This form contains the information submitted by measure developers/stewards, organized according to NQF’s measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

<table>
<thead>
<tr>
<th>NQF #: 0571</th>
<th>NQF Project: Renal Endorsement Maintenance 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>(for Endorsement Maintenance Review)</td>
<td></td>
</tr>
<tr>
<td>Original Endorsement Date: Dec 04, 2009 Most Recent Endorsement Date: Dec 04, 2009</td>
<td></td>
</tr>
</tbody>
</table>

### BRIEF MEASURE INFORMATION

- **De.1 Measure Title:** CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH)
- **Co.1.1 Measure Steward:** IMS Health
- **De.2 Brief Description of Measure:** To ensure that members with chronic kidney disease are monitored for PTH levels at least once annually.
- **2a1.1 Numerator Statement:** Members who received a PTH level test during the measurement year.
- **2a1.4 Denominator Statement:** Members with chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or the year prior (at least 1 of which must be during the year prior to the measurement year), or members on dialysis or who utilized dialysis during the year prior to the measurement year.
- **2a1.8 Denominator Exclusions:** Members who are in hospice during the measurement year.
- **1.1 Measure Type:** Process
- **2a1.25-26 Data Source:** Administrative claims
- **2a1.33 Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Clinician: Team, Health Plan
- **1.2-1.4 Is this measure paired with another measure?** No

### STAFF NOTES

**Comments on Conditions for Consideration:**

- Is the measure untested? Yes [ ] No [X] If untested, explain how it meets criteria for consideration for time-limited endorsement:

1. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):
2. Similar/related endorsed or submitted measures (check 5.1):

**Other Criteria:**

Staff Reviewer Name(s):

### 1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)
1a. **High Impact:** M L I

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

**De.4 Subject/Topic Areas** (Check all the areas that apply): Renal, Renal : Chronic Kidney Disease (CKD), Renal : End Stage Renal Disease (ESRD)

**De.5 Cross Cutting Areas** (Check all the areas that apply): Population Health

1a.1 **Demonstrated High Impact Aspect of Healthcare:** A leading cause of morbidity/mortality, Patient/societal consequences of poor quality

1a.2 If “Other,” please describe:

1a.3 **Summary of Evidence of High Impact** *(Provide epidemiologic or resource use data):*

Approximately 26 million people in the US have chronic kidney disease (CKD),[1] and nearly 400,000 require dialysis.[2] CKD patients account for 27.6% of general Medicare expenditure.[3, 4] In addition, an estimated 80,000 people are diagnosed annually with CKD.[5,6] Nearly all members with CKD would present with osteodystrophy, a disorder of bone remodeling, without appropriate monitoring and treatment for inbalances in calcium phosphate homeostatis.[7,8]

1a.4 **Citations for Evidence of High Impact cited in 1a.3:**

1b. **Opportunity for Improvement:** M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

Bone mineral disorders are common in patients with chronic kidney disease, and have potential for severe adverse impact on both mortality and morbidity. The diagnosis of bone mineral disorders is dependent on laboratory testing of calcium, phosphorus, and parathyroid hormone. This measure assesses the lowest rate of parathyroid hormone measurement in patients with CKD, as advocated by national guidelines. Thus, the use of this measure would increase physician compliance with quality of care in the management of bone mineral disorders among patients with CKD and to allow for identification of bone mineral disorders and referral of patients for appropriate treatment.

