

## Form 9.1: Measure Information Form

<b>Measure ID</b>	<b>1.1</b>
<b>Measure Set:</b>	Medication Measures
<b>Measure Name</b> ( <i>should be brief, concise</i> ):	Potential Drug-Drug Interactions (DDI)
<b>Measure Description:</b>	Percentage of Part D beneficiaries prescribed selected object or precipitant drugs that have at least one potential drug-drug interaction (DDI) during the measurement period
<b>Version Effective Date:</b>	01/01/2007
<b>Effective date basis:</b>	Date of Service
<b>CMS GTL/PO:</b>	Noni Bodkin / Malini Krishnan
<b>CMS Back-up:</b>	Shaheen Halim
<b>CMS Division Director:</b>	Shaheen Halim
<b>Measure Contractor:</b>	FMQAI
<b>Measure contractor contact:</b>	Kyle Campbell
<b>Measure custodian:</b>	CMS

### Version Changes

#### What has changed in this version?

These measure specifications represent the version of the measure used in the 9<sup>th</sup> SOW for the Patient Safety Theme. Therefore, this version of the measure was adapted from the specifications originally developed by BearingPoint and includes the original Measure Justification.

National Drug Codes (NDCs) for any medications released on or before 12/31/2007 are included. CMS is not planning additional updates to the measure specifications for the 9<sup>th</sup> SOW.

### Technical Specifications

#### Age

Lower Age Limit: No age criteria specified

Upper Age Limit: No age criteria specified

#### Gender

- ◆ Males and females

#### Continuous Enrollment

- ◆ Yes; during the measurement period, the beneficiary may not have more than a one-month gap in Part D coverage

#### Index Event

Overlapping days' supply of an object drug and a precipitant drug.

### Method of Data collection

- ◆ Electronic only

### Scoring

- ◆ Rate

### Interpretation of Score:

- ◆ Better quality is associated with a lower score

### Payer Source

- ◆ Medicare Advantage plans (MA-PD)
- ◆ Prescription Drug Plans (PDPs)

### Data source

- ◆ Pharmacy data
- ◆ Enrollment data

### Denominator

**Denominator Statement:** Part D enrollees who have at least one Part D claim for an object drug or a precipitant drug selected for a drug-drug interaction (DDI) during the measurement period as defined in Attachment A: Table 1.

#### *Object Drug –*

The drug in which effects or pharmacokinetics are impacted by prior or subsequent administration of another drug (precipitant drug).

#### *Precipitant Drug –*

The drug which triggers the change in effects or pharmacokinetics of another drug being administered (object drug).

#### *Drug-Drug Interaction (DDI) –*

A drug-drug interaction can be defined as the phenomenon that occurs when the effects or pharmacokinetics of a drug are altered by prior administration of another drug.

### Denominator inclusions/exclusions

Exclude the following enrollees from the denominator:

- Enrollees who are actively enrolled in more than one Part D coverage plan concurrently on the last day of the measurement period
- Enrollees who expired during the measurement period

Exclude the following claims from the denominator:

- Claims that have a prescription service date outside the measurement period

- Claims that have an NDC code that is not within the specified DDI NDC code list
- Claims with a status code that indicates it is not a covered drug
- Claims that are not in “final action” status
- Claims that are deleted by an Adjustment/Deletion record
- Claims with a missing or zero days’ supply
- Claims with a process date > the last day of the measurement period + 3 months

**Denominator Time Window:** 6-month measurement period

## Numerator

**Numerator Statement:** The number of Part D enrollees in the denominator with  $\geq 1$  DDI in Part D claims during the measurement period.

### Numerator inclusions/exclusions

Drug-Drug Interaction (DDI): The phenomenon that occurs when the effects or pharmacokinetics of a drug are altered by prior administration of another drug.

DDI Event: The presence of pharmacy claims for overlapping days’ supply for the object and precipitant drugs (Refer to Attachment A: Table 1). There are two types of object-precipitant drug combinations and associated definitions of potential DDIs:

- 1) Object-precipitant drug pairs that have overlapping days’ supply (defined below).
- 2) Object-precipitant drug pairs in which one or both drugs have residual effects after days’ supply is expended.

