#### NQF #0645 Biopsy Follow-up

# NATIONAL QUALITY FORUM

#### Measure Submission and Evaluation Worksheet 5.0

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 <u>submitting standards web page</u>.

#### NQF #: 0645 NQF Project: Care Coordination Project

(for Endorsement Maintenance Review)

Original Endorsement Date: May 05, 2010 Most Recent Endorsement Date: May 05, 2010

#### BRIEF MEASURE INFORMATION

De.1 Measure Title: Biopsy Follow-up

Co.1.1 Measure Steward: American Academy of Dermatology

**De.2 Brief Description of Measure:** Percentage of patients who are undergoing a biopsy whose biopsy results have been reviewed by the biopsying physician and communicated to the primary care/referring physician and the patient.

**2a1.1 Numerator Statement:** Patients who are undergoing a biopsy whose biopsy results have been reviewed by the biopsying physician and communicated to the primary care/referring physician and the patient, denoted by entering said physician's initials into a log, as well as by documentation in the patient's medical record.

2a1.4 Denominator Statement: All patients undergoing a biopsy.

2a1.8 Denominator Exclusions: Patients not undergoing a biopsy.

1.1 Measure Type: Process

2a1. 25-26 Data Source: Electronic Clinical Data : Registry, Paper Records

2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): N/A

**STAFF NOTES** (issues or questions regarding any criteria)

Comments on Conditions for Consideration:

Is the measure untested?	Yes No	If untested, explain how it meets criteria for consideration for time-lin	nited
endorsement:			

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*):
5. Similar/related <u>endorsed</u> or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

#### 1. IMPACT, OPPORTUITY, 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 <u>guidance on evidence</u>. *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: H M L

(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): De.5 Cross Cutting Areas (Check all the areas that apply): Care Coordination, Safety

1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure

1a.2 If "Other," please describe:

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

Diagnostic errors are defined as those in which diagnosis was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information. Communication breakdowns are an increasingly recognized preventable factor in medical mishaps, and emerging data suggest a high prevalence of communication breakdowns among physicians, patients, and important members of the health care team who assist with the diagnostic process.

Lawsuits are usually subject to the civil law of negligence. Communication issues, in addition to commentary from expert witnesses, likely lend themselves to lay assessment by jurors. Although an individual juror or judge may not possess the expertise to assess the significance of radiographic or clinical findings, jurors may integrate their own notions of proper conduct when it comes to the lay aspect of direct communication. The findings in this study support the contention that, regardless of the reasons, higher awards are found against radiologists who do not directly communicate positive findings to the treating physician in cases involving delay in the diagnosis of breast cancer.

Pathologists should be aware than many medicolegal actions against our colleagues, the radiologists, are based on failure to communicate "abnormal" results in a timely manner.

Critical value reporting is increasingly scrutinized by regulatory agencies and quality-management organizations as an important marker for excellence in patient centric care. In 2003, the Joint Commission on Accreditation of Healthcare Organizations listed the read-back of critical values by receiving health care professionals as a key patient safety standard. Two years later, the Commission mandated an additional requirement for monitoring the turnaround time for critical values reporting. This new emphasis has caused hospital and health care organization administrators to focus with renewed vigor on critical values and their role in safe and effective patient care.

Following the introduction of the Critical Value (CV) concept and these regulatory requirements, the practice of notifying physicians of CV's has become the standard of practice in clinical pathology, with well-established guidelines about which laboratory results require the technologist to immediately contact the clinician or the nurse responsible for the patient. Surgical pathology and cytology examinations identify abnormalities that can be at variance from normal findings, may be potentially life-threatening, and would require rapid corrective action for improved patient outcome.

It is essential that day-to-day health communications within a multi-disciplinary team convey the necessary detail and meaning. They should also be couched in an easily understandable common (standard) language and format, which, unfortunately, free text does not always confer. Sharing information has been shown to improve record-keeping and it might improve outcomes. Adequate written communication is essential for good teamwork, particularly for hand-over, referrals within and to other specialties and in multi-disciplinary care. In these situations, the main source of the information communicated is the health record. The quality of the record determines the quality of the information contained in communications between members of a team, and thus a standard that can provide a common language may improve care. (Strength of Evidence, IIIC)

In 1999, the Institute of Medicine published its famous report "To Err is Human: Building a Safer Health System," which estimated that between 44,000 and 98,000 patients die each year as a result of medical error. Many more patients suffer from morbidities associated with medical error. The Institute of Medicine defined a medical error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim, although others have advocated alternative definitions of error. (Strength of Evidence, IIIC)

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Quality patient care can only be achieved when study results are conveyed in a timely fashion to those ultimately responsible for treatment decisions. An effective method of communication should: (a) be tailored to satisfy the need for timeliness, (b) support the role of a diagnostic imager as a physician consultant by encouraging physician to physician communication, and (c) minimize the risk of communication errors. Various factors and circumstances unique to a clinical scenario may influence the methods of communication between diagnostic imagers and referring clinicians. Timely receipt of the report is more important than the method of delivery. Communication of information is only as effective as the system that conveys the information. There is a reciprocal duty of information exchange. The referring physician or other relevant health care provider also shares in the responsibility for obtaining results of imaging studies he or she has ordered. The final report is considered to be the definitive means of communicating to the referring physician or other relevant healthcare provider the results of an imaging examination or procedure. Additional methods for communication of results are encouraged in certain situations. Routine reporting of imaging findings is communicated through the usual channels established by the hospital or dignostic imaging facility. However, in emergent or other non-routine clinical situations, the diagnosing imager should expedite the delivery of a disgnostic imaging report (preliminary or final) in a manner that reasonably ensures timely receipt of the findings. Findings that the diagnostic imager reasonably believes may be seriously adverse to the patient's health and are unexpected by the treating or referreing physician: These cases may not require immediate attention but, if not acted upon, may worsen over time and possibly result in an adverse patient outcome. Diagnostic imagers should document all non-routine communications and include the time and method of communication and specifically name the person to whom the communication was made. The documentation may be placed in the radiology report, the patient's medical record, and/or in a department log or personal journal. Documentation may serve as evidence of such communication, if later contested. (Strength of Evidence IIB)

More broadly, specialities such as radiology and pathology must develop fail-safe mechanisms of results communication and explicit criteria to identify which results must be immediately communicated. In addition, explicit communication strategies and documentation of this communication (for example, acknowledgment of receipt of communication) and clear escalation strategies (for example, contact the head of the clinic if the primary care physician is not available or the attending physician if the resident does not answer) should be devised. Furthermore, the responsibility to communicate lies not only with the radiologist but also with the ordering provider. Ordering providers must document the reasoning underlying their test orders and their personal contact information. (Strength of Evidence, IIIC)

**1a.4 Citations for Evidence of High Impact cited in 1a.3:** Singh H, Naik AD, Rao R, Petersen LA. Reducing Diagnostic Errors through Effective Communication: Harnessing the Power of Information Technology. J Gen Intern Med 23(4):489-94.

Brenner JR, Bartholomew L. Communication Errors in Radiology: A Liability Cost Analysis. J Am Coll Radiol 2005;2:428-431.

LiVolsi VA. Critical Values in Anatomic Pathology How Do We Communicate?. Am J Clin Pathol 2004;122:171-172

Wagar EA, Stankovic AK, Wilkinson DS, Walsh M, Souers RJ. Assessment Monitoring of Laboratory Critical Values A College of American Pathologists Q-Tracks Study of 180 Institutions. Arch Pathol Lab Med. 2007 Jan;131:44-49.

Silverman JF, Pereira TC. Critical Values in Anatomic Pathology. Arch Pathol Lab Med. 2006;130:638-640

Lewis A. Health informatics: information and communication. Advances in Psychiatric Treatment (2002)8:165-171.

Raab SS, Grzybicki DM. Measuring Quality in Anatomic Pathology. Clin Lab Med 28(2008) 245-259.

