



## Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

### Brief Measure Information

**NQF #:** 0556

**De.2. Measure Title:** INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications

**Co.1.1. Measure Steward:** Centers for Medicare & Medicaid Services

**De.3. Brief Description of Measure:** Percentage of episodes with an International Normalized Ratio (INR) test performed three to seven days after a newly started interacting anti-infective medication for individuals receiving warfarin

**1b.1. Developer Rationale:** This measure focuses on International Normalized Ratio (INR) testing of patients on warfarin who are prescribed anti-infective medications that are known to interact with warfarin and result in a higher risk for adverse events. Warfarin is a vitamin K antagonist prescribed to prevent "further thromboembolism in patients with atrial fibrillation, after mechanical heart valve replacement, and following deep vein thrombosis or pulmonary embolism" (Dharmarajan, Gupta, Baig, & Norkus, 2011). Warfarin has a narrow therapeutic range and, therefore, requires regular monitoring with the INR test and dose adjustment for the patient to stay within the therapeutic range and avoid thromboembolism or bleeding complications. Since its approval by the Food and Drug Administration in 1954, warfarin has been used as an oral anticoagulant in clinical practice (Food and Drug Administration, 2011). It continues to be widely prescribed, with about 33 million prescriptions issued in the United States during 2011 (Pierson, 2012).

Several important benefits related to quality improvement are envisioned with the implementation of this measure. Specifically, the measure will help providers identify individuals on warfarin who are prescribed an anti-infective medication known to interact with warfarin. The measure will also encourage providers to conduct appropriate INR testing for those patients. An INR test within three to five days of starting the interacting anti-infective medications has been recommended (Keeling et al., 2011) to inform dose adjustment if needed and therefore would be expected to result in fewer warfarin-related adverse events and lower mortality.

Citations for Rationale Provided in 1b.1.

Dharmarajan, T. S., Gupta, A., Baig, M. A., & Norkus, E. P. (2011). Warfarin: Implementing its safe use in hospitalized patients from nursing homes and community through a performance improvement initiative. *Journal of the American Medical Directors Association*, 12(7), 518-523.

Food and Drug Administration. (2011). Warfarin (Coumadin) product labeling. Reference ID 3022954. Retrieved Oct. 16, 2013, from [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/009218s107lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf)

Keeling, D., Baglin, T., Tait, C., Watson, H., Perry, D., Baglin, C., . . . Makris, M. (2011). Guidelines on oral anticoagulation with warfarin—fourth edition. *British Journal of Haematology*, 154(3), 311-324.

Pierson, R. (2012, June 14). Insight: Top heart doctors fret over new blood thinners. Retrieved Oct. 30, 2013, from <http://www.reuters.com/article/2012/06/14/us-drugs-bloodthinners-idUSBRE85D06G20120614>

**S.4. Numerator Statement:** Number of episodes in the denominator with an INR test performed three to seven days after the start date of an anti-infective medication

**S.7. Denominator Statement:** Number of episodes with a newly started interacting anti-infective medication with an overlapping days' supply of warfarin.

**S.10. Denominator Exclusions:** We excluded the following individuals from the denominator:

- Individuals with a diagnosis of cancer
- Individuals who are monitoring INR at home

**De.1. Measure Type:** Process

**S.23. Data Source:** Administrative claims, Electronic Clinical Data : Pharmacy

**S.26. Level of Analysis:** Health Plan, Integrated Delivery System, Population : State

<b>IF Endorsement Maintenance – Original Endorsement Date:</b> <a href="#">Aug 05, 2009</a> <b>Most Recent Endorsement Date:</b> <a href="#">Nov 10, 2014</a>
<b>IF this measure is included in a composite, NQF Composite#/title:</b>  <b>IF this measure is paired/grouped, NQF#/title:</b>  <b>De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?</b> <a href="#">Not applicable</a>

