

Cancer, Spring 2020 Cycle: CDP Report

TECHNICAL REPORT FEBRUARY 22, 2021

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Executive Summary

Cancer remains a significant burden to patients and the United States (U.S.) healthcare system. According to the National Cancer Institute (NCI), an estimated 15.7 million people live with cancer in the U.S.¹ In 2020 alone, more than 1.8 million new cancer cases are expected to be diagnosed in the U.S. and more than 600,000 people will die from the disease.² Furthermore, the NCI estimates that the costs for cancer care could reach \$174 billion in 2020.³

Cancer care is complex and provided in multiple settings—hospitals, outpatient clinics, ambulatory infusion centers, radiation oncology treatment centers, radiology departments, palliative and hospice care facilities—and by multiple providers, including surgeons, oncologists, nurses, pain management specialists, and social workers. Due to the complexity of cancer, as well as the numerous care settings and providers, there is a need for quality measures that address the value and efficiency of cancer care for patients and their families.

The National Quality Forum's (NQF) portfolio of measures for cancer includes measures addressing cancer screening and appropriate cancer treatment (including surgery, chemotherapy, and radiation therapy).

For this project, the Cancer Standing Committee evaluated one measure undergoing maintenance review against NQF's standard measure evaluation criteria.

The Standing Committee did not recommend the following measure for endorsement, in which the Consensus Standards Approval Standing Committee (CSAC) upheld:

 NQF #0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms (American College of Radiology)

A detailed summary of the Standing Committee's evaluation of the measure is included in the body of the report; a detailed summary of the Standing Committee's discussion and ratings of the criteria for the measure is in Appendix A.

Introduction

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.² The NCI estimated that in 2020, 1.8 million new cases of cancer would be diagnosed in the U.S. and over 600,000 people will die from the disease.² Furthermore, nearly 40 percent of all men and women in the U.S. will develop cancer during their lifetime.⁴ In addition, diagnosis and treatment of cancer has great economic impact on patients, their families, and the U.S. healthcare system. For 2020, NCI estimates that the costs for cancer care could reach \$174 billion.³

Given these data points, cancer continues to be recognized as a national priority for quality improvement from the U.S. Department of Health and Human Services, the Centers for Medicare & Medicaid Services (CMS), and numerous other healthcare stakeholders, including commercial payers and medical professional societies. 5-7 These organizations are actively engaged in strategies to address quality of care issues in cancer, including the development and use of quality measures.

Quality measurement in cancer is increasing in significance as the U.S. healthcare system continues to shift from volume to value. In oncology specifically, value-based payment models include financial incentives for adhering to clinical practice guidelines, bundled payments, accountable care organizations, patient-centered medical homes, and the new Oncology Care First Model.^{8,9} These models of care have created a demand for measures that can address existing critical quality of care gaps and assess patient experience and quality of life across a range of cancers.

NQF Portfolio of Performance Measures for Cancer Conditions

The Cancer Standing Committee (Appendix C) oversees NQF's portfolio of Cancer measures (Appendix B), which includes measures for hematology, breast cancer, colon cancer, prostate cancer, and other cancer measures. This portfolio contains 18 measures: 17 process measures and one outcome and resource use measure (see Table 1 below).

Table 1. NQF Cancer Portfolio of Measures

	Process/Structure	Outcome
Breast Cancer	8	0
Colon Cancer	4	0
Prostate	2	0
Cancer		
Other Cancer	3	1
Measures		
Total	17	1

Additional measures have been assigned to other portfolios. The additional measures address appropriateness of care (Geriatrics and Palliative Care), cancer screening (Prevention and Population Health), screening for pain, pain related to chemotherapy or radiation therapy, and surgical care.

Cancer Measure Evaluation

On July 10, 2020, the Cancer Standing Committee evaluated one measure undergoing maintenance review against NQF's <u>standard measure evaluation criteria</u>.

