American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI™)

Measures Development, Methodology, and Oversight Advisory Committee (MDMO)

Specification and Categorization of Measure Exceptions: Recommendations to PCPI Work Groups

Approved by the PCPI: April 5, 2013

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1. Policy Purpose and Goals

The following recommendations are provided to guide PCPI measure development Work Groups on the appropriate use of measure exceptions, measure exception examples and documentation of exceptions rationale in the medical record. The appropriate construction and use of measure exceptions will help promote greater consistency and standardization in PCPI measures.

The goals of this framework are to:

- Define the PCPI approach to exclusions and exceptions
- Provide a rationale for a revised approach to the PCPI exception methodology
- Describe guiding principles that serve as a foundation for the PCPI exception methodology; and
- Provide recommendations to PCPI Work Groups on the use of exclusions and exceptions

These recommendations should be used by PCPI Work Groups throughout the measure development process when considering a denominator exception in a measure.

2. Defining Exclusions and Exceptions

Definition of Exclusions and Exceptions

**Exclusions** arise when patients who are included in the initial patient or eligible population for a measure do not meet the denominator criteria specific to the intervention required by the numerator. Exclusions are absolute and apply to all patients and therefore are not part of clinical judgment within a measure.

**Exceptions** are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate due to specific reasons for which the patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences (see section 4 for more detail on the PCPI approach to exclusions and exceptions).

3. Need for a Revised Framework on Exceptions

Since the initial exceptions framework was developed in 2007, the PCPI has heard feedback that the current methodology for exceptions (three broad categories) should be evaluated and reconsidered, given the changes in the measurement development landscape and the types of measures being developed by the PCPI. The PCPI has engaged with its membership around the continued use of exceptions and solicited their feedback in several advisory committee forums. The majority of the membership believes that there is value in continuing the consideration of measure exceptions, and utilizing feedback from these data for quality improvement in clinical practice. Clinicians who use PCPI measures have provided feedback that indicated that exceptions allow for a valid way to ensure appropriate care for patients, and track quality improvement and compare outcomes across providers. The PCPI has also received feedback that more specificity is desired—to name and individually code each medical reason, patient reason, etc.

The reevaluation of the current exceptions approach has provided a better understanding of how PCPI exceptions are used and what types of exceptions are used most frequently. Through analysis of our measure sets, we have recognized that each PCPI work group may be applying different criteria and thresholds to the identification of exceptions. For example, some work groups use measure exceptions liberally, while others are more judicious in their approach. In addition, there have been instances in which measures with “medical” exceptions would have been more accurately represented with an exclusion.

The PCPI has also made great strides around measure specifications and standards for capturing clinical data. As such, PCPI measures have moved towards a focus on specifications for electronic health records.
The previous methodology did not reflect the current environment of expanded EHR use and eMeasure specifications and was focused primarily on claims-based specifications and reporting. As such, there was more of an emphasis on the categories that were used for measure exceptions.

The PCPI has been engaged with EHR vendors and other standards and informatics professionals in an effort to share learned experiences and methodologies for capturing data and developing measures in a new era of electronic health records. Through these discussions, the PCPI has learned that challenges still exist around capturing exceptions in EHRs. To address this challenge, the PCPI has held discussions with several large EHR vendors to bring key stakeholders together to develop more consistent approaches to recording and capturing measure exceptions. Going forward, this collaboration is expected to continue.

4. Current PCPI Approach to Measure Exclusions and Exceptions

Exclusions

The PCPI and other measure developers use exclusions in measure definitions and clinical logic. Exclusions arise when patients who are included in the initial patient or eligible population for the measure set do not meet the denominator criteria specific to the intervention required by the numerator (eg, HF and Left Ventricular Systolic Dysfunction). Patients without left ventricular systolic dysfunction are excluded from the measure given beta-blockers are not indicated in this subset of the HF population, and those patients are removed from the measure denominator in calculating performance. Exclusions are absolute and apply to all patients and therefore are not part of clinical judgment within a measure. Specific exclusions may be derived from evidence-based guidelines or other relevant research.

PCPI Approach to Exceptions

Exceptions are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate due to specific reasons; otherwise, the patient would meet the denominator criteria. Exceptions are not absolute, and the application of exceptions is based on clinical judgment, individual patient characteristics, or patient preferences.

The PCPI exception methodology uses three categories of exception reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians.

Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients’ medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician’s exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception.

Proposed Revised Approach to Exceptions

In March 2012, the PCPI invited multiple stakeholders to engage in a dialogue with the membership and advisory committees around measure exceptions. At that meeting, the PCPI reviewed a number of options regarding our exception methodology, including:

- Eliminate use of exceptions, maintain use of exclusions
- Reaffirm current approach of 3 broad categories
• Delete system reason from current approach
• Enhance current approach with additional examples that are coded
• Include Sub-categories under current 3 broad categories; EHR Passive Search Documentation
• Include Sub-categories under current 3 broad categories; Provider Active Documentation or Attestation

As a result of these discussions, there was general agreement the PCPI should discontinue the use of the “system” exception. The rationale behind this decision is twofold: 1) the “system” reason for exception is used infrequently. PCPI testing projects and reports from the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting System (PQRS) consistently show that the use of the system reason (when available in a measure) is less than 3%; and 2) the “system” reason for exception does not reflect the PCPI’s approach to exceptions, namely that they relate to the individual patient characteristic, patient preference, or are part of clinical judgment. System issues cut across hospitals, health systems, and communities and do not apply at the individual patient-level.

During further discussions, the MDMO Advisory Committee agreed with earlier discussions that going forward, PCPI measures should not implement the “system” reason for exception, and that the “medical” and “patient” reasons for exceptions should continue to be available. There was also agreement that work groups should be more judicious in the use of exceptions and in many instances, no exceptions would be warranted. Exclusions (not exceptions) should be used in cases where there is a clinical evidence base that is not primarily determined by individual patient characteristics. While agreeing to maintain the “medical” and “patient” categories, the MDMO has provided additional recommendations for the sub-categories that are used in the medical and patient reasons, to more accurately reflect examples in current practice and to prevent inappropriate use of exceptions.

5. Capturing and Reporting PCPI Exceptions in Current National Programs

Capturing and Reporting Exceptions in Current National Programs

**CMS EHR-based PQRS Reporting (2012):** Eligible Professionals must submit measure data elements, including numerators, denominators and denominator exclusions. PCPI measures exceptions are termed exclusions by CMS, and counts of exceptions are included with counts of denominator exclusions in performance calculations. Starting in 2013, CMS states that they will be able to separate out exclusions from exceptions, and these data will be accessible. The measure exceptions can be submitted using either HL7 ACTREASON codes, or with SNOMED Clinical Terms® (SNOMED-CT) codes for medical reason and patient reason exceptions. Recent CMS PQRS Experience Reports present national level performance rates by measure, but do not present measure exception rates. Exception rates are not currently reported back to physicians participating in the program.

**CMS EHR Incentive Program:** For Stage 1, certified EHRs must be able to calculate measure numerators, denominators and exclusions for each clinical quality measure (CQM). Eligible professionals are required to attest to the calculated results for initial patient populations, numerators, denominator and exclusions (where exclusions include PCPI exceptions) as automatically calculated by the certified EHR. Electronic specifications include the measure data elements, logic, data element attributes and filters, and value sets for implementation in structured data field, not in narrative text.

**CMS EHR Incentive Program:** For Stage 2, it is proposed that certified EHRs be able to calculate measure initial patient populations, numerators, denominators and exclusions for each CQM. It is proposed that eligible professionals and groups (eligible professional in the same group practice) are required to report the calculated results for numerators, denominator and exclusions (where exclusions include PCPI exceptions) as automatically calculated by the certified EHR. Electronic specifications will include the
measure data elements, logic, data element attributes and filters, and value sets for implementation into structured data fields, not in narrative text with the certified EHR.