Overlapping Days’ Supply: The timeframe between the start date and end date of an object drug overlaps the timeframe between the start date and end date of the precipitant drug. The start date of a drug is the date of service for the drug claim. The end date of a drug is the date of service plus the days’ supply, except for monoamine oxidase inhibitors (MAOIs) and selective serotonin reuptake inhibitors (SSRIs), where a washout period is clinically advisable. For MAOIs and SSRIs, the end date of the drug is the date of service plus the days’ supply plus 30 days. Note: The “days’ supply” field is used for all potential interacting drugs including warfarin, even though this field is thought to be unreliable for warfarin specifically.

**Numerator Time Window:** 6-month measurement period

## Risk Adjustment

### Status

- ◆ None, no risk adjustment necessary.

### Methodology

- ◆ N/A

## Resources

### Algorithm attached?

Yes (Attachment C)

### Sampling methodology attached?

No

### Instruction manual attached?

No

## Copyright

### Intellectual property status

Public Domain

### Copyright Statement:

N/A

### Code Set Copyright Statement:

N/A

## Measure Justification

### Rationale:

#### I. Importance/Relevance

##### *Epidemiological relevance, financial relevance, policy relevance:*

Drug interactions resulting in increased morbidity and mortality are a widely recognized public health issue. Economic costs related to drug interactions and resultant adverse drug events (ADEs) have been estimated at \$177.4 billion.<sup>1</sup> The rate of ADE increases exponentially when one takes 4 or more drugs.<sup>2</sup> The agreement on the criteria for DDI is methodologically challenging as pointed out by Abarca et al.<sup>3</sup>

This measure will describe the percentage of Part D enrollees with claims for drugs potentially interacting but cannot identify sequelae or specific outcomes from these potential DDI. Notwithstanding the limitations of this measure, QIOs can work with drug plans and providers to alert them of results from the PDE data and to recommend vigilant documentation and reporting of ADE from DDI in connection with or outside of the drug pairs in Attachment A: Table 1. In particular, providers should focus on enrollees receiving  $\geq 4$  medications concurrently.

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<sup>1</sup> Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc.* 2001;41:192-195.

<sup>2</sup> <http://www.fda.gov/cder/drug/drugReactions/default.htm#ADRs:%20Prevalence%20and%20Incidence>

<sup>3</sup> Abarca, Jacob et al. Concordance of severity rating from four drug compendia. *J Am Pharm Assoc.* 2004;44:136-141.

Selection of Candidate DDI: The selection of these potentially interacting drug pairs is based on the following:

1. The frequency of utilization published by CMS as the top 100 drugs purchased with drug discount cards by Medicare beneficiaries in 2004,
2. References indicating the most common potential DDIs with potentially serious adverse effects from concomitant administration as evidenced in the PDE data, and
3. Quantifiable effects from the potentially interacting drugs (e.g., increase in INR) as opposed to qualitative results such as increased drowsiness from taking two drugs with additive sedation.

## II. Scientific Soundness

### *Explicit evidence base:*

Complete one literature citation for each guideline or study on which the measure is based, stating level of evidence and rating scheme used. A suggested format is below; another format may be used.

Literature citation for clinical guideline:	
Author Last Name/Organization:	Tatro (ed.)
Author First Name:	David D.
Title of Chapter or Article:	N/A
Title of Book or Journal:	Drug Interactions Facts, Facts and Comparisons
Publication Date:	2005
Journal Volume and Number:	N/A
Pages:	1699
Web link:	<a href="http://online.factsandcomparisons.com/Viewer.aspx?">http://online.factsandcomparisons.com/Viewer.aspx?</a>
Level of Evidence and Rating Scheme:	B for drug-drug interactions

Literature citation for supporting evidence/study:	
Author Last Name/Organization:	Malone
Author First Name:	Daniel
Title of Chapter or Article:	Identification of Serious Drug-Drug Interactions: Results of the Partnership to Prevent Drug-Drug Interactions
Title of Book or Journal:	American Pharmacy Association
Publication Date:	2004
Journal Volume and Number:	44(2)
Pages:	142-151
Web link:	
Level of Evidence and Rating Scheme:	B

***Other aspects of scientific soundness:***

**Reliability, validity, and adequacy of risk adjustment:**

This is the first time in the history of Medicare that prescription drug benefits are offered to the beneficiaries. This is also the first time that electronic pharmacy claims data are collected on such a scale.