Table 2. Cancer Measure Evaluation Summary

	Maintenance	New	Total
Measures under review	1	0	1
Measures not endorsed	1	0	1

Comments Received Prior to Standing Committee Evaluation

NQF accepts comments on endorsed measures on an ongoing basis through the <u>Quality Positioning System (QPS)</u>. In addition, NQF accepts comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on May 11, 2020, and closed on September 14, 2020. Pre-meeting commenting closed on June 19, 2020. As of that date, no comments were submitted (<u>Appendix F</u>).

Comments Received After Standing Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on September 15, 2020. Following the Standing Committee's evaluation of the measures under review, NQF received two comments from two member organizations and individuals pertaining to the draft report and to the measures under review. All comments for each measure under review have been summarized in Appendix A.

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support (either *support* or *do not support*) for each measure submitted for endorsement consideration to inform the Standing Committee's recommendations. No NQF members provided their expression of support.

Summary of Measure Evaluation

The following summary of the measure evaluation highlights the major issues that the Standing Committee considered. Details of the Standing Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

#0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms (American College of Radiology): Not Endorsed

Description: Percentage of final reports for screening mammograms that are classified as "probably benign"; **Measure Type**: Process; **Level of Analysis**: Clinician : Individual; **Setting of Care**: Outpatient Services; **Data Source**: Claims, Registry Data

The Standing Committee did not vote on the recommendation for endorsement because the Standing Committee did not pass the measure on validity—a must-pass criterion.

The Standing Committee began its discussion with evidence, which was updated by the developer to include the American College of Radiology Breast Imaging-Reporting and Data System (ACR B-RADS) Atlas, which provides guidance on using a "probably benign" category versus other categories. The Standing Committee also discussed the logic model presented within the evidence document to describe the steps/decision process when implementing this measure. Specifically, the logic model states that if an abnormality is not malignant and the radiologist is also not 100 percent sure that it is benign, an evaluation of a patient's prior mammography exams is required, rather than an additional diagnostic scan. The developer clarified that the recommendation is to use prior mammography exams to resolve issues. Based on that information, a Standing Committee member noted that it is important to capture that this measure is applicable to follow-up mammograms rather than first-time mammograms. Overall, the Standing Committee agreed with the evidence provided.

At the outset of the discussion on performance gap, NQF shared the preliminary analysis rating of low for this criterion, which indicates the measure is topped out (mean performance reported was 2.93 percent, lower score is better). NQF noted that such a high-performance rate allowed the Standing Committee to consider this measure for Reserve Status. The purpose of Reserve Status is to retain endorsement of reliable and valid measures that have overall high levels of performance so that performance can be monitored, as necessary, to ensure that performance does not decline. NQF noted that Reserve Status should be applied only to highly credible, reliable, and valid measures that have high levels of performance due to quality improvement actions (e.g., not due to documentation practices only).

During the discussion on performance gap, the Standing Committee reviewed the data presented from the developer from more than 100,000 providers with at least 10 patients who received a mammogram each year between 2015-2018. The average performance across all physicians was 0.52 percent. The measure developer clarified the interpretation of the performance rate, which uses inverse terminology and therefore *not* meeting the measure is the correct quality action. Providers' case volume, as it relates to implementation of this measure, also was noted by the Standing Committee as rates of compliance for providers with a low case volume could be very different. The Standing Committee did not reach consensus on performance gap.

The Standing Committee reviewed and discussed the measure's reliability testing; a beta-binomial model measuring the ratio of signal-to-noise was provided showing a reliability statistic of 0.99 for physicians having a minimum of 10 events for the period 2015-2018. This suggested the measure has high reliability. This Standing Committee agreed with this assessment, concluding it is reliable.