Accountability/Public Reporting Specific PCPI Recommendations:
- Exception rates should be reported along with measure performance rates. (For physician level reporting the same caveats apply in terms of sample sizes for exception rate reporting as in reporting performance rates.)
- CMS should provide updated and regular reports on PQRS measure exception rates and performance rates at the measure level (see Telligen, formerly Iowa Foundation for Medical Care, “2007 Physician Quality Reporting Initiative Preliminary Participation, as of November 2007.”)
- CMS should provide physicians exception and performance rates in Physician Feedback Reports for those physicians participating in PQRS.

Quality Improvement Specific PCPI Recommendations:
- Clinical information in captured exceptions, eg, medical reasons related to allergies, or patient reasons related to costs, should be used to promote physician-patient engagement and reduce barriers to care.
- Exceptions should be used to provide real-time feedback for clinical decision making and enhance clinical decision support capabilities.
- Systematic review and analysis of physician’s exceptions data should be available to physicians and the physician group to aid in identifying practice patterns and opportunities for quality improvement.

6. Guiding Principles on Measure Exceptions

The following are guiding principles for PCPI measure exceptions.

- Exceptions provide a means for physicians to document specific clinical information and judgment on a case-by-case basis
- Exceptions allow patient preferences to be reflected in quality measurement
- Exceptions may create more homogeneity in the denominator populations to enhance comparability across providers
- Exceptions may reduce the possibility that physicians’ performance would be unfairly evaluated when treating severely ill or vulnerable populations.
- There must be a clear rationale to develop a measure with an exception.
- The measure logic outlines the process to capture exception information (eg, clinical information, patient preferences) related to a therapy or service which would not be applicable, due to individual patient considerations for which the patient otherwise meets the measure criteria.
- The specific reasons for exceptions must be documented in patients’ medical records for the purposes of optimal patient management and audit-readiness.
- Measure exception language and specifications must include examples of the instances that may constitute an exception and are intended to serve as a guide to clinicians, users and implementers of the measure.
- Where examples of exceptions are included in the measure, these examples should be specified in clinical vocabularies and corresponding value sets for the measure and included in the eSpecifications.
- Measure exceptions and exception rates should be audited for validity or misuse and analyzed for reliability of appropriateness.
Exceptions Methodology Selection Criteria

PCPI recommends that the following key elements be used for consideration of the criteria to evaluate methodologies for capturing and reporting exceptions. The PCPI believes that these would be accepted by practicing physicians and other stakeholders. The criteria include the following:

- **Transparency** – to providers and to EHR vendors to integrate in the EHR
- **Strength of evidence-base** – exceptions included are based on RCT, natural history of the patient’s disease, etc.
- **Feasibility** – implementable
- **Impactful** - clinical importance– studies suggest that exception rates are low, but documented exceptions with low reporting rates could be clinically important
- **Actionable** – Valuable information is available in documented exceptions for providers and patients for clinical decision making
- **Valid** – review of verbatim exceptions reported during measure testing indicates exceptions reflect clinical judgment on a case-by-case basis; allow patient preferences to be reflected in shared clinical decision making; or for reevaluating the measure and measure specification

7. Recommendations for PCPI Work Groups

1) **Categories for PCPI Exceptions**

Policy Recommendation: PCPI measures exceptions use two categories: medical and patient. Use of exceptions should be considered for each measure on a case-by-case basis.

For process, structural, and outcome measures, the PCPI provides two broad categories of reasons for which a patient may be excluded from the denominator of an individual measure. Exceptions are used to indicate that a treatment or service was considered but due to medical or non-medical reason(s) documented in the medical record, the treatment or service was not provided.

*Additional guidance may be needed for outcome measures as the PCPI’s outcome measures portfolio becomes more developed.*

**a) Documentation of medical reason for exception**

A medical reason for an exception should be used in the presence of clinical contraindications such as a previous allergy; severe co-morbidities resulting in a preponderance of potential risks over health benefits to a patient; or other extenuating medical circumstances in a patient’s history.