<b>1. Evidence, Performance Gap, Priority – Importance to Measure and Report</b>
<p>Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. <b><i>Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.</i></b></p>
<b>1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form</b> <a href="#">NQF_0556_Evidence_Form.docx</a>
<b>1b. Performance Gap</b> <p>Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:</p> <ul style="list-style-type: none"> <li>considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or</li> <li>disparities in care across population groups.</li> </ul> <p><b>1b.1. Briefly explain the rationale for this measure</b> (<i>e.g., the benefits or improvements in quality envisioned by use of this measure</i>)  This measure focuses on International Normalized Ratio (INR) testing of patients on warfarin who are prescribed anti-infective medications that are known to interact with warfarin and result in a higher risk for adverse events. Warfarin is a vitamin K antagonist prescribed to prevent "further thromboembolism in patients with atrial fibrillation, after mechanical heart valve replacement, and following deep vein thrombosis or pulmonary embolism" (Dharmarajan, Gupta, Baig, &amp; Norkus, 2011). Warfarin has a narrow therapeutic range and, therefore, requires regular monitoring with the INR test and dose adjustment for the patient to stay within the therapeutic range and avoid thromboembolism or bleeding complications. Since its approval by the Food and Drug Administration in 1954, warfarin has been used as an oral anticoagulant in clinical practice (Food and Drug Administration, 2011). It continues to be widely prescribed, with about 33 million prescriptions issued in the United States during 2011 (Pierson, 2012).</p> <p>Several important benefits related to quality improvement are envisioned with the implementation of this measure. Specifically, the measure will help providers identify individuals on warfarin who are prescribed an anti-infective medication known to interact with warfarin. The measure will also encourage providers to conduct appropriate INR testing for those patients. An INR test within three to five days of starting the interacting anti-infective medications has been recommended (Keeling et al., 2011) to inform dose adjustment if needed and therefore would be expected to result in fewer warfarin-related adverse events and lower mortality.</p> <p>Citations for Rationale Provided in 1b.1.  Dharmarajan, T. S., Gupta, A., Baig, M. A., &amp; Norkus, E. P. (2011). Warfarin: Implementing its safe use in hospitalized patients from nursing homes and community through a performance improvement initiative. <i>Journal of the American Medical Directors Association</i>, 12(7), 518-523.  Food and Drug Administration. (2011). Warfarin (Coumadin) product labeling. Reference ID 3022954. Retrieved Oct. 16, 2013, from <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf</a>  Keeling, D., Baglin, T., Tait, C., Watson, H., Perry, D., Baglin, C., . . . Makris, M. (2011). Guidelines on oral anticoagulation with warfarin—fourth edition. <i>British Journal of Haematology</i>, 154(3), 311-324.  Pierson, R. (2012, June 14). Insight: Top heart doctors fret over new blood thinners. Retrieved Oct. 30, 2013, from <a href="http://www.reuters.com/article/2012/06/14/us-drugs-bloodthinners-idUSBRE85D06G20120614">http://www.reuters.com/article/2012/06/14/us-drugs-bloodthinners-idUSBRE85D06G20120614</a></p> <p><b>1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.</b> (<i>This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>). <i>This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.</i>  Sample Characteristics: All Medicare Parts A, B, and D claims data during calendar years 2007 and 2008 from 8 states (Arizona,</p>

Delaware, Florida, Indiana, Iowa, Mississippi, Rhode Island, and Washington). The sample consisted of 4,789,034 Medicare beneficiaries.

All Medicare Parts A, B, and D claims data during calendar years 2011 and 2012 from 10 states (Arizona, Delaware, Florida, Iowa, Indiana, Mississippi, Missouri, Rhode Island, Texas, and Washington); the sample consisted of 14,162,440 Medicare beneficiaries, 26,182 Physician Groups, and 83 Prescription Drug Plans (Part D plans). For the states-level performance, results are calculated using the 2007-2008 and 2010-2011 data. For the plan-level performance, results are calculated using the 2010-2011 data. Results for physician groups are not presented because measure rates are not reliable at the physician group level.

#### State

Year	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
2008	8	22.52%	22.00%	15.83%	31.88%	4.59%	3.16%	15.83%	20.53%	22.00%	23.70%	31.88%
2012	10	21.98%	21.52%	16.09%	32.04%	4.21%	3.41%	17.14%	19.92%	21.52%	23.33%	27.70%

#### Prescription Drug Plan

Plan with at least 2,500 episodes (minimum denominator for reliability >0.7):

Year	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
2012	10	20.69%	20.65%	17.82%	23.79%	1.59%	1.40%	18.73%	19.78%	20.65%	21.18%	23.00%

Sample Characteristics: Parts A, B, and D data for 682,036 beneficiaries (9,344) attributed to 31 ACOs from calendar year 2011:

#### ACO

Year	n	Mean	Median	Min	Max	STD	IQR	P10	P25	P50	P75	P90
2011	31	21.69%	21.41%	13.04%	32.86%	5.52%	8.12%	14.81%	17.36%	21.41%	25.48%	29.66%

**1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.**

Please see Section 1b.2. for performance data on the measure.

