2009 PQRI MEASURE-APPLICABILITY VALIDATION PROCESS FOR CLAIMS-BASED REPORTING OF INDIVIDUAL MEAURES

As required by statute, the 2009 Physician Quality Reporting Initiative (PQRI) will include validation processes. Under the claims-based reporting method of individual measure(s), the determination of satisfactory reporting, as defined by statute, will itself serve as a general validation because the analysis will assess whether quality-data codes are appropriately submitted in a sufficient proportion of the instances when a reporting opportunity exists. In addition, for those professionals who satisfactorily submit quality-data codes for fewer than three PQRI measures, a measure-applicability validation process will determine whether they should have submitted quality-data codes for additional measures.

CMS will apply a two-step process to operationalize measure-applicability validation: (1) a "clinical relation" test, and (2) a "minimum threshold" test. Those who fail the validation process will not earn the PQRI incentive payment for 2009.

CMS may determine that it is necessary to modify the measure-applicability validation process after the start of the 2009 reporting period. However, any changes will result in the process being applied more leniently, thereby (1) allowing a greater number of professionals to pass validation and (2) causing no professional who would otherwise have passed to fail.

Prerequisites for Measure-Applicability Validation. Eligible professionals who submit quality-data codes for <u>only one or only two</u> PQRI measures for at least 80 percent of their patients or encounters eligible for each measure—and who do not submit <u>any</u> quality-data codes for <u>any</u> <u>other</u> measure—will be subject to the measure-applicability validation process. Selection of professionals for measure-applicability validation may be accomplished through a sampling mechanism.

Step 1: Clinical Relation Test. The clinical relation test is the first step in the two-step measure-applicability validation that will be applied to those who are subject to the validation process. This test is based on: (1) an extension of the statutory presumption that if a professional submits data for a measure, then that measure applies to her/his practice and (2) the concept that if one measure in a cluster of measures related to a particular clinical topic or professional service is applicable to a professional's practice, then other closely-related measures (measures in that same cluster) <u>may</u> also be applicable.

The following is an example of how the clinical relation test will be applied: A professional who is subject to measure-applicability validation submitted quality-data codes for one of the PQRI measures related to pneumonia. That professional's claims will then be analyzed using the minimum threshold test described below to determine whether another pneumonia measure (or two more pneumonia measures) could also have been submitted.

The list of clusters of related measures and the PQRI measures that are included within each cluster are presented below. CMS may determine this list should be modified to apply the measure-applicability validation process more leniently. Any such modifications will be published on the CMS PQRI website as soon as possible after a determination has been made.

Cluster Number	Cluster Title	Measure Number	Measure Title
1	Preventive	39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older
	-	48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older
		110	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old
		111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older
		112	Preventive Care and Screening: Screening Mammography
		113	Preventive Care and Screening: Colorectal Cancer Screening
2	Chronic Diabetic Care	1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus
	-	2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus
		3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus
		163	Diabetes Mellitus: Foot Exam
3	COPD Care	51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation
		52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy
4	Chronic Cardiac Care	5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
	-	6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD
	-	8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
		118	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)

Clusters of Clinically Related Measures Used in Step 1 of 2009 PQRI Measure-Applicability Validation for Claims-Based Reporting of Individual Measures

Cluster Number	Cluster Title	Measure Number	Measure Title
4	Chronic Cardiac Care (continued)	152	Coronary Artery Disease (CAD): Lipid Profile in Patients with CAD
5	Asthma Care	53	Asthma: Pharmacologic Therapy
	-	64	Asthma: Asthma Assessment
6	Pneumonia Care	56	Community-Acquired Pneumonia (CAP): Vital Signs
	-	57	Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation
	-	58	Community-Acquired Pneumonia (CAP): Assessment of Mental Status
		59	Community-Acquired Pneumonia (CAP): Empiric Antibiotic
7	Cancer Care 1	67	Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow
	-	68	Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy
	-	69	Multiple Myeloma: Treatment with Bisphosphonates
	-	70	Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry
8	Cancer Care 2	71	Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
	-	72	Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients
9	Cancer Care 3: Radiation Oncology	104	Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients
		105	Prostate Cancer: Three-Dimensional (3D) Radiotherapy
10	Cancer Care 4	143	Oncology: Medical and Radiation – Pain Intensity Quantified
	-	144	Oncology: Medical and Radiation – Plan of Care for Pain
11	Urinary Incontinence Care	49	Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older
	-	50	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Cluster Number	Cluster Title	Measure Number	Measure Title
12	Fracture Follow-up Care	24	Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture
		40	Osteoporosis: Management Following Fracture
13	Ear, Nose, Throat Care	91	Acute Otitis Externa (AOE): Topical Therapy
	-	92	Acute Otitis Externa (AOE): Pain Assessment
	-	93	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use
14	Pediatric ENT	65	Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use
		66	Appropriate Testing for Children with Pharyngitis
	-	94	Otitis Media with Effusion (OME): Diagnostic Evaluation – Assessment of Tympanic Membrane Mobility
15	Emergency Care	28	Aspirin at Arrival for Acute Myocardial Infarction (AMI)
	-	54	12-Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain
	-	55	12-Lead Electrocardiogram (ECG) Performed for Syncope
16	Pathology	99	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
	-	100	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade
17	Diagnostic Imaging	10	Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports
	-	11	Stroke and Stroke Rehabilitation: Carotid Imaging Reports
	-	145	Radiology: Exposure Time Reported for Procedures Using Fluoroscopy
	-	146	Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening
		147	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy
18	Depression	9	Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD
	-	106	Major Depressive Disorder (MDD): Diagnostic Evaluation
	-	107	Major Depressive Disorder (MDD): Suicide Risk Assessment