To Err is Human: Building a Safer Health System. Institute of Medicine. 1999

ACR Practice Guideline for Communication of Diagnostic Imaging Findings. The American College of Radiology. 2005.

Gandhi TK. Fumbled Handoffs: One Dropped Ball After Another. Ann Intern Med. 2005;142:352-358.

1b. Opportunity for Improvement: H 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:

Failure to follow up on abnormal diagnostic test results is a critical weakness in patient safety, particularly in outpatient care. One study found that 75% of physicians did not routinely notify patients of normal test results (2) and that up to 33% of physicians did not even always notify patients about abnormal test results. In addition, less than 25% of physicians had a reliable method for identifying patients who were overdue for follow-up. Several studies underscore the ongoing need to address this quality gap. For example, 31% of women with abnormal mammograms do not receive follow-up care consistent with well-established guidelines, while up to 33% of physicians did not even always notify patient care. One study found that 75% of physicians did not routinely notify patients of normal test results (2) and that up to 33% of women with abnormalFailure to follow up on abnormal diagnostic test results is a critical weakness in patient safety, particularly in outpatient care. One study found that 75% of physicians did not routinely notify patients of normal test results (2) and that up to 33% of physicians did not even always notify patients about abnormal test results. In addition, less than 25% of physicians had a reliable method for identifying patients who were overdue for follow-up. Several studies underscore the ongoing need to address this quality gap. For example, 31% of women with abnormal test results. In addition, less than 25% of physicians had a reliable method for identifying patients who were overdue for follow-up. Several studies underscore the ongoing need to address this quality gap. For example, 31% of women with abnormal mammograms do not receive follow-up care consistent with well-established guidelines, while up to 33% of women with abnormal Papanicolaou (Pap) smears are "lost to follow-up."

A recent analysis by a large malpractice insurer showed that about 25% of diagnosis-related malpractice cases were due to failures in follow-up. Other studies reveal that communication breakdowns are causative factors in 80% of malpractice lawsuits. Lawsuits alleging failure to communicate radiology results are particularly prevalent and are becoming more so. In nearly 60% of these suits, the referring physician was not directly contacted about urgent clinically significant unexpected findings.

A recent study shows that delays in reviewing test results are common, and many physicians are not satisfied with how they manage test results. Many reasons potentially underlie this dissatisfaction. First, the volume of data to be reviewed is large; a typical primary care provider may review up to 800 results from chemistry and hematology reports, 40 radiology reports, and 12 pathology reports per week. Second, test results in the outpatient setting become available at times ranging from an hour to weeks after the tests are ordered, making it easy for physicians to forget to look for their results. Third, paper-based test-reporting systems are subject to delivery delays and misfiling. Fourth, specialists in testing areas often do not have adequate clinical information about why the test was ordered and do not have clear criteria for which results require a telephone call. For example, a recent study found little agreement between pathologists and clinicians about the types of results that constitute a critical value and the degree of urgency for contacting a physician. Even assuming consensus as to the latter, often no information is noted about the preferred and absolutely fail-safe communication mode (for example, how to proceed when a page is not answered or when a physician is out of town).

There is little consensus or benchmark data about critical values in the clinical laboratory. Procedures are not standardized and the definition of a critical value remains uncertain in the minds of many clinicians and laboratory professionals. A recently described analysis of Q-Probes data from 623 institutions highlights this variability. In the present study, the choice of analyses and high and low critical limits varied considerably. Calling of critical values also varied, depending on patient status, with a mean time of 6.1 minutes for inpatient calls versus 13.7 minutes for outpatient calls.

The Q-Tracks monitoring program was designed to determine the rate of undocumented critical values per 1000 results in a group of voluntary participants, monitored on a quarterly basis. Three variables were found to be significantly associated with lower total and inpatient rates of undocumental critical values per 1000 results: (1) unit secretary/clerical staff not authorized to accept inpatient critical values notification; (2) procedures for handling inpatients who are known to have critical values that repeatedly include always notifying the health care provider, regardless of the previous results; and (3) AABB [American Association of Blood Banks] inspection within the past 2 years.

One analysis of court transcripts disclosed that communication problems were present in more than 70% of depositions obtained on plaintiffs in malpractice cases. Another study revealed that breakdown in communication was found to be a causative factor in as many as 80% of malpractice lawsuits. A survey categorizing causes of malpractice litigation involving radiologists released in 1997 by the Physician Insurers Assocation of America and the American College of Radiology (ACR) was more specific. It found that the number of medical malpractice claims alleging communication failure had grown to become the fourth most frequent primary allegation against radiologists. This survey also disclosed that in nearly 60% of malpractice lawsuits involving radiologists, the referring physician had not been directly contacted regading urgent or significant unexpected findings, even though in 75% of these cases, the medical record had shown that a radiology report was issued in a timely manner.

A more recently conducted cumulative analysis of radiologic malpractice lawsuits filed in the United States from January 1985 through December 2000 disclosed that the medical-legal issue of poor communication between providers resulted in the second

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highest average and third highest total amount of indemnificaiton paid to plaintiffs.

A prospective study was performed to assess the efficiency of communication of both a written report and telephone call to the clinician's office for all interpretations of mammographic abnormalities. Although all abnormal reports were telephoned and mailed to the referring physician, errors in their transmission from the radiology department apparently occurred. Several doctors complained that they never received a report, but further investigation revealed that sometimes office personnel noted the report had been received and subsequently misplaced. The report was misunderstood by some physicians or their aides, and follow-up mammography was scheduled in 6 months rather than immediately, as suggested by the radiologist who interpreted the screening examination. Several reports were sent to the wrong address. Some physicians have more than one address (ie, various office and clinic locations) from which they may request mammograms. Other delays were caused by clinical factors. The report was filed without being seen or acted on by the clinician. Regardless of the reasons for failure of communication, several patients did not receive mammographic evaluation or surgical consultation for several months after initial mammographic screening. The marked drop in unresolved cases after repeated telephone calls to referring clinicians suggests that repeated contact was likely beneficial to communication and thus to patient care.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

**1b.3 Citations for Data on Performance Gap:** [For <u>Maintenance</u> – 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 <u>Maintenance</u> – Descriptive statistics for performance results* <u>for this measure</u> by population group] Measure is not reflective of disparities.

1b.5 Citations for Data on Disparities Cited in 1b.4: [For <u>Maintenance</u> – 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]

N/A

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.						
Quantity: H M L I Quality: H M L I Consistency: H M L I						
Quantity	Quality	Consistency	Does the measure pass s	subcriterion1c?		
M-H	M-H	M-H	Yes			
L	M-H	М	Yes IF additional resea harms: otherwise No	rch unlikely to change conclusion that benefits to patients outweigh		
M-H	L	M-H	Yes IF potential benefit	s to patients clearly outweigh potential harms: otherwise No		
L-M-H	-M-H L-M-H L No					
	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): The measure focus is to evaluate whether care, for patients undergoing a biopsy, has been coordinated with the appropriate parties [a) the patient and b) the referring physician]. The goal of this process measure is to decrease the likelihood that any critical value						

would be overlooked, thus delaying treatment. A treatment delay could result in negative patient outcome. By tracking biopsy

results, the clinician is working towards eliminating the likelihood that a negative patient outcome will occur downstream.

1c.2-3 **Type of Evidence** (*Check all that apply*): Selected individual studies (rather than entire body of evidence)

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):

1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): 1

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):

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect):

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

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: Graded by performance measurement work group - all conflicts of interest were managed through the AAD's COI standards. No direct conflicts of interest were noted. Balance of private practice, academic and military clinicians.

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

1c.12 If other, identify and describe the grading scale with definitions: Evidence is graded per article/study. Overall grade could not be determined.

The available evidence was evaluated using a unified system called the Strength of Recommendation Taxonomy developed by editors of the US family medicine and primary care journals (ie, American Family Physician, Family Medicine, Journal of Family Practice, and BMJ USA). Evidence was graded using a 3-point scale based on the quality of methodology as follows: I. Good-quality patient-oriented evidence.

II. Limited-quality patient-oriented evidence.

III. Other evidence including consensus guidelines, opinion, or case studies.

Clinical recommendations were developed on the best available evidence tabled in the guideline.

These are ranked as follows:

A. Recommendation based on consistent and good quality patient-oriented evidence.

B. Recommendation based on inconsistent or limited-quality patient-oriented evidence.

C. Recommendation based on consensus, opinion, or case studies

1c.13 Grade Assigned to the Body of Evidence: Evidence is graded per article/study. Overall grade could not be determined.

1c.14 **Summary of Controversy/Contradictory Evidence:** In spite of a long history of reporting panic values and the incorporation of critical values into multiple regulations, there is little standardization of procedures. Performance benchmarks and definitions are variable or nonexistent.

One problematic issue is how do pathologists communicate the "critical" information? This seems obvious and intuitive. We should call or email (if compliant with privacy issues) the data to the patient's attending physician. Well, this is easier said than done.

Sometimes, the physician who performed the procedure was simply a technician. A surgeon performed a lymph node biopsy to rule out lymphoma, and the node shows caseating granulomas and acid-fast organisms. The pathologist calls the surgeon who refers the pathologist to the patient's oncologist; that physician, who does not treat infections, refers the pathologist to the patient's internist or primary care provider, who might or might not know the biopsy had even been done! (There are cases in which a physician refused to accept the result because the physician is no longer on service!) The pathologist now has spent much time trying to communicate important data that will affect patient care to someone who will not accept the information. This is not efficient use of pathologist professional time.

It is apparent from the few previous studies that there is a range of opinion among pathologists and between pathologists and clinicians about the need for clinician notification, the degree of urgency, and the method of communication to be used.

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):

Wagar EA, Stankovic AK, Wilkinson DS, Walsh M, Souers RJ. Assessment Monitoring of Laboratory Critical Values A College of American Pathologists Q-Tracks Study of 180 Institutions. Arch Pathol Lab Med. 2007 Jan;131:44-49.

LiVolsi VA. Critical Values in Anatomic Pathology How Do We Communicate?. Am J Clin Pathol 2004;122:171-172.

Critical Diagnoses (critical values) in anatomic pathology. Association of Directors of Anatomic and Surgical Pathology. Human Pathology (2006)37:982-984.

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

It is imperative that communications between the radiologic and surgical consultants and the primary care provider are thorough and consistent. (Main Algorithm, Annotation #13)

The importance of communication between the radiologic and surgical consultants and the primary care provider cannot be overstated. Patients undergoing biopsy should have results reported to both the radiologist or surgeon performing the biopsy and to the primary care provider. More importantly, patients who do not require biopsy following radiologic or surgical consultation should be returned to the routine screening process. This process is under the supervision of the primary care provider. Therefore, it is absolutely necessary for the primary care provider to know when the patient reenters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care provider using the primary care evaluation process of this guideline.

Key Implementation Recommendations The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline. Primary Care, Radiology, and Surgery establish a communication plan to include all providers involved in the patient's treatment plan:

Patients undergoing biopsy should have results reported to the radiologist and/or surgeon performing the procedure as well as the primary care provider.

Documentation Develop a system to document time frame from receipt of pathology to patient information.

Telephone call documentation

1c.17 Clinical Practice Guideline Citation: Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 47 p. [63 references]

NOTE: An updated version of this guideline has been released: http://www.icsi.org/breast\_disease\_diagnosis/diagnosis\_of\_breast\_disease\_2.html Evaluation of evidence transition to the GRADE method.

1c.18 National Guideline Clearinghouse or other URL: http://www.icsi.org/breast\_disease\_diagnosis/diagnosis\_of\_breast\_disease\_2.html

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Graded by performance measurement work group - all conflicts of interest were managed through the AAD's COI standards. No direct conflicts of interest were noted. Balance of private practice, academic and military clinicians.

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

1c.22 If other, identify and describe the grading scale with definitions: RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

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

1c.24 Rationale for Using this Guideline Over Others: Multi-disciplinary approaches are often used in diagnosing breast diseases. This guideline stresses the importance of communication between the primary care physician and all specialists

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: Low 1c.26 Quality: Moderate1c.27 Consistency: Moderate

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, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when 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 <u>guidance on measure testing</u>.

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 <u>this</u> 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): Patients who are undergoing a biopsy whose biopsy results have been reviewed by the biopsying physician and communicated to the primary care/referring physician and the patient, denoted by entering said physician's initials into a log, as well as by documentation in the patient's medical record.

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

This measure is to be reported once per measurement year for patients who are seen for an office visit and have a biopsy performed during the reporting period.

Note: While this measure is only required to be reported once per eligible patient per reporting period, it is recommended that the eligible professional performing the biopsy communicates the results to the primary care/referring physician and patient each time a biopsy is done.

The steering committee noted that a more specific time frame would be helpful in implementing the measure. The AAD agrees and feels that a 30 day time window is reasonable, with an exception allowance for processing and/or interpretation delays outside of the reporting clinician's control.

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: Patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and the patient by the physician performing the biopsy. The physician performing the biopsy must also acknowledge and/or document the communication in a biopsy tracking log and document in the patient's medical record.

### [NUMERATOR INSTRUCTIONS]

- To satisfy this measure, the biopsying physician must:
- Review the biopsy results with the patient
- · Communicate those results to the primary care/referring physician
- Track communication in a log
- Document tracking process in the patient's medical record

The components of a tracking log incorporate the following:

- · Initials of physician performing the biopsy
- Patient name
- Date of biopsy
- Type of biopsy
- Biopsy result
- Date of biopsy result

2a1.4 **Denominator Statement** (*Brief, narrative description of the target population being measured*): All patients undergoing a biopsy.

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*): 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*): All patients undergoing a biopsy

Eligible Cases:

All patients regardless of age on date of encounter

AND

Patient encounter during the reporting period (CPT): CPT procedure codes for biopsies include:

49000(Biopsy, abdomen); 60540(Biopsy, adrenal gland); 60541(Biopsy, adrenal gland); 60542(Biopsy, adrenal gland); 60543(Biopsy, adrenal gland); 60544(Biopsy, adrenal gland); 60545(Biopsy, adrenal gland); 46606(Biopsy, anal endoscopy); 27613(Biopsy, ankle); 27614(Biopsy, ankle); 27620(Biopsy, ankle); 25065(Biopsy, arm; lower); 25066(Biopsy, arm; lower); 24065(Biopsy, arm; upper); 24066(Biopsy, arm; upper); 37609(Biopsy, temporal artery); 69105(external auditory canal); 21920(Biopsy, back or flank); 21921(Biopsy, back or flank); 21922(Biopsy, back or flank); 21923(Biopsy, back or flank); 21924(Biopsy, back or flank); 21925(Biopsy, back or flank); 47553(Biopsy, bile duct endoscopy); 52354(Biopsy, bladder; cystourethroscope); 52224(Biopsy, bladder; cystourethroscopy); 52250(Biopsy, bladder; cystourethroscopy); 75970(Biopsy, blood vessel; transcatheter); 20220(Biopsy, bone); 20221(Biopsy, bone); 20222(Biopsy, bone); 20223(Biopsy, bone); 20224(Biopsy, bone); 20224( bone); 20225(Biopsy, bone); 20226(Biopsy, bone); 20227(Biopsy, bone); 20228(Biopsy, bone); 20229(Biopsy, bone); 20230(Biopsy, bone); 20231(Biopsy, bone); 20232(Biopsy, bone); 20233(Biopsy, bone); 20234(Biopsy, bone); 20235(Biopsy, bone); 20236(Biopsy, bone); 20237(Biopsy, bone); 20238(Biopsy, bone); 20239(Biopsy, bone); 20240(Biopsy, bone); 20241(Biopsy, bone); 20242(Biopsy, bone); 20243(Biopsy, bone); 20244(Biopsy, bone); 20245(Biopsy, bone); 38221(Biopsy, bone); 20245(Biopsy, bone); 20245(Bio marrow); 61140(Biopsy, brain); 61750(Biopsy, brain; stereotactic); 61751(Biopsy, brain; stereotactic); 61575(Biopsy, brainstem); 61576(Biopsy, brainstem); 19100(Biopsy, breast); 19101(Biopsy, breast); 19102(Biopsy, breast); 19103(Biopsy, breast); 19295(Biopsy, metallic localization clip placement); 77031(Biopsy, metallic localization clip placement; stereostatic localization); 31717(Biopsy, bronchi; catheterization); 31625(Biopsy, bronchi; endoscopic); 31626(Biopsy, bronchi; endoscopic); 31627(Biopsy, bronchi: endoscopic): 31628(Biopsy, bronchi: endoscopic): 31629(Biopsy, bronchi: endoscopic): 31632(Biopsy, bronchi: endoscopic); 31633(Biopsy, bronchi; endoscopic); 31717(Brush biopsy, bronchi); 52007(Brush biopsy, renal pelvis); 52007(Brush biopsy, ureter); 52204(Brush biopsy, ureter; with cystourethroscopy); 26100(Biopsy, carpometacarpal joint; synovium); 57454(Biopsy, cervix); 57455(Biopsy, cervix); 57460(Biopsy, cervix); 57500(Biopsy, cervix); 57520(Biopsy, cervix); 59015(Biopsy, chorionic villus); 44025(Biopsy, colon); 44100(Biopsy, colon); 44389(Biopsy, colon; endoscopy); 45380(Biopsy, colon; endoscopy); 45391(Biopsy, colon; endoscopy); 45392(Biopsy, colon; endoscopy); 44322(Biopsy, colon; colostomy, cecostomy); 45305(Biopsy, colon-sigmoid; endoscopy); 45331(Biopsy, colon-sigmoid; endoscopy); 68100(Biopsy, conjunctiva); 65410(Biopsy, cornea); 44010 (Biopsy, duodenum); 69100(Biopsy, ear; external); 24065(Biopsy, elbow); 24066(Biopsy, elbow); 24101(Biopsy, elbow); 24100(Biopsy, elbow; synovium); 89290(Biopsy, embryo blastomere); 89291(Biopsy, embryo blastomere); 58100(Biopsy, endometrium); 58101(Biopsy, endometrium); 58102(Biopsy, endometrium); 58103(Biopsy, endometrium); 58104(Biopsy, endometrium); 58105(Biopsy, endometrium); 58106(Biopsy, endometrium); 58107(Biopsy, endometrium); 58108(Biopsy, endometrium); 58109(Biopsy, endometrium); 58110(Biopsy, endometrium); 58558(Biopsy, endometrium); 54800(Biopsy, epididymis); 54865(Biopsy, epididymis); 43202(Biopsy, esophagus; endoscopy); 3150F(Biopsy, esophagus; forceps); 67346(Biopsy, eye muscle); 67810(Biopsy, eyelid); 43261(Biopsy, gallbladder; endoscopy); 43239(Biopsy, upper gastrointestinal; endoscopy): 26100(Biopsy, hand joint; synovium); 93505(Biopsy, heart); 27040(Biopsy, hip); 27041(Biopsy, hip); 27052(Biopsy, hip; joint); 42802(Biopsy, hypopharynx); 44382(Biopsy, Ileum; endoscopy); 26110(Biopsy, interphalangeal joint; finger); 28054(Biopsy, interphalangeal joint; toe); 28050(Biopsy, intertarsel joint; toe); 44020(Biopsy, small intestine); 44361(Biopsy, small intestine; endoscopy); 44377(Biopsy, small intestine; endoscopy); 50200(Biopsy, kidney); 50201(Biopsy, kidney); 50202(Biopsy, kidney); 50203(Biopsy, kidney); 50204(Biopsy, kidney); 50205(Biopsy, kidney); 50555(Biopsy, kidney; endoscopic); 50556(Biopsy, kidney; endoscopic); 50557(Biopsy, kidney; endoscopic); 50574(Biopsy, kidney; endoscopic); 50575(Biopsy, kidney; endoscopic); 50576(Biopsy, kidney; endoscopic); 52354(Biopsy, kidney; endoscopic); 27323(Biopsy, knee); 27324(Biopsy, knee); 27330(Biopsy, knee, knee joint; synovium); 68510(Biopsy, lacrimal gland); 68525(Biopsy, lacrimal sac); 31510(Biopsy, larynx; endoscopy); 31576(Biopsy, larynx; endoscopy); 27613(Biopsy, leg; lower); 27614(Biopsy, leg; lower); 27323(Biopsy, leg; upper); 27324(Biopsy, leg; upper); 40490(Biopsy, lip); 47000(Biopsy, liver); 47001 (Biopsy, liver); 47100(Biopsy, liver); 32405(Biopsy, lung; needle); 32095(Biopsy, lung; thoracotomy); 32096(Biopsy, lung; thoracotomy); 32097(Biopsy, lung; thoracotomy); 32098(Biopsy, lung; thoracotomy); 32099(Biopsy, lung; thoracotomy); 32100(Biopsy, lung; thoracotomy); 38500(Biopsy, lymph nodes); 38501(Biopsy,