**1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.**

The summary of data on disparities by population group is discussed in the overview of disparities by population group, summary of published studies on disparities by population group, and testing results based on Medicare data.

This measure was stratified for disparities by age, race/ethnicity, and dual-eligibility (beneficiaries covered by both Medicare and Medicaid). The results/scores are presented for these categories/cohort.

Rates by age and race/ethnicity for the entire 10-state sample:

Category or Cohort / Denominator / Numerator / Measure Rate

All Ages / 103,025 / 21,345 / 20.7%

White / 90,748 / 18,998 / 20.9%

African American / 7,862 / 1,541 / 19.6%

Hispanic / 2,650 / 460 / 17.4%

Other / 1,765 / 346 / 19.6%

18 - 24 / 77 / 11 / 14.3%

White / 40 / 6 / 15.0%

African American / 21 / 2 / 9.5%

Hispanic / 8 / 1 / 12.5%

Other / 8 / 2 / 25.0%

25 - 44 / 2,740 / 474 / 17.3%  
 White / 1,768 / 306 / 17.3%  
 African American / 753 / 127 / 16.9%  
 Hispanic / 155 / 33 / 21.3%  
 Other / 64 / 8 / 12.5%

45 - 64 / 13,973 / 2,457 / 17.6%  
 White / 10,447 / 1,817 / 17.4%  
 African American / 2,722 / 493 / 18.1%  
 Hispanic / 452 / 90 / 19.9%  
 Other / 352 / 57 / 16.2%

65 - 74 / 32,473 / 6,419 / 19.8%  
 White / 29,118 / 5,769 / 19.8%  
 African American / 2,054 / 419 / 20.4%  
 Hispanic / 662 / 109 / 16.5%  
 Other / 639 / 122 / 19.1%

75 - 84 / 35,952 / 7,750 / 21.6%  
 White / 32,995 / 7,156 / 21.7%  
 African American / 1,576 / 342 / 21.7%  
 Hispanic / 850 / 143 / 16.8%  
 Other / 531 / 109 / 20.5%

85+ / 17,810 / 4,234 / 23.8%  
 White / 16,380 / 3,944 / 24.1%  
 African American / 736 / 158 / 21.5%  
 Hispanic / 523 / 84 / 16.1%  
 Other / 171 / 48 / 28.1%

Rates by age and dual-eligible status for the entire 10-state sample:

Category or Cohort / Denominator / Numerator / Measure Rate

Dual-Eligible / 31,050 / 6,518 / 21.0%

18 - 24 / 73 / 11 / 15.1%

25 - 44 / 2,081 / 374 / 18.0%

45 - 64 / 8,546 / 1,554 / 18.2%

65 - 74 / 7,909 / 1,620 / 20.5%

75 - 84 / 7,972 / 1,774 / 22.3%

85+ / 4,469 / 1,185 / 26.5%

Not Dual-Eligible / 71,975 / 14,827 / 20.6%

18 - 24 / 4 / 0 / 0%

25 - 44 / 659 / 100 / 15.2%

45 - 64 / 5,427 / 903 / 16.6%

65 - 74 / 24,564 / 4,799 / 19.5%

75 - 84 / 27,980 / 5,976 / 21.4%

85 + / 13,341 / 3,049 / 22.9%

The measure rates for White, African American, or Hispanic race/ethnicity groups are statistically different from all groups except for Other (p-value<0.011).

Measure rates for patients ages 25 to 64 are significantly lower than the measure rates for patients 65 or older (p-value=<0.002). There is no difference between age groups for patients less than 65. However, the measure rate increases as the age increases (p-value<0.0001) for all age groups 65 or older.

There is no statistical difference in the measure rate between dually eligible and non-dually eligible patients.

**1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.**

Please see Section 1b.5. for disparities data on the measure.