Cluster Number	Cluster Title	Measure Number	Measure Title
19	Eye Care 1	12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation
		141	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care
20	Eye Care 2	18	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy
		19	Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care
21	Eye Care 3	14	Age-Related Macular Degeneration (AMD): Dilated Macular Examination
		140	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement
22	Hepatitis Care	83	Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia
		84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment
		85	Hepatitis C: HCV Genotype Testing Prior to Treatment
		86	Hepatitis C: Antiviral Treatment Prescribed
		87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment
		89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption
		90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Treatment
		183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV
		184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV
23	Renal Disease Care	79	End Stage Renal Disease (ESRD): Influenza Immunization in Patients with ESRD
		121	Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile)
		122	Chronic Kidney Disease (CKD): Blood Pressure Management
		123	Chronic Kidney Disease (CKD): Plan of Care – Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA)
		135	Chronic Kidney Disease (CKD): Influenza Immunization

Cluster Number	Cluster Title	Measure Number	Measure Title
23	Renal Disease Care (continued)	153	Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula
24	Stroke Management	31	Stroke and Stroke Rehabilitation: Deep Vein Thrombosis Prophylaxis (DVT) for Ischemic Stroke or Intracranial Hemorrhage
		35	Stroke and Stroke Rehabilitation: Screening for Dysphagia
25	Stroke Discharge	32	Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy
	-	36	Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services
26	Surgical Care	20	Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician
	-	21	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin
	_	22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures)
		23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)
27	Cardiac Surgical Care	43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery
		44	Coronary Artery Bypass Graft (CABG): Preoperative Beta- Blocker in Patients with Isolated CABG Surgery
	-	45	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)
28	Diabetic Foot Care	126	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation
	-	127	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear
29	Osteoarthritis Care	109	Osteoarthritis (OA): Function and Pain Assessment
	-	142	Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications
30	Rheumatoid Arthritis Care	108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy
	-	176	Rheumatoid Arthritis (RA): Tuberculosis Screening
	-	177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity
	-	178	Rheumatoid Arthritis (RA): Functional Status Assessment

Cluster Number	Cluster Title	Measure Number	Measure Title
30	Rheumatoid Arthritis Care (continued)	179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis
		180	Rheumatoid Arthritis (RA): Glucocorticoid Management
31	Dermatologic Care	136	Melanoma: Follow-Up Aspects of Care
	_	137	Melanoma: Continuity of Care – Recall System
	_	138	Melanoma: Coordination of Care
32	Falls	154	Falls: Risk Assessment
	_	155	Falls: Plan of Care

Measures not included within a cluster in 2009 PQRI. For 2009 measure-applicability validation, CMS will not include measures that are deemed to be generally or broadly applicable to all or many Medicare patients and therefore potentially unreasonable to attribute to individual professionals using claims-based data. Other measures are not included in a cluster of closely clinically related measures for other clinical or technical reasons, such as: (1) the measure may not fit any cluster; or (2) the measure may fit reasonably with more than one cluster.

Measures excluded from 2009 measure-applicability validation for claims-based participation may or may not be included in groupings of measures used in validation protocols for other mechanisms of data submission, such as those based on extracts from medical registries or electronic health records, or for other purposes or programs. Based on such developments as refinements to a particular measure's specifications or enhancements of the PQRI list of available claims-based measures, any measure excluded from measure-applicability validation for 2009 may also, in subsequent program years, be included in a measure-applicability validation for claims-based participation in PQRI.