During the discussion on validity, NQF noted the preliminary analysis rating was insufficient. NQF stated that the developer conducted construct validity, calculating Pearson's coefficients. NQF noted, however, that the developer was unable to find a correlation of this measure with two other process measures (including an NQF-endorsed measure), having hypothesized that good performance on this measure likely indicates physicians who follow guidelines are working within practices that have good systems for tracking patients or do not unnecessarily recall patients. The Standing Committee agreed this measure has high face validity, but also acknowledged that it is not the preferred validity for maintenance measures, since NQF requires empiric validity testing. The Standing Committee did not pass NQF #0508

on validity, and therefore, since validity is a must-pass critrion, the measure did not proceed with being evaluated against the remaining criteria. Additionally, the measure was not recommended for endorsement. CSAC upheld the Standing Committee's recommendation. The Standing Committee also considered two public comments during their evaluation of the measure. These comments 1) expressed concern that the phrasing of the measure is confusing, particularly the use of "probably benign" as an assessment category and 2) disagreed with the Standing Committee's recommendation to re-specify the measure for "follow-up" mammograms only.

Measures Withdrawn From Review

Two measures previously endorsed by NQF were withdrawn during the endorsement evaluation process. Endorsement for these measures will be removed.

Table 3. Measures Withdrawn From Consideration

Measure	Reason for withdrawal
#0225 At Least 12 Regional Lymph Nodes Are Removed and Pathologically Examined for Resected Colon Cancer	The developer is not in a position to adequately address concerns with the lack of empiric validity testing data at this time.
#0559 Combination Chemotherapy or Chemo- Immunotherapy (if HER2 Positive), Is Recommended or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 With AJCC T1cN0 or Stage IB – III Hormone Receptor Negative Breast Cancer	The developer is not in a position to adequately address concerns with the lack of empiric validity testing data at this time.

References

- 1 Howlander N, Noone A, Krapcho M, et al. *SEER Cancer Statistics Review (CSR) 1975-2017*. National Cancer Institute. Bethesda, MD; 2020. SEER Cancer Statistics Review (CSR) 1975-2017.
- 2 SEER Cancer Statistics Review, 1975-2017. SEER. https://seer.cancer.gov/csr/1975_2017/index.html. Last accessed July 2020.
- 3 Cancer Prevalence and Cost of Care Projections. https://costprojections.cancer.gov/. Last accessed July 2020.
- 4 Cancer Facts & Figures 2020 | American Cancer Society. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2020.html. Last accessed July 2020.
- 5 Blues plans to launch high-performance network nationwide in 2021. FierceHealthcare. https://www.fiercehealthcare.com/payer/blues-plans-to-launch-high-performance-network-nationwide-2021. Last accessed July 2020.
- 6 Commission on Cancer. American College of Surgeons. https://www.facs.org/quality-programs/cancer/coc. Last accessed July 2020.
- 7 Cancer Care Initiatives. ASCO. https://www.asco.org/practice-policy/cancer-care-initiatives. Published January 21, 2016. Last accessed July 2020.
- 8 Deloitte. The evolution of oncology payment models: what can we learn from early experiments? https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-evolution-of-oncology-payment-models.pdf. Last accessed July 2020.
- 9 Oncology Care First Model: informal request for information. https://innovation.cms.gov/files/x/ocf-informalrfi.pdf. Last accessed July 2020.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Note: Vote totals may differ between measure criteria and between measures as Standing Committee members often have to join calls late or leave calls early. NQF ensures that quorum is maintained for all live voting. All voting outcomes are calculated using the number of Standing Committee members present for that vote as the denominator. During the July 10, 2020 meeting, quorum was met and maintained throughout the proceedings.

Measures Not Endorsed

#0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Submission

Description: Percentage of final reports for screening mammograms that are classified as "probably benign"

Numerator Statement: Final reports classified as "probably benign" **Denominator Statement**: All final reports for screening mammograms **Exclusions**: No Denominator Exclusions or Denominator Exceptions

Adjustment/Stratification:

Level of Analysis: Clinician: Individual **Setting of Care:** Outpatient Services

Type of Measure: Process

Data Source: Claims, Registry Data

Measure Steward: American College of Radiology (ACR)

STANDING COMMITTEE MEETING 07/10/2020

1. Importance to Measure and Report: The measure does not meet the Importance criteria.

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-1; M-16; L-0; I-0 1b. Performance Gap: H-0; M-7; L-10; I-0

Rationale:

- The developer noted that it provided updated evidence to include the ACR BI-RADS Atlas, which provides guidance on using a "probably benign" category versus other categories.
- The Standing Committee had a specific question about the logic model presented within the evidence document, which states that if an abnormality is not malignant and the radiologist is also not 100% sure that it is benign, an evaluation of a patient's prior mammography exams is required, rather than an additional diagnostic scan. The developer confirmed that prior mammography exams are used to resolve issues related to abnormal diagnostic tests and mentioned the challenges with diagnostic tests among patients with dense tissue is a frequent topic of discussion among radiologists.
- A Standing Committee member noted that it is important to mention that the measure is more
 appropriate for follow-up mammograms rather than first time-mammograms, due to the logic model
 rationale for abnormal diagnostic tests: If an abnormal result was detected, having a prior
 mammogram for comparison would not be possible for patients who were receiving their first
 mammogram.
- During the discussion of performance gap, the Standing Committee questioned the BI-RADS categories
 and scales that determine whether the measure was met. The measure description indicates
 screening, but the scale in the BI-RADS manual allows for the selection of "3," which is based on a
 diagnostic test, not a screening. The developer clarified that the distinction for using BI-RADS 3 is only
 based on screening and diagnostic mammograms, rather than the first or follow-up mammograms. An
 indication of BI-RADS 3 as "benign" should not routinely be used on a screening exam unless there are
 unusual circumstances and additional diagnostic tests are recommended.

#0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

- The Standing Committee also discussed the average performance across all physicians from 2015-2018, which was 0.52%, with the data from more than 100,000 providers with at least 10 patients who received a mammogram. The measure developer clarified the interpretation of the performance rate, which uses inverse terminology and therefore *not* meeting the measure is the correct quality action. For this measure, 97% of the providers were not compliant.
- The Standing Committee commented on the data from the CMS Physician Quality Reporting System provided by the developer, specifically the difference in the number of physicians who were compliant between the 25th and 75th percentile, which is approximately 170,000. Some members noted this difference is important when deciding if the gap is low or moderate.
- The Standing Committee asked about the performance from physicians with low volume or the
 variance in performance for physicians who have 20 patients or 100 patients, as this should be viewed
 differently. The developer responded that it does not receive that level of data from CMS but would try
 to review the performance of physicians within the national mammography database and compare it
 to those physicians who report through the Merit-Based Payment System (MIPS) to measure any
 variance.
- The Standing Committee's discussion of the performance gap continued as it reviewed the guidelines for qualified mammography centers, citing that the 10-mammogram requirement for this measure seems low.
- The developer shared that the mammography quality standards act requires U.S. radiologists to interpret at least 960 mammograms within a two-year period to be certified. Based on this information, the Standing Committee considered whether the gap was in fact smaller than what was currently shown and how that would equate to the actual numbers of patients for which this measure could be applied.
- The Standing Committee agreed overall that this measure highlights what could be potential harm, such as the physical and emotional harm of a delayed diagnosis.
- The Standing Committee's vote on evidence passed; however, the vote on performance gap did not reach consensus.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability</u> criteria.

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-15; M-1; L-0; I-0; 2b. Validity: H-0; M-4; L-5; I-8

Rationale:

- The developer provided reliability testing; a beta-binomial model measuring the ratio of signal-to-noise was provided showing a reliability statistic of 0.99 for physicians having a minimum of 10 events for the period 2015-2018, suggesting the measure has high reliability. This Standing Committee agreed with this assessment citing it to be reliable.
- The developer conducted construct validity, calculating Pearson's coefficients; however, a correlation between this measure and two other process measures was not found. The hypothesis was that good performance on this measure likely indicates that physicians who follow guidelines are working within practices that have good systems for tracking patients or do not unnecessarily recall patients.
- One Standing Committee member noted that perfect correlation is not always preferred as it could require a stronger rationale for the need for separate measures.
- The Standing Committee mentioned that face validity data included by the measure developer showed high face validity; most Standing Committee members seemed to agree with this assessment. It also was acknowledged, however, that as a maintenance measure, NQF requires empiric validity testing.
- After deliberating on these issues, the Standing Committee passed the measure on reliability, but did not pass the measure on validity.