1b.2 **Summary of Data Demonstrating Performance Gap** *(Variation or overall less than optimal performance across providers)*:

[For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

A 2007 study examining adherence within a managed care setting to the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines found that the percentages of patients with Stage 3, Stage 4 and Stage 5 CKD who received AT LEAST annual PTH testing were 7.3%, 17.5%, and 38.2%, respectively.[1] Additionally, rates of parathyroid hormone testing are low regardless of provider specialty, but especially low among those seen by primary care providers. A 2008 study conducted on a privately insured population found that overall rates of PTH testing were low, but were significantly lower among those patients seen by internists, as
compared to nephrologists (0.6%, vs 7.1%, P=0.0002).[2]

1b.3 Citations for Data on Performance Gap: [For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]


1b.4 Summary of Data on Disparities by Population Group: [For Maintenance – Descriptive statistics for performance results for this measure by population group]

Little research has been done regarding receipt of KDOQI guidelines among disadvantaged groups. However, it has been reported that CKD patients who are female, non diabetic and being treated by an internist (rather than a nephrologist) may be less likely to receive appropriate monitoring.[1,2]

1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]


1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.)

Is the measure focus a health outcome?  Yes[ ] No[ ]  If not a health outcome, rate the body of evidence.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Quality</th>
<th>Consistency</th>
<th>Does the measure pass subcriterion1c?</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-H</td>
<td>M-H</td>
<td>M-H</td>
<td>Yes[ ]</td>
</tr>
<tr>
<td>L</td>
<td>M-H</td>
<td>M</td>
<td>Yes[ ] IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No[ ]</td>
</tr>
<tr>
<td>M-H</td>
<td>L</td>
<td>M-H</td>
<td>Yes[ ] IF potential benefits to patients clearly outweigh potential harms: otherwise No[ ]</td>
</tr>
<tr>
<td>L-M-H</td>
<td>L-M-H</td>
<td>L</td>
<td>No[ ]</td>
</tr>
</tbody>
</table>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?  Yes[ ] IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process-health outcome; intermediate clinical outcome-health outcome):

This measure assesses the annual laboratory measurement of blood parathyroid hormone levels in patients with chronic kidney disease. This is a process measure. The laboratory measurement of blood parathyroid hormone is the first step in identifying patients with bone mineral disorders in need of treatment. In the medical literature there is direct relationship between aberrant levels of Ca, PO4 and PTH and disease.

1c.2-3 Type of Evidence (Check all that apply):
Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

The patient population addressed by measure is patients with chronic kidney disease, and there are no differences between the measure focus and measure target population.
1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): There are numerous studies showing aberrancy of Ca, PO4, and PTH measurements starting at chronic kidney disease level three (Levin et al Kidney Int 2007, Melamed ML et al Nephrol Dial Transplant 2008). There are no studies indicating the appropriate frequency in which measurements of Ca, PO4, or PTH should be followed in chronic kidney disease. The evidence regarding the frequency of measurements of Ca, PO4 or PTH is based on expert opinion.

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): There are numerous cross-sectional studies showing aberrancy of Ca, PO4, and PTH measurements starting at chronic kidney disease level three (Levin et al Kidney Int 2007, Melamed ML et al Nephrol Dial Transplant 2008). Usually the best data to guide diagnostic monitoring is obtained from cross-sectional population-based or cohort-based studies. There are no studies indicating the appropriate frequency in which measurements of Ca, PO4, or PTH should be followed in chronic kidney disease.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Studies show that, although changes in Ca, PO4, and PTH begin in CKD stage 3, the rate and magnitude of these changes are highly variable among different patients.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms): The benefit of laboratory monitoring of Ca, PO4, and PTH would be timely diagnosis of metabolic bone disease. The harm of a laboratory blood draw is minimal.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The recommendation for laboratory monitoring of Ca, PO4, and PTH was graded by the National Kidney Foundation (NKF) and Kidney Disease Improving Global Outcome (KDIGO).

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: National Kidney Foundation categorized their statements as their “Evidence” or “Opinion”. “Evidence” statements are backed by studies, and “Opinion” statements are based on expert consensus.