At a minimum, the following claim-based measures will be excluded from measureapplicability validation for 2009:

Measure	30 Perioperative Care: Timing of Prophylactic Antibiotics – Administering Physician
Measure	34 Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered
Measure	41 Osteoporosis: Pharmacologic Therapy
Measure	47 Advance Care Plan
Measure	76 Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol
Measure	95 Otitis Media with Effusion (OME): Hearing Testing
Measure	102 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients

- Measure 114 -- Preventive Care and Screening: Inquiry Regarding Tobacco Use
- Measure 115 -- Preventive Care and Screening: Advising Smokers to Quit
- Measure 116 -- Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use
- Measure 117 -- Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient
- Measure 119 -- Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
- Measure 124 -- Health Information Technology (HIT): Adoption/Use of Electronic Health Records
- Measure 128 -- Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up
- Measure 130 -- Documentation and Verification of Current Medications in the Medical Record
- Measure 131 -- Pain Assessment Prior to Initiation of Patient Therapy and Follow-Up
- Measure 134 -- Screening for Clinical Depression and Follow-Up Plan
- Measure 139 -- Cataracts: Comprehensive Preoperative Assessment for Cataract Surgery with Intraocular Lens (IOL) Placement
- Measure 156 -- Oncology: Radiation Dose Limits to Normal Tissues
- Measure 157 -- Thoracic Surgery: Recording of Clinical Stage for Lung Cancer and Esophageal Cancer Resection
- Measure 158 -- Endarterectomy: Use of Patch During Conventional Endarterectomy
- Measure 172 -- Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula
- Measure 173 -- Preventive Care and Screening: Unhealthy Alcohol Use Screening
- Measure 175 -- Pediatric End Stage Renal Disease (ESRD): Influenza Immunization
- Measure 181 -- Elder Maltreatment Screen and Follow-Up Plan
- Measure 182 -- Functional Outcome Assessment in Chiropractic Care
- Measure 185 -- Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use
- Measure 186 -- Wound Care: Use of Compression System in Patients with Venous Ulcers

Prior to performing the analysis to determine satisfactory PQRI reporting, CMS may determine that additional PQRI measures should be excluded from measure-applicability validation. Any additions to this list will be published on the CMS PQRI website as soon as possible after a determination has been made.

Step 2: Minimum Threshold Test. This second step will be applied to those who are subject to measure-applicability validation and who have potential additional measures that could have been submitted identified during the clinical relation test. The minimum threshold test is based on the concept that only if, during the 2009 reporting period (January 1, 2009 through December 31, 2009), a professional treated more than a certain number of Medicare patients with a condition to which a certain measure applied (that is, the professional treated more than a "threshold" number of patients or encounters), then that professional should be accountable for submitting the quality-data code(s) for that measure. For the 2009 reporting period, the common minimum threshold, based on statistical and clinical frequency considerations, will not be less than 15 patients or encounters for each 2009 PQRI measure.

The following are examples of how the minimum threshold test will be applied: An emergency department (ED) physician treated 20 Medicare patients with pneumonia during the 2009 12-month reporting period. If that ED physician is subject to validation and was found to have submitted a quality-data code for at least one of the pneumonia measures under the clinical relation test, then the physician would be deemed responsible for submitting quality-data codes for at least one other PQRI pneumonia measure and will not earn the 2009 incentive payment. Alternatively, if an internist was subject to validation and was found to have submitted a quality-data code for at least one of the pneumonia measures under the clinical relation test but treated only two Medicare patients with pneumonia during the same period, then the internist would not be responsible for submitting the additional pneumonia measures and would not be precluded from receiving an incentive payment.

During the reporting period, CMS will determine a minimum threshold for each individual PQRI measure based on analysis of Part B claims data. However, no threshold will fall below the common threshold of 15 patients or encounters described above.

Other Program Integrity Considerations. Quality-data codes submitted on claims must be supported in medical record documentation. Other laws and regulations relating to Medicare program integrity may also apply to the PQRI.

Measures Reported via Registry or Measure Group Only - Not Applicable to Measure-Applicability Validation. The following list of measures will be reported through registries or by measure group reporting only, therefore, are not subject to measure-applicability validation.

- Measure 7 -- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)
- Measure 33 -- Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge
- Measure 46 -- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility
- Measure 81 -- End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients
- Measure 82 -- End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis
- Measure 148 -- Back Pain: Initial Visit
- Measure 149 -- Back Pain: Physical Exam
- Measure 150 -- Back Pain: Advice for Normal Activities
- Measure 151 -- Back Pain: Advice Against Bed Rest

Measure 159 -- HIV/AIDS: CD4+ Cell Count or CD4+ Percentage

- Measure 160 -- HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis
- Measure 161 -- HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy
- Measure 162 -- HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy
- Measure 164 -- Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Ventilation)
- Measure 165 -- Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate
- Measure 166 -- Coronary Artery Bypass Graft (CABG): Stroke/Cerebrovascular Accident (CVA)

Measure 167 -- Coronary Artery Bypass Graft (CABG): Postoperative Renal Insufficiency

Measure 168 -- Coronary Artery Bypass Graft (CABG): Surgical Re-exploration

Measure 169 -- Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge

Measure 170 -- Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge

- Measure 171 -- Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling
- Measure 174 -- Pediatric End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis