The 2010 Physician Quality Reporting Initiative (PQRI) will include validation processes. Under the claims-based reporting method of individual measure(s), the determination of satisfactory reporting 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 EPs who satisfactorily submit quality-data codes (QDCs) for fewer than three PQRI measures, a measure-applicability validation process will determine whether they should have submitted QDCs 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 2010.

CMS may determine that it is necessary to modify the measure-applicability validation process after the start of the 2010 reporting period. However, any changes will result in the process being applied more leniently, thereby (1) allowing a greater number of EPs to pass validation and (2) causing no EP who would otherwise have passed to fail.

Prerequisites for Measure-Applicability Validation. EPs who submit QDCs 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 QDCs</u> for <u>any other</u> measure will be subject to the measure-applicability validation process. Selection of EPs 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 an EP 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 EP service is applicable to an EPs 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: An EP who is subject to measure-applicability validation submitted QDCs for one of the PQRI measures related to pneumonia. That EPs 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.

Clusters of Clinically Related Measures Used in Step 1 of 2010 PQRI Measure-Applicability Validation for Claims-Based Reporting of Individual Measures

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	Asthma Care	53	Asthma: Pharmacologic Therapy
		64	Asthma: Asthma Assessment
5	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
6	Cancer Care 1	67	Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Cluster Number	Cluster Title	Measure Number	Measure Title
	Cancer Care 1 (continued)	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
7	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
	-	194	Oncology: Cancer Stage Documented
8	Cancer Care 3: Radiation Oncology	104	Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients
		105	Prostate Cancer: Three-Dimensional (3D) Radiotherapy
9	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 i Women Aged 65 Years and Older
10	Fracture Follow-up Care	24	Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine, or Distal Radius f Men and Women Aged 50 Years and Older
		40	Osteoporosis: Management Following Fracture of Hip, Spine, or Distal Radius for Men and Women Aged 50 Years and Old
11	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
12	Pediatric ENT	65	Treatment for Children with Upper Respiratory Infection (UR Avoidance of Inappropriate Use
		66	Appropriate Testing for Children with Pharyngitis
	_	94	Otitis Media with Effusion (OME): Diagnostic Evaluation – Assessment of Tympanic Membrane Mobility
13	Emergency Care	28	Aspirin at Arrival for Acute Myocardial Infarction (AMI)
	-	54	12-Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain

Cluster Number	Cluster Title	Measure Number	Measure Title
	Emergency Care (continued)	55	12-Lead Electrocardiogram (ECG) Performed for Syncope
14	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
15	Diagnostic Imaging	10	Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) 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
16	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
17	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 Pla of Care
18	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
19	Eye Care 3	14	Age-Related Macular Degeneration (AMD): Dilated Macular Examination
		140	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement
20	Hepatitis Care	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

Cluster Number	Cluster Title	Measure Number	Measure Title
	Hepatitis Care (continued)	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
21	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
		153	Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula
22	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
23	Stroke Discharge	32	Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy
		36	Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services
24	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)
25	Cardiac Surgical Care	43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery

Cluster Number	Cluster Title	Measure Number	Measure Title
	Cardiac Surgical Care (continued)	44	Coronary Artery Bypass Graft (CABG): Preoperative Beta- Blocker in Patients with Isolated CABG Surgery
		45	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)
26	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
27	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
28	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
		179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis
		180	Rheumatoid Arthritis (RA): Glucocorticoid Management
29	Falls	154	Falls: Risk Assessment
		155	Falls: Plan of Care
30	Anesthesia Care 1	30	Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics
		76	Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol
		When report	ing # 76 alone, it is not subject to MAV
31	Anesthesia Care 2	76	Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol
		193	Perioperative Temperature Management
		When report	ing # 76 alone, it is not subject to MAV
32	Ear Care	188	Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear
Varaion 4	0		

Cluster Number	Cluster Title	Measure Number	Measure Title
	Ear Care (continued)	189	Referral for Otologic Evalulation for Patients with a History of Active drainage from the Ear within Previous 90 Days
		190	Referral for Otolgic Evaluation for Patients with a History of Sudden or Rapidaly Progressive Hearing Loss
33	Ischemic Vascular Disease	201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control
		202	Ischemic Vascular Disease (IVD): Complete Lipid Profile
		203	Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL-C) Control
		204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Anti-Thrombotic

Measures not included within a cluster in 2010 PQRI. For 2010 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 EPs 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 2010 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 2010 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 measure-applicability validation for 2010:

Measure 6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD
Measure 41	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older
Measure 46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility
Measure 47	Advance Care Plan
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 and Tobacco Users 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 (EHR)
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 -- Carotid Endarterectomy: Use of Patch During Conventional Carotid 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
- Measure 195 -- Stenosis Measurement in Carotid Imaging Studies

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 during the 2010 reporting periods January 1, 2010 through December 31, 2010; **OR** July 1, 2010 through December 31, 2010, if an EP treated more than a certain number of Medicare patients with a condition to which a certain measure applied (that is, the EP treated more than a "threshold" number of patients or encounters), then that EP should be accountable for submitting the quality-data code(s) for that measure. For the 2010 reporting periods, the common minimum threshold, based on statistical and clinical frequency considerations, will not be less than 15 patients (or encounters) for the 12-month reporting period or 8 patients (or encounters) for the 6-month reporting period for each 2010 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 2010 12-month reporting period. If that ED physician is subject to validation and was found to have submitted a quality-data code (QDC) for at least one of the pneumonia measures under the clinical relation test, then the physician would be deemed responsible for submitting QDCs for at least one other PQRI pneumonia measure and will not earn the 2010 incentive payment. Alternatively, if an internist was subject to validation and was found to have submitted a QDC 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. QDCs 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 program.

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

- Measure 5 -- Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- Measure 7 -- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)
- Measure 8 -- Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- Measure 33 -- Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge
- 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 83 -- Hepatitis C: Testing for Chronic Hepatitis C Confirmation of Hepatitis C Viremia
- Measure 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)
- Measure 136 -- Melanoma: Follow-Up Aspects of Care
- Measure 137 -- Melanoma: Continuity of Care-Recall System
- Measure 138 -- Melanoma: Coordination of Care
- Measure 143 -- Oncology: Medical and Radiation Pain Intensity Quantified
- Measure 144 -- Oncology: Medical and Radiation Plan of Care for Pain
- 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
- Measure 187 -- Stroke and Stroke Rehabilitation: Thrombolytic Therapy Administered
- Measure 191 -- Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Measure 192	Cataracts: Complication within 30 Days Following Cataract Surgery Requiring Additional
	Surgical Procedures
Measure 196	Coronary Artery Disease (CAD): Symptom and Activity Assessment
Measure 197	Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol
Measure 198	Heart Failure: Left Ventricular Function (LVF) Assessment
Measure 199	Heart Failure: Patient Education
Measure 200	Heart Failure: Warfarin Therapy Patients with Atrial Fibrillation
Measure 205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea
Measure 206	HIV/AIDS: Screening for High Risk Sexual Behaviors
Measure 207	HIV/AIDS: Screening for Injection Drug Use
Measure 208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis
Measure 209	Functional Communication Measure - Spoken Language Comprehension
Measure 210	Functional Communication Measure - Attention
Measure 211	Functional Communication Measure - Memory
Measure 212	Functional Communication Measure - Motor Speech
Measure 213	Functional Communication Measure - Reading
Measure 214	Functional Communication Measure - Spoken Language English
Measure 215	Functional Communication Measure - Writing
Measure 216	Functional Communication Measure - Swallowing