The examples provided are intended to guide clinicians and are not all-inclusive lists of all possible reasons for why a patient could be an exception from a measure.

**Example of measure with a medical exception:**

**Coronary Artery Disease: Beta-blocker Therapy – Prior Myocardial Infarction (MI)**

**Measure description:**
Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease and prior myocardial infarction (MI) who were prescribed beta-blocker therapy

**Denominator exception:**
Documentation of a medical reason (s) for not prescribing beta-blocker therapy (contraindications: eg: Bradycardia, History of Class IV congestive heart failure, History of 2nd or 3rd degree AV block without permanent pacemaker)
b) **Documentation of patient reason for exception**

Patient exceptions should be used for cases in which fully informed patients refuse treatment or services. Patient exceptions are justified in cases in which the patient has communicated directly with the physician that for personal reasons, (financial, social, religious, etc.) they do not wish to have the service or treatment.

Example of a measure with a “patient” (non-medical) exception

**Stroke and Stroke Rehabilitation**

Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation, who were prescribed an anticoagulant at discharge

Documentation of patient reason(s) for not prescribing an anticoagulant at discharge (e.g., patient is receiving comfort care only, patient left against medical advice, other patient reason(s)).

2) **Sub-categories**

| Policy Recommendation: To guide the selection of appropriate exception type(s) for each measure, the sub-categories listed below are provided as guidance. |

In deciding if an exception is appropriate, Work Groups should review each sub-category listed below for applicability. Sub-categories (contraindicated, already received/performed, patient declined, etc.) for each measure exception category are provided for additional guidance to Work Groups when developing exceptions and listing examples of frequent reasons for patients not meeting the numerator criteria.

Sub-categories are listed below:

**Medical reason(s)**
- Contraindicated in patient (potential allergy due to previous reported allergic history, potential adverse drug interaction, other)
- Already received/performed
- Intolerant (therapy was tried and the patient was intolerant)
- Other medical reason(s)

**Patient or Non-medical reason(s)**
- Patient refused/declined
- Access issues or insurance coverage/payor-related limitations (patient not covered for treatment)
- Patient functional limitations
- Patient preference: Social reason(s) (e.g., family or support system not supportive of intervention/treatment); Religious reason(s) (e.g., religious beliefs regarding blood transfusion)
- Other patient reason(s)
3) Providing Examples of Exceptions

**Policy Recommendation:** Work Groups should consider adding one or more examples of diagnoses or clinical scenarios that might qualify as exceptions. Examples should not be an attempt to provide a comprehensive list of exception reasons.

Work Groups should attempt to provide examples each time that there is a justifiable reason to use an exception. As Work Groups examine what exceptions will apply, they should review the above-mentioned sub-categories and provide examples that correspond to the sub-categories. For each potential reason identified for justification of allowing exception of a patient from a measure, consider adding examples of potential reasons for exception from that measure (within the medical or patient category). When providing examples in PCPI exceptions, Work Groups should decide in which sub-category within each broad exception category an example is appropriate. Examples are not intended to be an all-inclusive list of reasons why a patient should be excluded, but are based on the experience and judgment of each topic-focused Work Group. Having a relevant example decreases the possible number of times that physicians will inappropriately exclude a patient from a measure, thereby promoting greater reliability.

Examples should be considered only conditional reasons to except a patient from the measure. In some cases, patients meeting the exception example criteria may be appropriate to include in the measure. The decision to exclude a patient, then, should rest on the clinical judgment of the provider caring for the patient. For any measure for which the list of examples of exception reasons becomes lengthy (as may be the case with multiple potential drug interactions), consider limiting the list to the 1-5 reasons expected to apply most frequently.

Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications. Value sets include coding and the following standards in the development of our EHR specifications: The Quality Data Model, developed by the National Quality Forum, the vocabulary recommendations named by the Health IT Standards Committee of the Office of the National Coordinator for Health IT, (eg, SNOMED, RxNorm, LOINC)

Measure with medical exception and examples:

*Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.*

*Documentation of medical reason(s) for patient having computerized tomography ordered at the time of diagnosis or received within 28 days after date of diagnosis (eg, persons with sinusitis symptoms lasting at least 7 to 10 days, antibiotic resistance, immunocompromised, recurrent sinusitis, acute frontal sinusitis, acute sphenoid sinusitis, periorbital cellulitis, other medical reasons).*

4) Documenting the Rationale for the Exception

Policy Recommendation: Work Groups should document the rationale for each exception. This should be clearly stated in the measure worksheet.

Work Groups should be able to document actual reason(s) for exceptions and their potential value (ie, rationale for exception). A section in the measure worksheets is designated for providing additional information on the measure exception. In this section, Work Groups should describe the reason(s) for the exception, using examples, if appropriate and provide any available data or supporting evidence.
8. Capturing Exceptions in the Medical Record

Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients’ medical records for purposes of optimal patient management and audit-readiness.


Performance Calculation: \[
\frac{\text{# of patients meeting numerator criteria}}{\text{(# of patients in denominator) – (# of patients who did not meet the numerator but have valid denominator exceptions)}}
\]

Exception Calculation: \[
\frac{\text{# of patients who did not meet the numerator but have valid denominator exceptions}}{\text{# of patients in denominator}}
\]

Exceptions can be captured and searched for in EHRs using the following methodologies, or combination of methods:

1. Discrete fields, and searching and reporting on these discrete fields.
2. Natural language processing to search on strings of text to find specific exceptions noted in the text field.
3. Exceptions documented in response to an indication in the EHR that the patient does not meet the clinical performance measure, and can be reported from this specifically documented exception via automated reporting.

For example, a heart failure patient for whom Warfarin is not prescribed due to a history of bleeding should have documentation in the medical record that states why the patient did not receive the drug. Documentation in the chart provides several benefits that support clinical decision making, such as establishing the linkage between the action of the clinician and the reason why treatment was provided/not provided to the patient. In addition, documenting exceptions provides additional information for quality improvement and provides a rationale for the exception during audit. By analyzing patients by exception category or reason, it may be possible to identify opportunities for clinical improvement. For example, a physician could analyze all patient exceptions for an influenza vaccination measure to determine if additional educational materials or translator services could be of benefit to patients declining the vaccine.

**EHRs Considerations**

The categories of exceptions and accompanying examples may be useful to EHR vendors attempting to include functionalities to report on performance measures within their products. When selecting exception reasons to be listed as examples, Work Groups should also consider the appropriateness of such a list if provided in an EHRs. PCPI staff have begun collaborations with EHR vendors and will continue to work with the electronic health vendor community to streamline the process for implementing exceptions into electronic systems.
Guidance to vendors:

To address the issue of documentation for exceptions via automated reporting vs. documentation of the exception and the rationale for the exception captured, the PCPI recommends that the EHR provide for the capture of an exception and documentation of rationale (e.g., clinicians could check a box or fill a structured data field to indicate that, for example, there was a medical reason why the measure was not met AND describe the specific reason in a free-text comment).

9. PCPI Exception Methodology: Strengths and Weaknesses

**Strengths:**

- Exceptions provide a mechanism for avoiding perverse incentives to provide inappropriate care
- Exceptions may allow patient preferences to be reflected in quality measurement,
- Exceptions may create more homogeneity in the denominator populations to enhance comparability, and
- Exceptions may reduce the possibility that performance would be inaccurately characterized.

**Weaknesses:**

- Because there is no widely agreed upon approach to capturing exceptions in EHRs, the current PCPI methodology of providing example exceptions as part of the measure set, while preserving physician judgment, provides challenges in translation to an EHR environment. Research shows that individual workflow and documentation issues have an impact on EHR-derived quality measures and can undercount practice performance (Parsons A, et al. Validity of electronic health record-derived quality measurement for performance monitoring. *J Am Med Inform Assoc*. 2011).
- There is lack of consistency across sites and systems in the capture, identification, documentation and reporting of exceptions.
- The list of exception examples currently included in measure specifications, which is not meant to be exhaustive, can create confusion as to what exceptions are allowed in addition to the examples.
- Exception implementation and reporting create a burden from both an HIT perspective (e.g., programming exception example lists and value sets) and a physician perspective (e.g., capturing and documenting exceptions using free text or extensive lists on items or options in menus).

10. Testing and Evaluation of Exception Methodology

PCPI measure testing will provide feedback on the current exception methodology. The goal of PCPI measure testing is to help determine whether: the current approach is reliable and feasible; if additional specificity of exceptions is needed; and whether there is potential for unintended consequences. See Table 1 on pages 15-16 for example reported exception rates and validation, as reported from U.S. studies and the United Kingdom.

**Feasibility/Implementation of Exceptions Methodology**

The PCPI continues to tests its measures for feasibility through ongoing testing work, grant-funded projects, and through measures that are implemented in public programs. In the current CMS PQRS program, physicians will be provided feedback on the percentage of patients identified as meeting exceptions by the physician.
Reliability of Exception Methodology
Ongoing grant-funded research undertaken by the AMA and various collaborators may provide empirical evidence on the accuracy of data elements for exceptions, as well as the reliability of existing exclusion methodology. Additionally, through collaboration and research overseen by the PCPI Measures Implementation and Evaluation Advisory Committee, PCPI measures are tested for validity, reliability, and feasibility in concordance with the PCPI Testing Protocol. The PCPI is also engaged in ongoing consultations with EHRS vendors to assess performance measures and exceptions. It is the intent that these testing opportunities will provide feedback on the appropriateness of the current exception methodology and the use of sub-categories and examples in the measure exceptions. The PCPI will examine the information received through testing and evaluation and make recommendations for maintaining or modifying its exception methodology.
In calculating performance measures, all patients to whom a given measure’s eligibility criteria are applicable (denominator) are identified, and all positive incidences of quality (numerator) are subsequently identified. For all eligible patients who are not identified as part of the numerator, exception criteria are applied to determine whether a patient did not receive the service in question for an allowable reason.

11. PCPI Algorithm for How Measures are Calculated for Performance Measurement

- Are the denominator criteria applicable to patient?
  - No → Stop
  - Yes →

- Was the process/outcome described in numerator performed/achieved for the patient?
  - No → Are one or more exception criteria met?
    - No → Stop (Measure not met for this patient) Keep patient in denominator; do not count in numerator.
    - Yes → Include in count for numerator.
  - Yes → Remove patient from denominator for calculation of performance.
If there is a reason for the process/outcome described in numerator to have not been performed/achieved for the patient, review the exception categories and sub-categories listed below for appropriateness.

**Medical Exception**

**Sub-Categories**
- Contraindicated
- Not indicated
- Intolerant
- Other medical reason

**Criteria for Consideration**
Medical reason for exception should be considered when there is a clinical contraindication or co-morbidity.

**Patient Exception**

**Sub-Categories**
- Patient preference
  - Social reason(s)
  - Religious reason(s)
  - Other patient reason(s)

**Criteria for Consideration**
Patient reason for exception should be considered when patient preference for a given treatment/service needs to be taken into account.

Do any exception categories apply to this measure?

- **No** → Stop
- **Yes**

Identify the most important examples of exceptions based on the sub-categories. Examples are not intended to represent a comprehensive set of reasons for exception.
12. Frequently Asked Questions

Q. **What is an exception?**

A. In the context of physician performance measurement, an exception from a PCPI measure refers to the allowance for physicians to exclude patients who would ordinarily be included in a measure, but meet certain criteria for removal from the denominator of a performance measure. Exceptions are case by case considerations, based upon specific patient characteristics or preferences. Exception data are intended to be collected and reported back to the user of the measures to facilitate improved patient care.