3. Feasibility: H-X; M-X; L-X; I-X <u>The Standing Committee did not vote on this criterion since the measure did not pass Scientific Acceptability.</u>

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

#0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

4. Usability and Use: <u>The Standing Committee did not vote on this criterion since the measure did not pass Scientific Acceptability.</u>

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use: Pass-X; No Pass-X; 4b. Usability: H-X; M-X; L-X; I-X

5. Related and Competing Measures

No related or competing measures were noted.

Standing Committee Recommendation for Endorsement: Yes-X; No-X

6. Public and Member Comment

- The American Geriatrics Society (AGS) expressed concern that the phrasing of the measure is
 confusing, particularly the use of "probably benign" as an assessment category. Additional comments
 addressed concerns around when the measure should be used and how the measure considers
 mammogram screening intervals.
- ACR provided a comment that conveyed its disagreement with the Standing Committee's
 recommendation to re-specify the measure for "follow-up" mammograms only. Comment also
 described ACR's intention to determine the necessary data elements that are necessary to identify
 disparities and reassess the methodology appropriate for establishing validity.
- **8.** Consensus Standards Approval Standing Committee (CSAC) Endorsement Decision: Yes-11; No-0 The Standing Committee did not recommend the measure for continued endorsement because the measure did not pass validity—a must-pass criterion.

9. Appeals

• No appeals were received.

Appendix B: Cancer Portfolio—Use in Federal Programs^a

NQF #	Title	Federal Programs: Finalized or Implemented as of June 22, 2020
0219	Post-Breast Conservation Surgery Irradiation	N/A
0220	Adjuvant Hormonal Therapy	N/A
0223	Adjuvant Chemotherapy Is Recommended or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 With AJCC III (Lymph Node Positive) Colon Cancer	N/A
0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (Paired With #0384)	Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented); Merit-Based Incentive Payment System (MIPS) Program (Implemented)
0384	Oncology: Medical and Radiation – Pain Intensity Quantified	MIPS Program (Implemented); Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented)
0385	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A
0385e	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A
0387	Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	N/A
0387e	Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	N/A
0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients	MIPS Program (Implemented)
0389e	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients	MIPS Program (Implemented); Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented)
0390	Prostate Cancer: Combination Androgen Deprivation Therapy for High-Risk or Very High-Risk Prostate Cancer	MIPS Program (Implemented)
0509	Diagnostic Imaging: Reminder System for Screening Mammograms	MIPS Program (Implemented)
1857	HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment With HER2-Targeted Therapies	N/A
1858	Trastuzumab Administered to Patients With AJCC Stage I (T1c) – III and Human Epidermal Growth Factor Receptor 2 (HER2) Positive	MIPS Program (Implemented)

^a Per CMS Measures Inventory Tool as of 02/18/2021

NQF #	Title	Federal Programs: Finalized or Implemented as of June 22, 2020
	Breast Cancer Who Receive Adjuvant Chemotherapy	
1859	KRAS Gene Mutation Testing Performed for Patients With Metastatic Colorectal Cancer Who Receive Anti-Epidermal Growth Factor Receptor Monoclonal Antibody Therapy	MIPS Program (Implemented)
1860	Patients With Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment With Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies	MIPS Program (Implemented)
2930	Febrile Neutropenia Risk Assessment Prior to Chemotherapy	N/A

Appendix C: Cancer Standing Committee and NQF Staff

STANDING COMMITTEE

Karen Fields, MD (Co-Chair)