lymph nodes); 38502(Biopsy, lymph nodes); 38503(Biopsy, lymph nodes); 38504(Biopsy, lymph nodes); 38505(Biopsy, lymph nodes); 38506(Biopsy, lymph nodes); 38507(Biopsy, lymph nodes); 38508(Biopsy, lymph nodes); 38509(Biopsy, lymph nodes); 38510(Biopsy, lymph nodes); 38511(Biopsy, lymph nodes); 38512(Biopsy, lymph nodes); 38513(Biopsy, lymph nodes); 38514(Biopsy, lymph nodes); 38515(Biopsy, lymph nodes); 38516(Biopsy, lymph nodes); 38517(Biopsy, lymph nodes); 38518(Biopsy, lymph nodes); 38519(Biopsy, lymph nodes); 38520(Biopsy, lymph nodes); 38521(Biopsy, lymph nodes); 38522(Biopsy, lymph nodes); 38523(Biopsy, lymph nodes); 38524(Biopsy, lymph nodes); 38525(Biopsy, lymph nodes); 38526(Biopsy, lymph nodes); 38527(Biopsy, lymph nodes); 38528(Biopsy, lymph nodes); 38529(Biopsy, lymph nodes); 38530(Biopsy, lymph nodes); 38792(Biopsy, lymph nodes; injection procedure for identification of sentinel node); 38570(Biopsy, lymph nodes; laparoscopic); 38571(Biopsy, lymph nodes; laparoscopic); 38572(Biopsy, lymph nodes; laparoscopic); 38505(Biopsy, lymph nodes; needle); 38500(Biopsy, lymph nodes; open); 38510(Biopsy, lymph nodes; open); 38511(Biopsy, lymph nodes; open); 38512(Biopsy, lymph nodes; open); 38513(Biopsy, lymph nodes; open); 38514(Biopsy, lymph nodes; open); 38515(Biopsy, lymph nodes; open); 38516(Biopsy, lymph nodes; open); 38517(Biopsy, lymph nodes; open); 38518(Biopsy, lymph nodes; open); 38519(Biopsy, lymph nodes; open); 38520(Biopsy, lymph nodes; open); 38521(Biopsy, lymph nodes; open); 38522(Biopsy, lymph nodes; open); 38523(Biopsy, lymph nodes; open); 38524(Biopsy, lymph nodes; open); 38525(Biopsy, lymph nodes; open); 38526(Biopsy, lymph nodes; open); 38527(Biopsy, lymph nodes; open); 38528(Biopsy, lymph nodes; open); 38529(Biopsy, lymph nodes; open); 38530(Biopsy, lymph nodes; open); 38500(Biopsy, lymph nodes; open; superficial); 39400(Biopsy, mediastinum); 32405(Biopsy, mediastinum; needle); 26105(Biopsy, metacarpophalangeal joint); 28052(Biopsy, metatarsophalangeal joint); 40808(Biopsy, mouth); 41108(Biopsy, mouth); 20200(Biopsy, muscle); 20201(Biopsy, muscle); 20202(Biopsy, muscle); 20203(Biopsy, muscle); 20204(Biopsy, muscle); 20205(Biopsy, muscle); 20206(Biopsy, muscle); 11755(Biopsy, nail); 42804(Biopsy, nasopharynx); 42805(Biopsy, nasopharynx); 42806(Biopsy, nasopharynx); 21500(Biopsy, neck); 64795(Biopsy, nerve); 31237(Biopsy, nose; endoscopic); 30100(Biopsy, nose; intranasal); 89290(Biopsy, oocyte polar body); 89291(Biopsy, oocyte polar body); 61332(Biopsy, orbit); 67400(Biopsy, orbit; exploration); 67450(Biopsy, orbit; exploration); 67415(Biopsy, orbit; fine needle aspiration); 42800(Biopsy, oropharynx); 58900(Biopsy, ovary); 42100(Biopsy, palate); 48100(Biopsy, pancreas); 27040(Biopsy, pelvis); 27041(Biopsy, pelvis); 54100(Biopsy, penis); 54105(Biopsy, penis; deep structures); 62269(Biopsy, percutaneous needle; spinal cord); 56605(Biopsy, perineum); 56606(Biopsy, perineum); 47561(Biopsy, peritoneum; endoscopic); 42800(Biopsy, pharynx); 42801(Biopsy, pharynx); 42802(Biopsy, pharynx); 42803(Biopsy, pharynx); 42804(Biopsy, pharynx); 42805(Biopsy, pharynx); 42806(Biopsy, pharynx); 32400(Biopsy, pleura; needle); 32401(Biopsy, pleura; needle); 32402(Biopsy, pleura; needle); 32095(Biopsy, thoracotomy); 32096(Biopsy, thoracotomy); 32097(Biopsy, thoracotomy); 32098(Biopsy, thoracotomy): 32099(Biopsy, thoracotomy): 32100(Biopsy, thoracotomy): 32402(Biopsy, pleural: open): 55700(Biopsy, prostate): 55701(Biopsy, prostate); 55702(Biopsy, prostate); 55703(Biopsy, prostate); 55704(Biopsy, prostate); 55705(Biopsy, prostate); 55706(Biopsy, prostate); 45100(Biopsy, rectum); 49010(Biopsy, retroperitoneal area); 27050(Biopsy, sacroiliac joint); 42405(Biopsy, salivary gland); 23066(Biopsy, shoulder; deep); 23065(Biopsy, shoulder; soft tissue); 23100(Biopsy, shoulder joint); 23101(Biopsy, shoulder joint); 31050(Biopsy, sinus; sphenoid); 31051(Biopsy, sinus; sphenoid); 11100(Biopsy, skin lesion); 11101(Biopsy, skin lesion); 63275(Biopsy, spinal cord); 63276(Biopsy, spinal cord); 63277(Biopsy, spinal cord); 63278(Biopsy, spinal cord); 63279(Biopsy, spinal cord); 63280(Biopsy, spinal cord); 63281(Biopsy, spinal cord); 63282(Biopsy, spinal cord); 63283(Biopsy, spinal cord); 63284(Biopsy, spinal cord); 63285(Biopsy, spinal cord); 63286(Biopsy, spinal cord); 63287(Biopsy, spinal cord); 63288(Biopsy, spinal cord); 63289(Biopsy, spinal cord); 63290(Biopsy, spinal cord); 62269(Biopsy, spinal cord; percutaneous); 63615(Biopsy, spinal cord; stereotaxis); 43605(Biopsy, stomach); 28050(Biopsy, tarsometatarsal joint; synovial); 54500(Biopsy, testis); 54501(Biopsy, testis); 54502(Biopsy, testis); 54503(Biopsy, testis); 54504(Biopsy, testis); 54505(Biopsy, testis); 21550(Biopsy, thorax); 42800(Biopsy, throat); 42801(Biopsy, throat); 42802(Biopsy, throat); 42803(Biopsy, throat); 42804(Biopsy, throat); 42805(Biopsy, throat); 42806(Biopsy, throat); 41100(Biopsy, tongue); 41101(Biopsy, tongue); 41102(Biopsy, tongue); 41103(Biopsy, tongue); 41104(Biopsy, tongue); 41105(Biopsy, tongue); 37200(Biopsy, transcatheter); 52354(Biopsy, ureter); 50955(Biopsy, ureter; endoscopic); 50956(Biopsy, ureter; endoscopic); 50957(Biopsy, ureter; endoscopic); 50974(Biopsy, ureter; endoscopic); 50975(Biopsy, ureter; endoscopic); 50976(Biopsy, ureter; endoscopic); 52204(Biopsy, urethra); 52354(Biopsy, urethra); 53200(Biopsy, urethra); 58100(Biopsy, uterus; endometrial); 58101(Biopsy, uterus; endometrial); 58102(Biopsy, uterus; endometrial); 58103(Biopsy, uterus; endometrial); 58104(Biopsy, uterus; endometrial); 58105(Biopsy, uterus; endometrial); 58106(Biopsy, uterus; endometrial); 58107(Biopsy, uterus; endometrial); 58108(Biopsy, uterus; endometrial); 58109(Biopsy, uterus; endometrial); 58110(Biopsy, uterus; endometrial); 58558(Biopsy, uterus; endoscopic); 42100(Biopsy, uvula); 57100(Biopsy, vagina); 57101(Biopsy, vagina); 57102(Biopsy, vagina); 57103(Biopsy, vagina); 57104(Biopsy, vagina); 57105(Biopsy, vagina); 57421(Biopsy, vagina); 20250(Biopsy, vertebral body); 20251(Biopsy, vertebral body); 56605(Biopsy, vulva); 56606(Biopsy, vulva); 56821(Biopsy, vulva); 23101(Biopsy, vulva; acromioclavicular joint); 23100(Biopsy, vulva; glenohumeral joint); 23101(Biopsy, vulva; sternoclavicular joint); 52354(Biopsy, vulva; w/cystourethroscopy); 25065(Biopsy, wrist); 25066(Biopsy, wrist); 25100(Biopsy, wrist); 25101(Biopsy, wrist)

2a1.8 **Denominator Exclusions** (Brief narrative description of exclusions from the target population): Patients not undergoing a biopsy.

2a1.9 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): Patients not undergoing a biopsy.

2a1.10 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

2a1.11 **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:

2a1.13 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

2a1.14-16 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:

2a1.17-18. Type of Score:

**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):

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.):

1. Identify target population (patients undergoing a biopsy during the measurement year): in order to identify the target population, practices must establish an internal process (i.e. query their practice management system or EHR for the applicable biopsy codes the practitioner performs).

2. Identify those instances where the quality action was performed in its entirety (measure met): Biopsy Results Reviewed and Communicated to the Patient and the Patient's Primary Care/Referring Physician, Communication Tracked in a Log, and Tracking Process Documented in the Patient's Medical Record.

Biopsy results reviewed, communicated, tracked, and documented

3. Identify instances that should be considered exlcusions:Documentation of Patient OR System Reason(s) for not Performing up to Three of the Four Components of the Numerator Details: Reviewing, Communicating, Tracking, and/or Documenting Biopsy Results, Patient not Eligible (e.g., patient asks that biopsy results not be communicated to the primary care/referring physician, patient does not have a primary care/referring physician or is a self-referred patient)

Clinician documented reason that patient's biopsy results were not reviewed

4. Indentify instances where none of the quality actions were performed (measure not met): Biopsy Results not Reviewed, not Communicated to the Patient and the Patient's Primary Care/Referring Physician, Communication not Tracked in a Log, and/or Tracking Process not Documented in the Patient's Medical Record.