The quality improvement (QI) measures have not been validated in terms of the predictiveness of drug proxies to identify disease conditions. Nor have they been tested in terms of linking process to outcome due to the unavailability of medical data (or medical records) during measure testing. Drug proxies are based on the known or most commonly used pharmacological properties of the drugs. These QI measures meet two criteria. They are important to providers and those involved in quality improvement intervention, and they can be tested using prescription drug event (PDE) data. Ultimately, the QI measures can be used to show ways in which care providers are different from one another, and the degree to which these providers can be influenced by quality improvement organizations (QIOs).

These QI measures are not risk adjusted or the population stratified.

### **III. Usability/Actionability**

***Provides actionable decision support, message is clear to recipient, operational relevance***

*Actionable decision support:* QIOs may use the measure results to identify the need for and type of clinical interventions to improve care.

*Message is clear to recipient:* Measure results should enable QIOs to draw conclusions on whether clinical intervention is warranted.

*Operational Relevance:* QIOs can work with providers or health systems to recommend clinical interventions such as prospective drug utilization review (DUR) and retrospective DUR to monitor potential DDIs. Both are being conducted at the pharmacy level and PBM (pharmacy benefits manager) level on behalf of health plans. Potentially, results can be shared and compared at the QIO level to evaluate if clinical interventions are warranted. This is especially relevant due to the many variables that may affect DDIs and their outcomes.

### **IV. Feasibility**

***Specifications are well-defined, reasonable burden of data collection, minimum distortion***

*Specifications well defined:* Explicit and detailed specifications for the numerator and denominator are included; statements of the requirements for data collection are included and have the potential for implementation.

*Reasonable burden of data collection:* The data source [Prescription Drug Events (PDEs)] needed to calculate the measure is readily available, accessible, and timely. Measurement would require identifying potential DDIs documented in a compendium or compendia and data extraction for drug utilization review to identify potential DDIs.

*Minimum distortion:* PDE data are part of the reporting requirements for Part D sponsors. The claims are processed at the point-of-care and adjudicated by pharmacy benefit managers (PBM) and have limited potential for distortion except for duplication of claims or misclassification of plan eligibility.

## History

### CMS Approval Date

(12/20/2006)

### Current Measure Status

In use 9<sup>th</sup> SOW QIO Program

### Upcoming Reviews

#### Frequency of Measure Update

N/A

#### Next Measure Update:

N/A

#### Next Comprehensive Reevaluation:

### NQF Endorsement

#### Initial Endorsement

- ◆ Planned Submission (Y/N): N

CMS Program Use	Date Measure implemented in Program	Status of Measure in Program	Date of Current Status in Program
QIO Program	August 1, 2008	In Use	August 1, 2008

### CMS measure purpose

- ◆ Internal quality improvement

### Measure Source

- ◆ New

### Measure Developer

- ◆ Centers for Medicare & Medicaid Services (CMS)
  - Contractor: BearingPoint, Inc.

### Effective Date of Original Measure Contract

09/29/2005

**End Date of Original Measure Contract**

3/15/2007

**End Date of Any Extensions to the Original Measure Contract**

N/A

**Indexing**

**Primary topic: Clinical conditions**

- ◆ N/A

**Primary topic: Components other than clinical conditions**

- ◆ Other (Patient Safety:  
Drug Safety, Medication  
Management)

**Consumer Care Need**

- ◆ Living With Illness

**Measure Care Setting**

- ◆ Health Plan
- ◆ Prescription Drug Plan

**Quality Domain**

- ◆ Safety

**Type of Measure**

- ◆ Process

**Unit of Measurement**

- ◆ Health Plan (Medicare Advantage)
- ◆ Prescription Drug Plan
- ◆ State



## Attachments

*Attachment A: Tables*

*Attachment B: National Drug Codes (NDCs)*

*Attachment C: Algorithms*

## Notes