**1c. High Priority** (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

**1c.1. Demonstrated high priority aspect of healthcare**

High resource use, Patient/societal consequences of poor quality, Other

**1c.2. If Other: Relationship to national priorities**

**1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare.**

**List citations in 1c.4.**

Three high-priority aspects of this measure are discussed below: the patient/societal consequences of poor quality, the resource use of warfarin-related adverse events, and the measure's relationship to national priorities.

**Patient/Societal Consequences of Poor Quality**

An important consideration for avoiding adverse outcomes in patients on warfarin therapy is maintaining the patient's international normalized ratio (INR) within the therapeutic range through appropriate and timely INR monitoring and dose adjustment. A recent systematic review, which incorporated data from 67 studies, with a goal of describing the effect of study setting on anticoagulation control, found that across patients in all settings, the time spent in the therapeutic range was 63.6%, whereas in the community setting, approximately 55% of the time was spent in the therapeutic range (Van Walraven, Jennings, Oake, Fergusson, & Forster, 2006; Van Walraven, Oake, Wells, & Forster, 2007). Similarly, in a study of nursing homes in Connecticut (Gurwitz et al., 2007), 490 residents on warfarin therapy were found to be within the therapeutic range only 49.6% of the time. Furthermore, the INR value was less than 2 in 36.5% of the study population, more than 3 to less than 4.5 in 11.9%, and 4.5 or more in 2.0%.

Several studies have reported higher risk of bleeding outcomes associated with initiation of anti-infective medications in patients on warfarin therapy. Elevated risks of bleeding among warfarin users taking interacting anti-infective medications range from 1.16 for cephalosporins (Zhang, Young, & Berger, 2006) to 5.9 for norfloxacin (Penning-van Beest, Erkens, Petersen, Koelz, & Herings, 2005). Guidelines from the British Committee for Standards in Haematology on oral anticoagulation with warfarin (Keeling et al., 2011) recommend that an INR test be performed three to seven days after an interacting drug is prescribed to avoid excess risk of bleeding.

Other studies have also shown high rates of bleeding outcomes associated with warfarin therapy. In a study of persons 65 years and older, warfarin was the most commonly implicated medication for hospitalizations attributed to adverse drug events, accounting for over 33% of such hospitalizations; 63% of the warfarin-related hospitalizations were for hemorrhage (Budnitz, Lovegrove, Shehab, & Richards, 2011). In the study population, an estimated 21,010 emergency hospitalizations for warfarin-related hemorrhages (95% CI, 10,126 to 31,894) occurred during a three-year period (2007-2009) based on data from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project (Budnitz et al., 2011). In addition, an analysis of the FDA's Adverse Drug Event Reporting System found that warfarin ranked seventh overall in drugs identified to cause disability or other serious adverse outcomes, which were defined as "hospitalization, required intervention, or life threatening or other serious outcome" (Moore, Cohen, & Furberg, 2007).

**Resource Use**

In a study of 2,346 community-dwelling persons 65 years of age and older (12% aged 70 or younger, 23% aged 71-75, 28% aged 76-80, 25% aged 81-85, and 12% 86 or older) taking warfarin, 126 hospitalizations due to warfarin-related bleeding occurred at a rate of 4.9% over a 24-month period (Kim et al., 2010). The mean cost of these hospitalizations was estimated to be \$10,819 with a mean length of stay of 7.8 days. Over the entire cohort of warfarin users, the additional cost related to the warfarin-related

hospitalizations was \$508 per warfarin user.

#### Relationship to National Priorities

National priorities related to patient safety support the potential high impact of this measure. The importance of this measure is highlighted by a goal from the set of 2013 National Patient Safety Goals developed by The Joint Commission: "Reduce the likelihood of patient harm associated with the use of anticoagulant therapy" (NPSG.03.05.01) (The Joint Commission, 2012). The National Quality Strategy has identified "making care safer" among the top priorities for quality improvement in the nation's health care (U.S. Department of Health and Human Services, 2013). Furthermore, the National Quality Forum (National Quality Forum, 2013) has identified gaps in the measurement system with regard to patient safety, specifically adverse drug events (ADEs). Finally, the recently published Draft National Action Plan for ADE Prevention has recognized anticoagulants as one of the most common causes of ADEs and recommended developing clinical decision support rules for INR monitoring and other methods of optimizing anticoagulation management (U.S. Department of Health and Human Services, 2013a). Therefore, several national priorities support the potential high impact of this measure.