Biopsy results not reviewed, communicated, tracked, or documented

The calculation of this measure would be as follows: measure met (minus) measure not met (divided by) denominator target population (minus) valid exclusions [system, patient reasons]

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: Electronic Clinical Data : Registry, Paper Records

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.): This measure was approved for inclusion in the 2012 PQRS program - only to be reported via an electronic registry. The AAD currently administers a PQRS registry and planned to add the biopsy measure as one of the reportable measures through the AAD's 2012 system. Since the testing of this measure needed to occur prior to 2012, the AAD issued a "demo" version of what the biopsy measure section of the registry would look like (it has been uploaded as a reference). The various sites that participated in the AAD's testing project manually entered information into this "demo" version of the electonic registry.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: Attachment BiopsyChartAbstraction2011.docx

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

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

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):

The AAD recruited five member dermatologists (making up three unique practices) to participate in the measure testing. All sites were asked to sample a typical week in their pratice and include all Medicare biopsies that were conducted that week - 50 patients total were evaluated for this testing project.

Site one - with 3 dermatologists, one of whom participated in the testing, is located in Florida. The entire practice sees 125 patients in one day (the majority are elderly). The practice uses paper charts and is a general dermatology and Mohs practice. The one physician performed 25 biopsies between March 7-9, 2011.

Site 2, located in Pennsylvania, has three locations 8 dermatologists and 1 dermatopathologist - three of whom (not the dermpath) participated in the testing project. The practice covers: general dermatology, Mohs, cosmetic, procedural, and dermatopathology. The three reported on do not do Mohs or dermatopathology. The practice has an EHR and sees all patients from infants to the elderly. The participating physicians see approximately 45 patients per day. Physician 1 performed 4 biopsies between May 3-5,2011. Physician 2 performed 8 biopsies between May 3-6, 2011. Physician 3 performed 9 biopsies between May 2-6, 2011.

Site 3 is located in Alabama - the practice has three dermatologists, but only one participated in the testing. They have an EHR and

see between 115-130 patients per day for the entire practice. The participating physician is a general medical dermatologist, who does not practice Mohs. The physician performed 4 biopsies between March 7-10, 2011.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

The practices entered those particular patient charts into a "demo" version of the AAD's PQRS registry (which already housed three melanoma measures that were active in the program - the sites participating in the testing project were already registry users, so they were familiar with the interface). The sites answered a series of questions (the screen shot from the "demo" registry is included under 2.1 (Supplemental Testing Methodology Information). The practices sent copies of the patients' respective medical records (copies of the chart that were relevant to the particular visit when the biopsy was performed) to a chart abstraction company (the verbatim instructions to the practices is included under 2.1 (Supplemental Testing Methodology Information) - please disregard the instructions regarding the melanoma measure). The chart abstraction company's staff, after receiving the patient records, reviewed those charts and answered the questions in the "demo" version of the registry.

Staff at the American Medical Association performed inter-rater reliability testing at the data element level (using the data from the participating practices and the chart abstracter). The 2x2 tables, as well as a list of the elements has been appended to this submission under 2.1 (Supplemental Testing Methodology Information).

2a2.3 Testing Results (*Reliability statistics, assessment of adequacy in the context of norms for the test conducted*): Many of the element level results were inconclusive, presumably based on the sample size.

The element level results have been appended to this submission under 2.1 (Supplemental Testing Methodology Information).

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

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:

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):

The AAD recruited five member dermatologists (making up three unique practices) to participate in the measure testing. All sites were asked to sample a typical week in their pratice and include all Medicare biopsies that were conducted that week - 50 patients total were evaluated for this testing project.

Site one - with 3 dermatologists, one of whom participated in the testing, is located in Florida. The entire practice sees 125 patients in one day (the majority are elderly). The practice uses paper charts and is a general dermatology and Mohs practice. The one physician performed 25 biopsies between March 7-9, 2011.

Site 2, located in Pennsylvania, has three locations 8 dermatologists and 1 dermatopathologist - three of whom (not the dermpath) participated in the testing project. The practice covers: general dermatology, Mohs, cosmetic, procedural, and dermatopathology. The three reported on do not do Mohs or dermatopathology. The practice has an EHR and sees all patients from infants to the elderly. The participating physicians see approximately 45 patients per day. Physician 1 performed 4 biopsies between May 3-5,2011. Physician 2 performed 8 biopsies between May 3-6, 2011. Physician 3 performed 9 biopsies between May 2-6, 2011.

Site 3 is located in Alabama - the practice has three dermatologists, but only one participated in the testing. They have an EHR and see between 115-130 patients per day for the entire practice. The participating physician is a general medical dermatologist, who does not practice Mohs. The physician performed 4 biopsies between March 7-10, 2011.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): Validity was assessed at the data element level. As described under the reliability testing methods, the five physicians sent copies of their patients' respective medical records to a chart abstraction company (the verbatim instructions to the practices are included under 2.1 (Supplemental Testing Methodology Information) - please disregard the instructions regarding the melanoma measure). They were instructed to send the portion of the patient chart that related directly to the specific visit date when the biopsy was performed. The chart abstraction company's staff, after receiving the patient records, reviewed those medical records and

#### NQF #0645 Biopsy Follow-up

answered questions in the "demo" version of the registry that related to the measure.

This project did not require that the entire medical record be sent, but just the specific portion(s) related to when the biopsy was performed - the instructions the practices were given were specific to include:

notes on whether the biopsying physician reviewed the biopsy results; documentation that the biopsy results were communicated to the primary care physician and to the patient; documentation that that biopsying physician noted his/her initials in a tracking log; documentation that the biopsy results were noted in the patient chart; noted system reason for not doing all of the above (3.b through 3.e), which could include that the exam or procedure was performed by another physician, resources to perform the service were not available, other reasons attributable to health care delivery system, patient asked that the plan not be communicated to physician providing primary care, or economic, social or religious reasons.

If the chart abstracter felt that any relevant portion of the patient record had not been sent - she worked closely with the practices to ascertain what was still needed and it was subsequently sent to her for review.

**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):

As the instructions were explicit as to what medical record documentation was needed for this project, the AAD asserts that the correct parts of the patient record(relevant to the measure) were reviewed and validity on the data element level was assessed.

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):

Exclusions are not explicitly detailed in the original measure specifications, but were built into the testing protocol. Patient level exclusions (e.g. if the patient asks that the biopsy results not be communicated to his/her referring physician) and system level exclusions (e.g. patient does not have a referring physician) were included in the testing project; however, neither the participating practices, nor the chart abstracter chose the exclusions for any of patients entered.

However, none of the

**2b3.2 Analytic Method** (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):

**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 (<u>Statistical risk model</u>: 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. <u>Risk stratification</u>: 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: N/A

**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):

**2b5.2 Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

**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*):

**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):

**2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the 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*):

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: Attachment

Kappa statistics 2x2 tables-634656733331391514.xls

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 *questions*): Public Reporting, Professional Certification or Recognition Program, Quality Improvement (Internal to the specific organization)

**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)*). <u>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 <u>Maintenance</u> – 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.*]</u>

Participants in Medicare's Physician Quality Reporting System are just now able to report on this measure, as 2012 is its first year of program inclusion. Public reporting of performance results will follow CMS' formal structure (i.e. Physician Compare, etc.). The AAD believes endorsement should be continued for a number of reasons: 1) this measure has not been tested in a large setting (like with PQRS) - the testing sample was limited at 5 physicians 2) this is a high volume measure and affects large numbers of patients, regardless of specialty 3) other specialties, including the American Society of Breast Surgeons and the American Academy of Ophthalmology, have contacted the Academy noting an interest in reporting this measure for PQRS 2012. Further details about this measure's use in public reporting will be better assessed after it is implemented in the 2012 PQRs program.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results: Rationale for why the measure performance results are meaningful, understandable, and useful for public reporting will be better assessed once eligible professionals have had a chance to report on it through the 2012 PQRS program.