Q. **Why does the PCPI believe that exceptions are still important for performance measures?**

A. Exceptions serve many critical functions in physician performance measurement: (1) they provide a means for physicians to document clinical judgment on a case-by-case basis; (2) they allow patient preferences to be reflected in quality measurement; (3) they may create more homogeneity in the denominator populations; (4) they may reduce the possibility that physicians who treat severely ill or vulnerable populations will be unfairly penalized; and (5) they reduce the possibility of patients receiving inappropriate care (procedures or services simply to meet performance measure).

Q. **Don't performance measures become more susceptible to "gaming" when exceptions are allowed?**

A. The potential for inappropriate use of exceptions to improve performance rates is a legitimate concern. However, PCPI instructions require the physician to document in the medical record the clinical justification for the exception. Any questionable exception rates are thus fully auditable. Furthermore, the incidence of gaming behavior is more likely related to external incentives available for gaming (eg, reimbursement policies) than to how the measures are designed by the PCPI. Until data become more readily available on the use of exceptions, it is difficult to assert whether there are legitimate reasons to be concerned about their inappropriate use.

Q. **Why are PCPI exceptions grouped into categories (medical, patient)?**

A. As the PCPI measure development work has evolved, the need to group exceptions into categories was a logical step for delineating specific reasons for why a patient did not meet a measure. Grouping the exceptions into these categories facilitates data collection, yet allows some information about the attribution of the exceptions to be transmitted. Grouping is also consistent with physician decision making and promotes audit readiness.

Q. **Do all exception categories need to be present for each measure?**

A. No, many PCPI measures do not allow for any exceptions and others may allow only one of the two categories. It is up to the individual Work Group to decide whether or not any of the categories are appropriate for a given measure as it is being developed.

Q. **Why is the PCPI emphasizing the use of examples in measure exceptions?**

A. Many users of PCPI measures have asked for greater specificity in measure exceptions. The PCPI believes that by providing examples in measure exceptions, users of the measures have more direction as to what types of exceptions are frequently found. Examples are not intended to be an all-inclusive list of reasons why a patient should be excluded. Exception examples may be individually coded, and are used as a guide for the clinician when deciding whether or not a patient
meets the criteria. Examples are based on the most frequent and significant reasons for why a patient should be excluded, and are based on the experience and judgment of each topic focused Work Group.

Q. Why not create a comprehensive list of all possible exceptions for each measure?

A. It is nearly impossible to generate an all-inclusive list of current reasons for why a patient should be excluded from a measure. Many potential medical reasons are relative contraindications and including all relative contraindications has the potential to suggest that some patients should not receive a therapy that is important and appropriate.

Q. What are the instructions for use of an exception in PCPI measures?

A. Using an exception in a PCPI measure is at the discretion of the individual Work Group. Work Groups should decide if there is a justifiable reason for excluding a patient from a measure, based on whether or not that reason is significant and occurs frequently enough.

Q. What types of data sources are the PCPI measures specified for?

A. PCPI measures are being specified with an emphasis on electronic health record systems. The measure specifications include the following components: 1) A text description of the measure; 2) The Data Requirements Table, which outlines the data elements that are required for the measure, including the identification of the clinical vocabularies applicable to a given data element, the NQF Quality Data Model category and state, as well as the timing parameters for each data element; 3) A visual flow diagram that uses Boolean logic to identify the Initial Patient Population, Exclusions, Denominator, Numerator and Exceptions included in the measure; 4) Measure Calculation; 5) Value sets for each of the data elements. The PCPI is currently working with the EHR vendor community on several initiatives to engage them in developing ways to capture measure exceptions more readily.