Kidney Disease Improving Global Outcome (KDIGO) grade the strength of their statement based on four factors: balance between desirable and undesirable effects, quality of the evidence, value and preferences, and cost. KDIGO assign a number and a letter to their consent statements. Letter grade “A” statements are of high quality, “B” statements are of moderate quality, “C” statements are of low quality and “D” statements are of very low quality. Numeric grade gives the strength of recommendation. Level 1 grade means for patients that “Most people in your situation would want the recommended course of action and only a small proportion would not” and for clinician “Most patient should receive the recommended course of action.” Level 2 grade means for patients that “The majority of people in your situation would want the recommended course of action, but many would not”, and for clinicians “Different choices will be appropriate for difference patients. Each patient needs help to arrive at a management decision consistent with her or his values and preferences.”

1c.13 Grade Assigned to the Body of Evidence: NKF graded the body of evidence for CA, PO4 and PTH monitoring starting in stage III kidney disease as “evidence” and frequency of measurement as “opinion”. KDIGO graded the body of evidence for CA, PO4 and PTH monitoring starting in stage III kidney disease as “1 C”. Of not although KDIGO graded the evidence of this statement as “Low quality evidence”, KDIGO gave this statement a level 1 recommendation implying that “most patients should receive the recommended course of action”. KDIGO did not grade the frequency of measurement.

1c.14 Summary of Controversy/Contradictory Evidence: There is no contradictory evidence.
1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):
The National Kidney Foundation recommends that patients with CKD initiate measurement of serum levels of calcium, phosphate, and parathyroid hormone once their glomerular filtration rate (GFR) drops below 60mL/min/1.73m2. Frequency of testing should be based on the stage of CKD.

KDIGO Clinical Practice Guideline
3.1.1 We recommend monitoring serum levels of calcium, phosphorus, PTH, and alkaline phosphatase activity beginning in CKD stage 3 (1C). In children, we suggest such monitoring beginning in CKD stage 2 (2D). (page 523)
3.1.2 In patients with CKD stages 3–5D, it is reasonable to base the frequency of monitoring serum calcium, phosphorus, and PTH on the presence and magnitude of abnormalities, and the rate of progression of CKD (not graded).

1c.17 Clinical Practice Guideline Citation: Kidney Disease Outcome Quality Initiative: Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease 2003, National Kidney Foundation.

1c.18 National Guideline Clearinghouse or other URL:

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: N/A

1c.23 Grade Assigned to the Recommendation: N/A

1c.24 Rationale for Using this Guideline Over Others: The National Kidney Foundation is a highly regarded organization whose guidelines are well respected within the medical community.

Based on the NQF descriptions for rating the evidence, what was the developer’s assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High  1c.26 Quality: High  1c.27 Consistency: High

Was the threshold criterion, Importance to Measure and Report, met? (1a & 1b must be rated moderate or high and 1c yes) Yes □ No □
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when...
NQF #0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH)

implemented. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? No

S.2 If yes, provide web page URL:

2a. RELIABILITY. Precise Specifications and Reliability Testing:  H M L I

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):
Members who received a PTH level test during the measurement year.

2a1.2 Numerator Time Window (The time period in which the target process, condition, event, or outcome is eligible for inclusion):
The measurement year.

2a1.3 Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses):
Numerator Logic: A

[A] Members who received a PTH level test during the measurement year.

CPT-4 code(s): 75893, 83970
CPT-4 category II code(s): 3278F

2a1.4 Denominator Statement (Brief, narrative description of the target population being measured):
Members with chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or the year prior (at least 1 of which must be during the year prior to the measurement year), or members on dialysis or who utilized dialysis during the year prior to the measurement year.

2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care

2a1.6 Denominator Time Window (The time period in which cases are eligible for inclusion):
The year prior to the measurement year.

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):
Denominator Logic: (A or (B and C) or D or E) and CE

[CE] Members continuously enrolled during the measurement year.

[A] Members with at least 1 inpatient encounter with chronic kidney disease (stage >= 3) during the year prior to the measurement year.