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): Physician Quality Reporting System

**3b. Usefulness for Quality Improvement:** H M L I 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 <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].

This measure will be used in an electronic web resource designed by the AAD to fulfill part 4 of the Maintenance of Certification program (Practice Performance Assessment) that will launch in early-mid 2012. The website is listed below.

http://www.aad.org/education-and-quality-care/aad-professional-education/clinical-performance-assessment-tool-cpat/clinical-performance-assessment-tool

**3b.2.** Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (*e.g.*, *Ql initiative*), describe the data, method and results: Rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement will be better assessed once it has been implemented in the AAD's resource for Part 4 of MOC.

Overall, to what extent was the criterion, *Usability*, met? H M L I Provide rationale based on specific subcriteria:

### 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

### 4a. Data Generated as a Byproduct of Care Processes: H M L I

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), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

### 4b. Electronic Sources: H M L I

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*): Some data elements are in electronic sources

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: A near-term path to electronic capture would require the assignment of a CPT code for the quality action. The application with the AMA for an associated code will be forthcoming, so that it could be queried throughout a combination of electronic sources.

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

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: N/A

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (regarding proprietary measures):

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): More information will be available once this measure has been used more widely, such as in the AAD's PQRS registry, which is scheduled to launch in Q1 2012.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I Provide rationale based on specific subcriteria:

### OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

### 5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NOF-endorsed measure(s)</u>: 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*): N/A

### CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): American Academy of Dermatology, 1445 New York Ave NW, Suite 800, Washington, District Of Columbia, 20005

Co.2 Point of Contact: Alison, Shippy, MPH, ashippy@aad.org, 202-712-2610-

Co.3 Measure Developer if different from Measure Steward: American Academy of Dermatology, 1445 New York Ave NW, Suite 800, Washington, District Of Columbia, 20005

Co.4 Point of Contact: Alison, Shippy, MPH, ashippy@aad.org, 202-712-2610-

Co.5 Submitter: Alison, Shippy, MPH, ashippy@aad.org, 202-712-2610-, American Academy of Dermatology

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

Co.7 Public Contact: Alison, Shippy, MPH, ashippy@aad.org, 202-712-2610-, American Academy of Dermatology

### 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.

Dirk Elston, chair of the AAD Performance Measurement Task Force, future AAD President in 2013, Director of the Ackerman Academy of Dermatopathology

Oliver Wisco, incoming chair of the AAD Performance Measurement Task Force, US Air Force

Milan Anadkat, Assistant Professor Washington University, St. Louis

Justin Ko, Resident Harvard Combined Dermatology Residency Program

Abrar Qureshi, Brigham and Women's Hospital Vice Chairman Department of Dermatology, Assistant Professor, Harvard Medical School

Arthur Sober, Massachusetts General Hospital Medical Director, Medical Dermatology

Janet "Jessie" Sullivan, Chief Medical Officer Hudson Health Plan (Medicaid Managed Care Plan), participates in clinical practice by seeing dermatology patients at the Open Door Family Medical Center (FQHC)

An-Wen Chan, Assistant Professor and Phelan Scientist Women's College Research Institute University of Toronto

Lisa Lerner, dermatopathology practice

Daniel Hogan, private pratice

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:

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2010

Ad.4 Month and Year of most recent revision:

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

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

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 01/09/2012

	OQuality Reporting Syste	m				
Complete Practice Info	Gather Charts & Enter Data	Reviev	v & S	ubmit	to CM	s
Complete CMS Profile	Print Chart Log Form	<ul> <li>Initiate Submit</li> </ul>				
Complete Data Entry Complete Waiver Form	Record Data from Charts/Review Saved Charts	Calculate Meas	ures			-
Complete Practice Characteristics						
Complete Contact Info						
	Add Chart - BIOPSY					
Patient ID:						
Create a de-identified Patient Identifier (co access to this data. This can be your inter	ontaining letters and numbers, no special characters, a nal ID. Please keep a record of these IDs.	and no names) for	each p	oatient to	enable y	our
Patient Information:			Yes	No	N/A	Help
1. Is this a traditional Medicare Part B p	patient?		$\bigcirc$	0		Tip
2. Date of Visit?		Month	h - I	Day 2	2011 -	Tip
3. Gender:			⊚ N ⊚ F	lale emale		
						Tip
4. Race:		Select				
4. Race:		Select				
4. Race: Biopsy:		Select	Yes	No	N/A	Hel
Biopsy:		Select				
		Select	Yes	No	N/A	Hel
Biopsy:	ed by the biopsying physician?	Select				
<ul><li>Biopsy:</li><li>5. Is this patient undergoing a biopsy?</li><li>6. Have the biopsy results been review</li></ul>	ed by the biopsying physician? eviewed by the biopsying physician, this is due to:		© ©	0	  Reason	Tip
<ul><li>Biopsy:</li><li>5. Is this patient undergoing a biopsy?</li><li>6. Have the biopsy results been review</li></ul>	eviewed by the biopsying physician, this is due to:		© ©	O O System F	  Reason	Tip
<ul><li>Biopsy:</li><li>5. Is this patient undergoing a biopsy?</li><li>6. Have the biopsy results been review</li><li>7. If the biopsy results have not been review</li></ul>	eviewed by the biopsying physician, this is due to: unicated to the primary care physician?			System F Dther Re	Reason  Reason	Tip Tip Tip

11. If the biopsy results have not been communicated to the patient, this is due to	<ul> <li>System Reason</li> <li>Patient Reason</li> <li>Other Reason</li> </ul>
12. Did the biopsying physician note his/her initials in a log?	• • • • • • • • • • • • • • • • • • •
13. If the biopsying physician's initials are not noted in a log, this is due to:	<ul> <li>System Reason</li> <li>Other Reason</li> </ul>
14. Are the biopsy results documented in the patient's chart?	• • • • •
15. If the biopsying physician's initials are not documented in the patient's chart, this is due to:	<ul><li>System Reason</li><li>Other Reason</li></ul>
Complete Chart CANCEL	
Main Menu   Overview   Update your Contact Info   Feedback	
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QuestionNum	Карра	Agreement Rate
1	Not calculable	100.00%
5	Not calculable	100.00%
6	0	92.00%
7	0	92.00%
8	0.485	96.00%
9	-0.05	38.00%
10	0	94.00%
11	0	94.00%
12	0	42.00%
13	0	42.00%
14	Not calculable	100.00%
15	Not calculable	100.00%

Sum of Co	ount			
QuestionN	OrigValue	AuditValue Total		
1	Yes	Yes	50	
10	Yes	No	3	
		Yes	47	
11	(blank)	Other	3	
		(blank)	47	
12	Yes	No	29	
		Yes	21	
13	(blank)	Other	29	
		(blank)	21	
14	Yes	Yes	50	
15	(blank)	(blank)	50	
5	Yes	Yes	50	
6	Yes	No	4	
		Yes	46	
7	(blank)	Other	4	
		(blank)	46	
8	No	No	47	
	Yes	No	2	
		Yes	1	
9	Other	Other	18	
		System	29	
	(blank)	Other	2	
		(blank)	1	
Grand Total				

1 OrigValue

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OrigValue

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OrigValue

	AuditValue	
	Y	N
Y	50	0
Ν	0	0

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	Υ	N
Y	50	0
Ν	0	0

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	Y	N
Y	46	4
Ν	0	0

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	Y	N	
Υ	46	4	
Ν	0	0	

	AuditValue	
	Y	Ν
Y	1	2
N	0	47

	AuditValue	
	Y	N
Y	18	29
Ν	2	1

	AuditValue	
	Y	N
Y	47	3
Ν	0	0

	AuditValue	
	Y	Ν
Y	47	3
Ν	0	0

	AuditValue	
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Y	21	29
Ν	0	0

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### Date: MM/DD/YYYY

### Re: REQUEST FOR MELANOMA and BIOPSY MEDICAL RECORDS

We are writing on behalf of the AAD. Currently, the AAD has four quality measures that received time-limited endorsement from the National Quality Forum (considered the "gold standard" in health care performance measurement in the US). This time-limited endorsement requires the Academy to perform various statistical analyses on the measures. In order to do so, we are asking some practices to help us with gathering more information on two of the four measures.