Q. What has been done to test this exceptions strategy?

A. Ongoing grant-funded research undertaken by the AMA-PCPI and various collaborators may provide empirical evidence on the accuracy of data elements for exceptions, as well as the reliability of existing exception methodology. As an example of such research, “Cardio-HIT Phase II” was an AHRQ-funded project which examined the prevalence and patterns of exception reporting in the ACC/AHA/PCPI Coronary Artery Disease and Heart Failure measure sets. Cardio-HIT II assessed the accuracy of exception reporting by validating a sample of reported exceptions against manual EHRS record review. See Table 1 for further information. The PCPI is also collaborating with EHR vendors to seek opportunities for testing and implementation of the measures.
Table 1: Example Reported Exception Rates and Validation

<table>
<thead>
<tr>
<th>Study</th>
<th>Average/ Total Number of Exceptions; Percentage of Exceptions Found to be Appropriate</th>
<th>Range</th>
<th>Number of Measures</th>
<th>Study Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doran T et al., Effect of financial incentives on incentivized and non-incentivized clinical activities: longitudinal analysis of data from the UK Quality and Outcomes Framework. BMJ 2011</td>
<td>Rate of Exception Reporting for Measurement Activities: 3% (2005-2006) Rate of Exception Reporting for Treatment and Prescribing Activities: 13% (2005-2006) Overall Exception Reporting Rate for Quality and Outcomes Framework Indicators: 8.3% (2006-2007)</td>
<td>N/A</td>
<td>42 indicators - Selected from 428 identified quality of care indicators; 23 incentivized under UK QOF, 19 not incentivized</td>
<td>United Kingdom - 148 general practices in England; 635,000 patients - Selected practices were nationally representative in terms of patient sex, age distribution, and SES, and tended to be larger practices</td>
</tr>
<tr>
<td>Doran T et al., Exclusion of Patients from Pay-for-Performance Targets by English Physicians. NEJM 2008</td>
<td>5.3% exception rate (median) (April 2005 to March 2006)</td>
<td>Interquartile range, 4.0 to 6.9</td>
<td>65 clinical indicators used in second year of UK’s pay-for-performance program</td>
<td>United Kingdom - Data from 8,105 family practices in England (96% of all practices), data from the UK Census, and data on practice characteristics from the UK Department of Health</td>
</tr>
<tr>
<td>NHS Information Centre, Quality and Outcomes Framework Exception Data 2010-2011</td>
<td>For 2010-2011, overall effective exception rate was 5.4% (unchanged from 2009-2010)</td>
<td>0.5 – 32.8% exception rate</td>
<td>68 clinical domain indicators</td>
<td>England</td>
</tr>
<tr>
<td>Study</td>
<td>Exception Rate</td>
<td>Quality Measures</td>
<td>Practice Type</td>
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<td>----------------------------------------------------------------------</td>
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<td>Kmetik K et al., Exceptions to Outpatient Quality Measures for Coronary Artery Disease in Electronic Health Records. <em>Ann Intern Med</em> 2011</td>
<td>3.5% exception rate</td>
<td>2.4 - 15.2% exception rate</td>
<td>5 internal medicine or cardiology practices</td>
<td></td>
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<tr>
<td>92.6% were found to be appropriate</td>
<td>90.3% - 94.9% appropriate</td>
<td>4 drug-related CAD quality measures</td>
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<tr>
<td>9.4% of exceptions were judged as appropriate, 3% inappropriate, and 3% of uncertain appropriateness</td>
<td>16 chronic disease and preventive care quality measures</td>
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<tr>
<td>Persell SD et al., Frequency of Inappropriate Medical Exceptions to Quality Measures. <em>Ann Intern Med</em> 2010</td>
<td>1.94% exception rate</td>
<td>Appropriate: 91.4- 95.4%</td>
<td>Data from large, urban, internal medicine practice with an EHR (Epic)</td>
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</tr>
<tr>
<td>94% of exceptions were judged as appropriate, 3% inappropriate, and 3% of uncertain appropriateness</td>
<td>Inappropriate: 1.9 - 4.8%</td>
<td>0.0% - 25.30% exception rate</td>
<td>50 measures</td>
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<tr>
<td>American Medical Association (AMA)-convened Physician Consortium for Performance Improvement (PCPI) and Medical Specialty Society Measure Testing Projects</td>
<td>Number of exceptions vary by sample sizes</td>
<td>Uncertain appropriateness: 2.0 - 5.0%</td>
<td>Various practice sites</td>
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</tbody>
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