Chronic kidney disease:
ICD-9 diagnosis code(s): 250.4x, 274.1x, 403.01, 403.11, 403.90, 403.91, 404.02, 404.03, 404.10, 404.11, 404.12, 404.13, 404.90, 404.91, 404.92, 404.93, 581.xx, 582.xx, 583.xx, 583.3-585.5, 586, 587, 588.xx, 753.0, 753.10, 753.11, 753.12, 753.13, 753.14, 753.15, 753.16, 753.17, 753.19

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
[B] Members with at least 1 face-to-face outpatient encounter with chronic kidney disease (stage >= 3) during the year prior to the measurement period.

Chronic Renal Disease:
ICD-9 diagnosis code(s): 250.4x, 274.1x, 403.01, 403.11, 403.90, 403.91, 404.02, 404.03, 404.10, 404.11, 404.12, 404.13, 404.90, 404.91, 404.92, 404.93, 581.xx, 582.xx, 583.xx, 585.3-585.5, 586, 587, 588.xx, 753.0, 753.10, 753.11, 753.12, 753.13, 753.14, 753.15, 753.16, 753.17, 753.19
DRG code(s): 316
MS-DRG code(s): 682-684
AND
Outpatient setting:
UB revenue code(s): 051x, 0520-0523, 0526-0529, 057x-059x, 077x, 082x-085x, 088x, 0982, 0983
Hospital observation:
CPT-4 code(s): 99217-99220, 99234-99236

[C] Members with at least 1 face-to-face outpatient encounter with chronic kidney disease (stage >= 3) during the measurement year.

Chronic kidney disease:
ICD-9 diagnosis code(s): 250.4x, 274.1x, 403.01, 403.11, 403.90, 403.91, 404.02, 404.03, 404.10, 404.11, 404.12, 404.13, 404.90, 404.91, 404.92, 404.93, 581.xx, 582.xx, 583.xx, 585.3-585.5, 586, 587, 588.xx, 753.0, 753.10-753.17, 753.19
DRG code(s): 316
MS-DRG code(s): 682-684
AND
Outpatient setting:
UB revenue code(s): 051x, 0520-0523, 0526-0529, 057x-059x, 077x, 082x-085x, 088x, 0982, 0983
Hospital observation:
CPT-4 code(s): 99217-99220, 99234-99236

[D] Members with at least 2 face-to-face outpatient encounters (on different dates of service) with chronic kidney disease (stage >= 3) during the year prior to measurement year.

Chronic kidney disease:
ICD-9 diagnosis code(s): 250.4x, 274.1x, 403.01, 403.11, 403.90, 403.91, 404.02, 404.03, 404.10, 404.11, 404.12, 404.13, 404.90, 404.91, 404.92, 404.93, 581.xx, 582.xx, 583.xx, 585.3-585.5, 586, 587, 588.xx, 753.0, 753.10-753.17, 753.19
DRG code(s): 316
MS-DRG code(s): 682-684
AND
Outpatient setting:
UB revenue code(s): 051x, 0520-0523, 0526-0529, 057x-059x, 077x, 082x-085x, 088x, 0982, 0983
Hospital observation:
CPT-4 code(s): 99217-99220, 99234-99236
Denominator Exclusions (Brief narrative description of exclusions from the target population):

Members who are in hospice during the measurement year.

Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

Denominator Exclusion Logic: A

Members who were in hospice care during the measurement year.

Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

N/A

Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):

N/A

Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
2a1.17-18. **Type of Score:** Rate/proportion

2a1.19 **Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Higher score

2a1.20 **Calculation Algorithm/Measure Logic** (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

The first step in calculating a performance score utilizing this measure is to identify the denominator, or patients with chronic kidney disease. Next, excluded patients are removed from the denominator; exclusions for this measure include patients in hospice. Next, the numerator, or the rate of parathyroid hormone measurement, can be determined. Calculating the numerator/denominator ratio provides the rate for a health plan, provider, etc. As this is a process measure, there is no risk adjustment necessary.

