator of 175 resulted in an overall reliability score of >0.7, which is within acceptable norms and indicates sufficient signal strength to discriminate performance between plans.

Table B3. 2011-2012 Physician Group Level Measure Rates and Reliability Assessments

	Min Denominator	# of Physician Groups	Mean Rate	Reliability Score
Original Measure	150	543	72.6%	0.697
Revised Measure	175	464	75.9%	0.713

Based on the revised measure and using the method of mean denominator and volume categories, a minimum denominator of 175 resulted in an overall reliability score of >0.7, which is within acceptable norms and indicates sufficient signal strength to discriminate performance between physician groups.

Table B4. ACO Level Measure Rates and Reliability Assessments

ACO	Original Measure				Revised Measure			
	Num	Denom	Rate	Reliability	Num	Denom	Rate	Reliability
Overall	42,619	57,454	74.2%	--	43,548	57,722	75.4%	--
1	1,327	1,669	79.5%	0.929	1,358	1,675	81.1%	0.932
2	923	1,205	76.6%	0.897	940	1,211	77.6%	0.898
3	1,409	1,854	76.0%	0.929	1,446	1,860	77.7%	0.932
4	760	1,018	74.7%	0.875	777	1,023	76.0%	0.877
5	947	1,276	74.2%	0.897	959	1,279	75.0%	0.897
6	691	892	77.5%	0.868	701	894	78.4%	0.869
7	926	1,199	77.2%	0.898	938	1,206	77.8%	0.898
8	2,013	2,773	72.6%	0.948	2,056	2,778	74.0%	0.948
9	1,984	2,732	72.6%	0.947	2,046	2,753	74.3%	0.949
10	873	1,283	68.0%	0.886	891	1,290	69.1%	0.886
11	1,694	2,244	75.5%	0.940	1,739	2,267	76.7%	0.942
12	528	709	74.5%	0.829	538	709	75.9%	0.831
13	1,465	1,891	77.5%	0.933	1,492	1,894	78.8%	0.935
14	1,035	1,267	81.7%	0.914	1,051	1,272	82.6%	0.916
15	1,470	1,943	75.7%	0.932	1,498	1,952	76.7%	0.933
16	2,284	2,996	76.2%	0.955	2,319	3,000	77.3%	0.956
17	1,677	2,241	74.8%	0.939	1.714	2,248	76.3%	0.940
18	798	1,026	77.8%	0.884	828	1,035	80.0%	0.890
19	659	799	82.5%	0.872	668	801	83.4%	0.874
20	1,112	1,485	74.9%	0.911	1,139	1,488	76.6%	0.913
21	783	982	79.7%	0.885	797	986	80.8%	0.888
22	427	633	67.5%	0.793	448	637	70.3%	0.799
23	2,382	3,148	75.7%	0.957	2,448	3,164	77.4%	0.958
24	2,471	3,436	71.9%	0.957	2,542	3,449	73.7%	0.958
25	1,097	1,589	69.0%	0.907	1,113	1,602	69.5%	0.907
26	750	1,069	70.2%	0.870	777	1,077	72.1%	0.873
27	1,190	1,654	72.0%	0.915	1,207	1,664	72.5%	0.915
28	768	1,129	68.0%	0.872	786	1,136	69.2%	0.873
29	847	1,210	70.0%	0.883	863	1,217	70.9%	0.884
30	1,119	1,425	78.5%	0.916	1,133	1,429	79.3%	0.916
31	6,210	8,677	71.6%	0.982	6,336	8,726	72.6%	0.982

We concluded that the reliability test was adequate, since all ACO-level reliability scores were much greater than 0.7, indicating that the measure would produce reliable scores at the ACO level.

Interpretation of the Results

The results from the reliability assessment indicated that the revised measure was reliable for state and ACO level regardless of the denominator size. For physician groups and plans, the reliable scores (i.e., >0.7) were identified with a minimum denominator sizes of 175.

Convergent Validity

We compared a related NQF-endorsed measure, NQF 0543, which assesses adherence to statin therapy for individuals with coronary artery disease (CAD) at the state, ACO, plan, and physician group levels. We would expect a positive correlation between the two measure scores since both measure medication adherence. We tested the measure distributions for normality at each unit of analysis and then selected the appropriate statistical test for the distribution and assessed the significance of the correlation coefficient.

Table B5. Convergent Validity: Distribution of State Measure Rates

Measure	n	Mean Measure Rate	Standard Deviation	Median	Minimum	Maximum
NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus	10	76.6%	3.9%	77.9%	70.2%	83.2%
NQF 0543: Adherence to Statin Therapy for Individuals with CAD	10	71.9%	3.7%	72.6%	65.3%	77.8%

The measure rate is positively correlated with NQF 0543 at the state level ($\rho = 0.95$, $p < 0.0001$).

Table B6. Convergent Validity: Distribution of Plan Measure Rates

Measure	n	Mean Measure Rate	Standard Deviation	Median	Minimum	Maximum
NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus	70	75.9%	10.9%	77.1%	40.0%	100%
NQF 0543: Adherence to Statin Therapy for Individuals with CAD	70	71.6%	7.6%	73.0%	50.0%	90.0%

The measure rate is positively correlated with NQF 0543 at the plan level ($\rho = 0.58$, $p < 0.0001$).

Table B7. Convergent Validity: Distribution of Physician Group Measure Rates

Measure	n	Mean Measure Rate	Standard Deviation	Median	Minimum	Maximum
NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus	6,461	73.4%	17.2%	75.0%	0.0%	100%
NQF 0543: Adherence to Statin Therapy for Individuals with CAD	6,461	67.7%	21.5%	69.4%	0.0%	100%

The measure rate is positively correlated with NQF 0543 at the physician group level ($\rho = 0.25$, $p < 0.0001$).

Table B8. Convergent Validity: Distribution of ACO Measure Rates

Measure	n	Mean Measure Rate	Standard Deviation	Median	Minimum	Maximum
NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus	31	75.9%	3.9%	76.5%	69.1%	83.4%
NQF 0543: Adherence to Statin Therapy for Individuals with CAD	31	70.3%	4.6%	70.8%	59.2%	80.2%

The measure rate is positively correlated with NQF 0543 at the ACO level ($\rho = 0.84$, $p < 0.0001$).

Interpretation of the Results

The measure was positively correlated with NQF 0543 (Adherence to Statin Therapy for Individuals with CAD) and statistically significant at all reporting levels with the state and ACO levels showing the strongest correlation.