2008 PQRI MEASURE-APPLICABILITY VALIDATION PROCESS FOR CLAIMS-BASED PARTICIPATION

As required by statute, the 2008 Physician Quality Reporting Initiative (PQRI) will include validation processes. Under the claims-based reporting method, 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 2008.

CMS may determine that it is necessary to modify the measure-applicability validation process after the start of the 2008 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 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.

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The list of clusters of related measures and the PQRI measures that are included within each cluster are presented below. CMS may determine that 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 2008 PQRI Measure-Applicability Validation for Claims-Based Participation

Cluster Number	Cluster Title	Measure Number	Measure Title
1	Preventive	39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older
	-	48	Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older
		110	Influenza Vaccination for Patients Greater than or Equal to 50 Years Old
		111	Pneumonia Vaccination for Patients 65 Years and Older
		112	Screening Mammography
		113	Colorectal Cancer Screening
	_	114	Inquiry Regarding Tobacco Use
		115	Advising Smokers to Quit
2	Chronic Diabetic Care	1	Hemoglobin A1c Poor Control in Type 1 or 2 Diabetes Mellitus
		2	Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus
		3	High Blood Pressure Control in Type 1 or 2 Diabetes Mellitus
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	Oral Antiplatelet Therapy Prescribed for Patients with Coronary Artery Disease
		7	Beta-Blocker Therapy for Coronary Artery Disease Patients with Prior Myocardial Infarction (MI)
		8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction

Cluster Number	Cluster Title	Measure Number	Measure Title
4	Chronic Cardiac Care (continued)	118	Angiotensin-Converting Enzyme Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB) Therapy for Patients with Coronary Artery Disease and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)
5	Asthma Care	53	Asthma: Pharmacologic Therapy
		64	Asthma Assessment
6	Pneumonia Care	56	Vital Signs for Community-Acquired Bacterial Pneumonia
		57	Assessment of Oxygen Saturation for Community-Acquired Bacterial Pneumonia
		58	Assessment of Mental Status for Community-Acquired Pneumonia
	•	59	Empiric Antibiotic for Community-Acquired Bacterial Pneumonia
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	Hormonal Therapy for Stage IC - III ER/PR Positive Breast Cancer
	•	72	Chemotherapy for Stage III Colon Cancer Patients
	·	73	Plan for Chemotherapy Documented Before Chemotherapy Administered
9	Cancer Care 3: Prostate Cancer Care	101	Appropriate Initial Evaluation of Patients with Prostate Cancer
		102	Inappropriate Use of Bone Scan for Staging Low-Risk Prostate Cancer Patients
	-	103	Review of Treatment Options in Patients with Clinically Localized Prostate Cancer

Cluster Number	Cluster Title	Measure Number	Measure Title
10	Urinary Incontinence Care	49	Characterization of Urinary Incontinence in Women Aged 65 Years and Older
	_	50	Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
11	Fracture Follow-up Care	24	Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture
		40	Osteoporosis: Management Following Fracture
12	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
13	Pediatric ENT	65	Appropriate Treatment for Children with Upper Respiratory Infection (URI)
	_	66	Appropriate Testing for Children with Pharyngitis
	-	94	Otitis Media with Effusion (OME): Diagnostic Evaluation – Assessment of Tympanic Membrane Mobility
	-	96	Otitis Media with Effusion (OME): Antihistamines or Decongestants – Avoidance of Inappropriate Use
	-	97	Otitis Media with Effusion (OME): Systemic Antimicrobials – Avoidance of Inappropriate Use
		98	Otitis Media with Effusion (OME): Systemic Corticosteroids – Avoidance of Inappropriate Use
14	Emergency Care	28	Aspirin at Arrival for Acute Myocardial Infarction (AMI)
	-	54	Electrocardiogram Performed for Non-Traumatic Chest Pain
	_	55	Electrocardiogram Performed for Syncope
15	Pathology	99	Breast Cancer Patients Who Have a pT and pN Category and Histologic Grade for Their Cancer
		100	Colorectal Cancer Patients Who Have a pT and pN Category and Histologic Grade for Their Cancer
16	Radiology	10	Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports
	-	11	Stroke and Stroke Rehabilitation: Carotid Imaging Reports
17	Depression	9	Antidepressant Medication During Acute Phase for Patients with New Episode of Major Depression
	-	106	Patients Who Have Major Depression Disorder Who Meet DSM IV Criteria