2a1.21-23 **Calculation Algorithm/Measure Logic Diagram URL or attachment:**

2a1.24 **Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

N/A

2a1.25 **Data Source** (Check all the sources for which the measure is specified and tested). If other, please describe:

Administrative claims

2a1.26 **Data Source/Data Collection Instrument** (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): Member demographics and member enrollment data.

2a1.27-29 **Data Source/data Collection Instrument Reference Web Page URL or Attachment:**

2a1.30-32 **Data Dictionary/Code Table Web Page URL or Attachment:**

2a1.33 **Level of Analysis** (Check the levels of analysis for which the measure is specified and tested): Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan

2a1.34-35 **Care Setting** (Check all the settings for which the measure is specified and tested): Ambulatory Care : Clinic/Urgent Care, Ambulatory Care : Clinician Office, Laboratory

2a2. **Reliability Testing.** (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

2a2.1 **Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Data from commercial health plans were used to generate rates of PTH testing. Included health plans range from 3 to 7 million members.

2a2.2 **Analytic Method** (Describe method of reliability testing & rationale):
Testing rates for Plan A and B were compared for stability over the course of two years. For Plan A, Year One represents 2008 data, while Year Two includes 2009 data. For Plan B, Year One represents data between 7/1/08 and 6/30/09, and Year Two represents data between 7/1/09 and 6/30/10.

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

<table>
<thead>
<tr>
<th>PLAN</th>
<th>Year One Rate</th>
<th>Year Two Rate</th>
<th>Year One Den</th>
<th>Year Two Den</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan A</td>
<td>29.54%</td>
<td>35.75%</td>
<td>7387</td>
<td>9491</td>
</tr>
<tr>
<td>Plan B</td>
<td>24.72%</td>
<td>28.42%</td>
<td>8652</td>
<td>10992</td>
</tr>
</tbody>
</table>

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:
The patient population addressed by measure is patients with chronic kidney disease; there are no differences between the measure focus and measure target population. Both the measure focus and target population are consistent with the evidence.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
2008 Data from six geographically diverse commercial health plans were used to generate rates of PTH testing. The sizes of the included health plans range from 580,000 members to 7 million members.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment):
PART 1: The algorithm for serum parathyroid hormone testing was run on all six plans. Denominator size and rate were calculated for each plan.
PART 2: Rates generated using this algorithm were compared to annual rates for PTH testing found in the literature.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):

<table>
<thead>
<tr>
<th>PLAN</th>
<th>RATE</th>
<th>DENOMINATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan A</td>
<td>29.54%</td>
<td>7387</td>
</tr>
<tr>
<td>Plan B</td>
<td>24.72%</td>
<td>8652</td>
</tr>
<tr>
<td>Plan C</td>
<td>22.27%</td>
<td>660</td>
</tr>
<tr>
<td>Plan D</td>
<td>14.95%</td>
<td>14974</td>
</tr>
<tr>
<td>Plan E</td>
<td>21.49%</td>
<td>3201</td>
</tr>
<tr>
<td>Plan F</td>
<td>18.32%</td>
<td>5856</td>
</tr>
</tbody>
</table>

Average Rate: 21.88% Standard Deviation: 5.05%
Average Denominator: 6788

PART 2:

Several U.S.-based studies have examined prevalence of PTH testing among patients with CKD, and have generally reported rates of testing in commercial settings between 3 and 15%.[1] Rates based on chart review have reported rates of 5%, 9% and 15% [2-4], while those based on administrative claims have reported PTH testing rates of 3.4% and 12%.[5,6] A recent study using administrative claims found that PTH testing rates ranged from 7.3% for stage 3 CKD to 38.2% for stage 5 CKD. [7] However, an administrative claims-based study by Philipneri et al. reported rates of PTH testing as low as 0.6% among patients seen by primary care providers and 7.1% among those seen by nephrologists.[1] However, this study was limited to patients with stage 3 CKD, in which lower testing rates would be expected) whereas the majority of other studies have included CKD up to stage 5.