Medical Director, Strategic Alliances, Moffitt Cancer Center Tampa, Florida

Shelley Fuld Nasso, MPP (Co-Chair)

CEO, National Coalition for Cancer Survivorship Washington DC

Afsaneh Barzi, MD, PhD

Associate Professor, USC – Norris Cancer Center Los Angeles, California

Gregary Bocsi, DO, FCAP

Medical Director, Strategic Alliances, University of Colorado Hospital Clinical Laboratory Denver, Colorado

Brent Braveman, PhD, OTR/L, FAOTA

Director, Department of Rehabilitation Services, University of Texas M.D. Anderson Cancer Center Houston Texas

Steven Chen, MD, MBA, FACS

Director of Surgical Oncology, OasisMD Duarte, California

Matthew Facktor, MD, FACS

Director, Department of Thoracic Surgery, Geisinger Medical Center Danville, Pennsylvania

Heidi Floyd

Patient Advocate
Washington, District of Columbia

Bradford Hirsch, MD

CEO, SignalPath Research, Medical Oncologist, TEXAS ONCOLOGY Raleigh, North Carolina

Jette Hogenmiller, PhD, MN, APRN/ARNP, CDE, NTP, TNCC, CEE

Oncology Nurse Practitioner Idaho Springs, Colorado

Wenora Johnson

Research Advocate, Fight Colorectal Cancer Joliet, Illinois

J. Leonard Lichtenfeld, MD, MACP

Deputy Chief Medical Officer, American Cancer Society Atlanta, Georgia

Stephen Lovell, MS

Seattle Cancer Care Alliance: Patient Quality, Safety & Service Committee (Board of Directors committee); Patient and Advisory Council; Clinic Design & Expansion Committee Washington, District of Columbia

Jennifer Malin, MD, PhD

Senior Medical Director, Oncology and Genetics, UnitedHealthcare Thousand Oaks, California

Jodi Maranchie, MD, FACS

Associate Professor, University of Pittsburgh, Department of Urology Pittsburgh, Pennsylvania

Denise Morse, MBA

Director of Quality and Value Analytics, City of Hope Cancer Center Duarte, California

Benjamin Movsas, MD

Chair, Radiation Oncology, Henry Ford Health System Detroit, Michigan

Beverly Reigle, PhD, RN

Associate Professor, Emerita, University of Cincinnati College of Nursing Cincinnati, Ohio

David J. Sher, MD, MPH

Associate Professor, UT Southwestern Medical Center Dallas, Texas

Danielle Ziernicki, PharmD

Senior Director, BeiGene Cambridge, Massachusetts

NQF STAFF

Sheri Winsper, RN, MSN, MSHA

Senior Vice President, Quality Measurement

Apryl Clark, MHSA

Acting Vice President, Quality Measurement

Michael Katherine Haynie,

Senior Managing Director, Quality Measurement

Matthew Pickering, PharmD

Senior Director, Quality Measurement

Nicole Williams, MPH

Director, Quality Measurement

Tamara Funk, MPH

Manager, Quality Measurement

Oroma Igwe, MPH

Manager, Quality Measurement

Teja Vemuganti, MPH

Analyst, Quality Measurement

Karri Albanese, BA

Analyst, Quality Measurement

Mike DiVecchia, MBA, PMP

Senior Project Manager, Quality Measurement

Robin Y. Nishimi, PhD

Consultant

Appendix D: Measure Specifications

Not applicable. Measure not endorsed.

Appendix E1: Related and Competing Measures (Tabular)

Not applicable. Measure not endorsed.

Appendix E2: Related and Competing Measures (Narrative)

Not applicable. Measure not endorsed.

Appendix F: Pre-Evaluation Comments

Pre-meeting commenting closed on June 19, 2020. No comments were submitted.

National Quality Forum 1099 14th Street NW, Suite 500 Washington, DC 20005 http://www.qualityforum.org