Measures to be tested through your participation:

- Overutilization of Imaging (2011 PQRS Measure #224)
- Biopsy Follow-Up (anticipated in 2012 PQRS program)

You have already agreed that your practice will participate in the measure validation project and the Academy sincerely appreciates your assistance in validating quality measures that are critical to physician performance improvement. AAD has contracted with Information Collection Enterprises (ICE) to request and to review medical records and validate your 2011 PQRS melanoma data, as well as a sample of your biopsy patients. As an organization, ICE is highly committed and sensitive to the need for protecting the security of protected health information (PHI) and has implemented reasonable electronic, physical, and technical safeguards to prevent unauthorized use or disclosure of PHI.

Enclosed is a coversheet for each record requested related to measure 224. Please submit a complete photocopy of the entire record and supporting documentation related to the listed date of service. Please ensure that all copies are complete, legible, and contain both sides of each page, including page edges. The cover sheet(s) provided should be placed on the top of each corresponding medical record prior to shipment.

Also enclosed is a template cover sheet for biopsy patients. We ask that you make a copy of this template for each biopsy patient that you enter and copy the patient records along with the created cover sheet, similar to what is described above for the measure 224 patient visits.

The coversheet for each record contains a line for you to indicate the total number of pages in the medical record. This is used to calculate your reimbursement for photocopying costs (\$0.12 per page). The reimbursement amount will be calculated directly from the information recorded on the coversheets. Please do not send a separate invoice for photocopying charges. If you utilize a photocopying service, please



ensure that the service does not invoice ICE. ICE can provide payments for photocopying only to providers, not to copy services.

To assist ICE in confirming that the correct medical records have been submitted, please record the patient name and date of birth on the coversheet.

Also enclosed is a questionnaire to assist AAD in verifying that you have included all necessary data. Please fill in all pertinent information and return the questionnaire with the medical records.

The medical records and questionnaire should be sent to ICE as soon as possible. A prepaid FedEx air bill has been provided to facilitate shipment. Please do not invoice ICE for the cost of shipping, as using the enclosed air bill will ensure no shipping costs will be incurred by your practice.

If you have any questions regarding the medical records being requested or the shipping instructions, please contact ICE at (717) 650-6772. Your cooperation is greatly appreciated.

Enclosures: Melanoma questionnaire

Medical record coversheets Instruction sheet Pre-paid FedEx air bill



### INSTRUCTIONS FOR COPYING CHARTS FOR THE AAD MEASURES TESTING PROJECT: Melanoma Patients

- 1. Fill out all information on cover sheet, including date of visit, and mapping of patient name or real ID to de-identified patient ID.
- 2. Copy proof they are a Medicare Part B FFS patient
- 3. Copy proof they have a diagnosis of Melanoma and/or a history of Melanoma (ICD-9 diagnosis code: 172.0, 172.1, 172.2, 172.3, 172.4, 172.5, 172,6, 172.7, 172.8 172.9, V10.82)
- 4. Copy all of the pages from the visit entered in the system, which should include (if exists):
  - a. proof of the valid encounter codes (CPT code: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215),
  - b. notes on whether imaging studies were ordered related to the melanoma. Imaging studies include: chest x-ray, CT, ultrasound, MRI, PET, and nuclear medicine scans.
  - c. documentation of the patient's cancer staging )
  - d. noted if patient exhibits signs or symptoms of melanoma. Examples of such signs or symptoms include respiratory, neurologic, musculoskeletal, gastrointestinal, skin/lymphatic or other clinical symptoms that may indicate disease progression or metastasis
  - e. noted system reason for not documenting any of the above (4.b through 4.d), which could include that another physician made the original diagnosis and you are not aware of what the stage was at the time of diagnosis, imaging studies were performed by another physician, , or other reasons attributable to health care delivery system.

### INSTRUCTIONS FOR COPYING CHARTS FOR THE AAD MEASURES TESTING PROJECT: Biopsy Patients

- 1. Create a cover sheet for each patient visit using the Biopsy Visit Template, including date of visit, and mapping of patient name or real ID to the de-identified patient ID.
- 2. Copy proof they are a Medicare Part B FFS patient
- 3. Copy proof they had a biopsy performed (*common* CPT procedure codes for dermatologists include [but are not limited to] : 11100(Biopsy, skin lesion); 11101(Biopsy, skin add-on); 40490(Biopsy of lip); 54100(Biopsy of penis); 54500(Biopsy of testis); 56605(Biopsy of vulva/perineum); 56606(Biopsy of vulva/perineum); 67810(Biopsy of eyelid); 69100(Biopsy of external ear); 11755(Biopsy of nail unit) other less common codes for dermatologists include: 21550(Biopsy, soft tissue of neck or thorax); 21920(Biopsy, soft tissue of back or flank; superficial);21925(Biopsy, soft tissue of back or flank; deep); 23065(Biopsy, soft tissue of shoulder area; superficial); 23066(Biopsy, soft tissue of shoulder area; deep); 24065(Biopsy, soft tissue of upper arm or elbow area; superficial); 24066(Biopsy, soft tissue of upper arm or elbow area; deep); 25065(Biopsy, soft tissue of forearm and/or wrist; superficial); 25066(Biopsy, soft tissue of upper arm or elbow area; deep); 27040(Biopsy, soft tissue of pelvis and hip area; superficial); 27324(Biopsy, soft tissue tumor of thigh and/or knee area; superficial); 27324(Biopsy, soft tissue tumor of thigh and/or knee area; deep)
- 4. Copy all of the pages from the visit entered in the system, which should include (if exists):
  - a. proof of the valid biopsy procedure codes (CPT code: TBD),



- b. notes on whether the biopsying physician reviewed the biopsy results
- c. documentation that the biopsy results were communicated to the primary care physician and to the patient
- d. documentation that that biopsying physician noted his/her initials in a tracking log
- e. documentation that the biopsy results were noted in the patient chart
- f. noted system reason for not doing all of the above (3.b through 3.e), which could include that the exam or procedure was performed by another physician, resources to perform the service were not available, other reasons attributable to health care delivery system, patient asked that the plan not be communicated to physician providing primary care, or economic, social or religious reasons.

#### INSTRUCTIONS FOR SUBMISSION OF MEDICAL RECORDS FOR MEASURES TESTING PROJECT

## Please Do...

- Copy on white paper
- Use blue coversheets provided
- Rubber band or staple each record separately
- Include patient name and DOB on coversheet
- Include page count on front of blue coversheet
- Use proper shipping tape
- Use proper packaging such as free FedEx supplies and/or tyvek material envelopes
- Complete sender info and use pre-printed FedEx airbill

## Please Do Not...

- Copy double sided
- Reduce and reproduce multiple pages on a single page
- Send invoices from copy services. ICE does not directly pay copy services for photocopy costs.
- Use any tape other than heavy duty shipping tape
- Use manila or paper envelopes
- Overpack boxes
- Ship for Saturday delivery

Ship Records To: Information Collection Enterprises 1501 Mount Rose Ave, Suite H-4 York, PA 17403

Should you have any questions regarding this request for medical records, please contact the ICE Help Desk at (717) 650-6772.



### QRS MELANOMA QUESTIONNAIRE

Please complete this form and return it to ICE along with the requested medical records.

Number of unique patients seen in 2011 to this point with any of the melanoma ICD-9-CM codes below:

Melanoma Diagnosis codes (ICD-9-CM): 172.0, 172.1, 172.2, 172.3, 172.4, 172.5, 172.6, 172.7, 172.8, 172.9

History of Melanoma codes (ICD-9-CM): V10.82

Accompanied by one of the following patient encounter codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215.