NQF #0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH)


POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
Data from a commercial health plan were used to generate rates of serum PTH testing. The data spanned from 7/1/09 to 6/30/10 and included a membership of 7 million members.

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):
Using data from this plan, the rates and numbers of excluded patients were determined. This measure excludes patients in hospice. We do not believe that a sensitivity analysis is relevant in this situation, given that this exclusion was determined a priori based on clinical acumen.

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):
Prior to exclusions, the denominator was 11021. Following the hospice exclusion, the denominator was 10992.

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
N/A.

2b4.2 Analytic Method (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):
N/A

2b4.3 Testing Results (Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):
N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: This is a process measure, therefore, there is no need for risk-adjustment.

2b5. Identification of Meaningful Differences in Performance. (The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
The data utilized for this analysis were from a plan with approximately 7 million members. The sample included a final denominator of 11021 patients. The data spanned from 7/1/09 to 6/30/10.

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):
In order to differentiate provider performance, we first identify individual providers and determine their rates. These individual rates can then be analyzed to determine mean and range, as well as the standard deviation. We can also divide the providers by quartile in order to determine the statistical significance of performance between quartiles.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

Total number of physicians with a denominator greater than 10: 1007
Mean: 32.0%
Standard Deviation: 33.6
Range: 0-100%
Mean performance of physicians in Q1: 13.3%
Mean performance of physicians in Q3: 38.0%
The mean performances of the Q1 and Q3 quartiles were found to be significantly different (P<.0001) using one-way ANOVA.

2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
N/A. Administrative data is the only data source for this measure.

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):
N/A. Administrative data is the only data source for this measure.

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):
N/A. Administrative data is the only data source for this measure.

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met? (Reliability and Validity must be rated moderate or high) Yes No
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following...
3a. Usefulness for Public Reporting:  H  M  L  I
(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

This measure is designed to be used for public reporting and incentive-based performance programs. Our organization is not a health plan, and thus, is unable to implement a public reporting program. However, we are currently in discussions with various health plans to encourage the use of this measure for public reporting.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: Bone mineral disorders are common in patients with chronic kidney disease, and have the potential for severe adverse impact on both mortality and morbidity. The diagnosis of bone mineral disorders is dependent on laboratory testing of calcium, phosphorus, and parathyroid hormone levels. This measure reports the percentage of patients with chronic kidney disease who received the indicated quality of care. A higher score indicates higher quality of care. The construction of this measure is similar to many other well recognized and established measures (e.g., percent of diabetics who received Hba1c).

Public reporting of physician compliance on this measure would improve physician performance potentially through two pathways. In one pathway stakeholders, such as patients, consumers, purchasers, and health plans can compare provider performance via publicly released data for this measure and reward better performance with increased volume. In the second pathway, these data can assist medical groups or physicians to identify areas to target for improvement. Public reporting of physician compliance with this measure may also increase patient awareness of the importance of laboratory testing for calcium, phosphorus, and parathyroid hormone in the setting of chronic kidney disease.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure is currently not being used in any of these capacities.

Most health plans that we had approached were interested in using this measure in pay-for-performance or transparency programs.

3b. Usefulness for Quality Improvement:  H  M  L  I
(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

This measure is currently in use by BlueCross BlueShield of Alabama for quality improvement through their program, Physician Quality and Transparency Program. The results are posted on an internal website that allows the physicians to view their performance and see how it compares to other physicians within the plan. The URL for this program is: http://www.bcbsal.org/providers/physicianqualityandtransparencyprogram/index.cfm

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results: In addition to reporting the percentage of patients with chronic kidney disease who received the indicated quality of care for this measure, IMS Health has developed an online tool (currently in use by health plans) that allows physicians to view the names and medical records of patients who did not receive the indicated quality of care. This tool can aid physicians in their quality improvement efforts.