Cluster Number	Cluster Title	Measure Number	Measure Title
17	Depression (continued)	107	Patients Who Have Major Depression Disorder Who Are Assessed for Suicide Risks
18	Eye Care	12	Primary Open Angle Glaucoma: Optic Nerve Evaluation
		14	Age-Related Macular Degeneration: Dilated Macular Examination
		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 Ongoing Diabetes Care
		117	Dilated Eye Exam in Diabetic Patient
19	Hepatitis Care	83	Testing of Patients with Chronic Hepatitis C (HCV) for Hepatitis C Viremia
		84	Initial Hepatitis C RNA Testing
		85	HCV Genotype Testing Prior to Therapy
		86	Consideration for Antiviral Therapy in HCV Patients
		87	HCV RNA Testing at Week 12 of Therapy
		88	Hepatitis A and B Vaccination in Patients with HCV
		89	Counseling of Patients with HCV Regarding Use of Alcohol
		90	Counseling of Patients Regarding Use of Contraception Prior to Starting Antiviral Treatment
20	Renal Disease Care	78	Vascular Access for Patients Undergoing Hemodialysis
		79	Influenza Vaccination in Patients with End Stage Renal Disease (ESRD)
		80	Plan of Care for ESRD Patients with Anemia
		81	Plan of Care for Inadequate Hemodialysis in ESRD Patients
		82	Plan of Care for Inadequate Peritoneal Dialysis
		120	ACE Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy in Patients with CKD
		121	Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile)

Cluster Number	Cluster Title	Measure Number	Measure Title
20	Renal Disease Care (continued)	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)
21	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
22	Stroke Discharge	32	Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy
	_	33	Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge
	_	36	Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services
23	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)
24	Cardiac Surgical Care	43	Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG) Surgery
		44	Preoperative Beta-blocker in Patients with Isolated Coronary Artery Bypass Graft (CABG) Surgery
		45	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)
25	Diabetic Foot Care	126	Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation
	_	127	Diabetic Foot and Ankle Care, Ulcer Prevention: Evaluation of Footwear
26	Allied Professional Care	128	Universal Weight Screening and Follow-Up
		129	Universal Influenza Vaccine Screening and Counseling
	-	130	Universal Documentation and Verification of Current Medications in the Medical Record

Measures not included within a cluster in 2008 PQRI. For 2008 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 2008 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 2008 may also, in subsequent program years, be included in a measure-applicability validation for claims-based participation in PQRI.

At least the following measures will be excluded from measure-applicability validation for 2008 claims-based participation:

- Measure 4 -- Screening for Future Fall Risk
- 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 46 -- Medication Reconciliation
- Measure 47 -- Advance Care Plan
- Measure 74 -- Radiation Therapy Recommended for Invasive Breast Cancer Patients Who Have Undergone Breast Conserving Surgery
- Measure 75 -- Prevention of Ventilator-Associated Pneumonia Head Elevation
- Measure 76 -- Prevention of Catheter-Related Bloodstream Infections (CRBSI) Central Venous Catheter Insertion Protocol
- Measure 77 -- Assessment of GERD Symptoms in Patients Receiving Chronic Medication for GERD
- Measure 95 -- Otitis Media with Effusion (OME): Hearing Testing
- Measure 104 -- Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients
- Measure 105 -- Three-Dimensional Radiotherapy for Patients with Prostate Cancer
- Measure 108 -- Disease Modifying Anti-Rheumatic Drug Therapy in Rheumatoid Arthritis
- Measure 109 -- Patients with Osteoarthritis Who Have an Assessment of Their Pain and Function
- Measure 116 -- Inappropriate Antibiotic Treatment for Adults with Acute Bronchitis
- Measure 119 -- Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
- Measure 124 -- HIT Adoption/Use of Health Information Technology (Electronic Health Records)
- Measure 125 -- HIT Adoption/Use of e-Prescribing
- Measure 131 -- Pain Assessment Prior to Initiation of Patient Treatment

Measure 132 -- Patient Co-Development of Treatment Plan/Plan of Care

Measure 133 -- Screening for Cognitive Impairment

Measure 134 -- Screening for Clinical Depression

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 2008 reporting period (January 1, 2008, through December 31, 2008), 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 2008 reporting period, the common minimum threshold, based on statistical and clinical frequency considerations, will not be less than 30 patients or encounters for each 2008 PQRI measure.

The following are examples of how the minimum threshold test will be applied: An emergency department (ED) physician treated 35 Medicare patients with pneumonia during the 2008 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 2008 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 30 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.