Overall, to what extent was the criterion, Usability, met?  H  M  L  I
Provide rationale based on specific subcriteria:
### Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. *(evaluation criteria)*

<table>
<thead>
<tr>
<th>4a. Data Generated as a Byproduct of Care Processes:</th>
<th>H</th>
<th>M</th>
<th>L</th>
<th>I</th>
</tr>
</thead>
</table>

**4a.1-2 How are the data elements needed to compute measure scores generated?** *(Check all that apply).*

Data used in the measure are:
- Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

<table>
<thead>
<tr>
<th>4b. Electronic Sources:</th>
<th>H</th>
<th>M</th>
<th>L</th>
<th>I</th>
</tr>
</thead>
</table>

**4b.1 Are the data elements needed for the measure as specified available electronically** *(Elements that are needed to compute measure scores are in defined, computer-readable fields):* ALL data elements in electronic claims

**4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:**

### Susceptibility to Inaccuracies, Errors, or Unintended Consequences:

<table>
<thead>
<tr>
<th>4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is an administrative claims-based quality indicator with certain potential biases, including coding variation between providers and missing data. Nevertheless, administrative claims data is the widely available and has been used to effectively examine and document patterns of health care utilization, detect opportunities to improve quality of care, estimate incidence of disease, and even assess outcomes of pharmaceutical, radiological, and surgical procedures.</td>
</tr>
</tbody>
</table>

### Data Collection Strategy/Implementation:

<table>
<thead>
<tr>
<th>4d.2 Please check if either of the following apply <em>(regarding proprietary measures):</em> Proprietary measure</th>
</tr>
</thead>
</table>

**4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures):***

*IMS Health has developed an online tool (currently in use by health plans), which allows physicians the opportunity to supplement their quality scores through self-report via a secured web site. Via this website, physicians are able to identify specific patients with whom they had an office visit during the measurement period and who reportedly did not have the indicated quality care. Physicians can then review their charts to verify whether in fact the quality care was performed. The physician can then manually enter corrections to the patient record via the website, indicating that the quality care was done. This data is subject to clinical review prior to acceptance. The hybrid quality score (via administrative claims and self report) can be updated on a quarterly basis.*

**Overall, to what extent was the criterion, Feasibility, met?**

Provide rationale based on specific subcriteria:
**NQF #0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0570</td>
<td>CHRONIC KIDNEY DISEASE (CKD): MONITORING PHOSPHORUS</td>
</tr>
<tr>
<td>0574</td>
<td>CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM</td>
</tr>
</tbody>
</table>

### 5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

### 5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

### CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): IMS Health, 21650 Oxnard Street, Suite 1850, Woodland Hills, California, 91367

Co.2 Point of Contact: Dan, Malloy, PhD, dmalloy@us.imshealth.com, 818-676-2820-

Co.3 Measure Developer if different from Measure Steward: IMS Health, 21650 Oxnard Street, Suite 1850, Woodland Hills, California, 91367

Co.4 Point of Contact: Irina, Yermilov, MD, MPHTM, iyermilov@us.imshealth.com, 818-676-2835-

Co.5 Submitter: Irina, Yermilov, MD, MPHTM, iyermilov@us.imshealth.com, 818-676-2835-, IMS Health

Co.6 Additional organizations that sponsored/participated in measure development: N/A

Co.7 Public Contact: Dan, Malloy, PhD, dmalloy@us.imshealth.com, 818-676-2820-, IMS Health

### ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.

N/A

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: N/A

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 02, 2011

Ad.5 What is your frequency for review/update of this measure? Annually

Ad.6 When is the next scheduled review/update for this measure? 02, 2012

Ad.7 Copyright statement/disclaimers: ©2011 IMS Health Incorporated or its affiliates. All Rights Reserved.

Ad.8 Additional Information/Comments: N/A

Date of Submission (MM/DD/YY): 06/08/2011