#### 1c.4. Citations for data demonstrating high priority provided in 1a.3

Budnitz, D. S., Lovegrove, M. C., Shehab, N., & Richards, C. L. (2011). Emergency hospitalizations for adverse drug events in older Americans. *New England Journal of Medicine*, 365, 2002-2013.

Gurwitz, J. H., Field, T. S., Radford, M. J., Harrold, L. R., Becker, R., Reed, G., . . . Verzier, N. (2007). The safety of warfarin therapy in the nursing home setting. *American Journal of Medicine*, 120(6), 539-544.

Keeling, D., Baglin, T., Tait, C., Watson, H., Perry, D., Baglin, C., . . . Makris, M. (2011). Guidelines on oral anticoagulation with warfarin—fourth edition. *British Journal of Haematology*, 154(3), 311-324.

Kim, M. M., Metlay, J., Cohen, A., Feldman, H., Hennessy, S., Kimmel, S., . . . Doshi, J. A. (2010). Hospitalization costs associated with warfarin-related bleeding events among older community-dwelling adults. *Pharmacoepidemiology and Drug Safety*, 19(7), 731-736.

Moore, T. J., Cohen, M. R., & Furberg, C. D. (2007). Serious adverse drug events reported to the Food and Drug Administration, 1998-2005. *Archives of Internal Medicine*, 167(16), 1752-1759.

National Quality Forum. (2013). Report from the National Quality Forum: 2012 NQF measure gap analysis. Retrieved March 31, 2013, from [http://www.qualityforum.org/Publications/2013/03/2012\\_NQF\\_Measure\\_Gap\\_Analysis.aspx](http://www.qualityforum.org/Publications/2013/03/2012_NQF_Measure_Gap_Analysis.aspx)

Penning-van Beest, F., Erkens, J., Petersen, K. U., Koelz, H. R., & Herings, R. (2005). Main comedications associated with major bleeding during anticoagulant therapy with coumarins. *European Journal of Clinical Pharmacology*, 61(5-6), 439-444.

The Joint Commission. (2012). 2013 National Patient Safety Goals. Retrieved October 14, 2013, from [http://www.jointcommission.org/assets/1/18/NPSG\\_Chapter\\_Jan2013\\_HAP.pdf](http://www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_HAP.pdf)

U.S. Department of Health and Human Services. (2013). National Strategy for Quality Improvement in Healthcare: 2013 Annual Progress Report to Congress. Washington, DC: Author. Available from <http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm>

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2013a). National Action Plan for Adverse Drug Event Prevention (draft). Washington, DC: Author. Retrieved November 4, 2013, from <http://www.hhs.gov/ash/initiatives/ade/ade-action-plan.pdf>

Van Walraven, C., Jennings, A., Oake, N., Fergusson, D., & Forster, A. J. (2006). Effect of study setting on anticoagulation control: A systematic review and metaregression. *Chest*, 129(5), 1155-1166.

Van Walraven, C., Oake, N., Wells, P. S., & Forster, A. J. (2007). Burden of potentially avoidable anticoagulant-associated hemorrhagic and thromboembolic events in the elderly. *Chest*, 131(5), 1508-1515.

Zhang, K., Young, C., & Berger, J. (2006). Administrative claims analysis of the relationship between warfarin use and risk of hemorrhage including drug-drug and drug-disease interactions. *Journal of Managed Care Pharmacy*, 12(8), 640.

**1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)**

Not applicable

## 2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**



**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

**De.5. Subject/Topic Area** (check all the areas that apply):

Cardiovascular

**De.6. Cross Cutting Areas** (check all the areas that apply):

Safety, Safety : Medication Safety

**S.1. Measure-specific Web Page** (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

Not applicable

**S.2a. If this is an eMeasure**, HQMF specifications must be attached. Attach the output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

No HQMF specs Attachment:

**S.2b. Data Dictionary, Code Table, or Value Sets** (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: NQF0556\_-\_Codes\_Table-635254586561790739.xls

**S.3. For endorsement maintenance**, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

The age requirement for the target population was changed from 18 years or older at the end of the measurement period to 18 years or older at the beginning of the measurement period to harmonize with other measures in the portfolio. ICD-9-CM, ICD-10-CM, and National Drug Codes have been updated annually. The new drugs on the market that are applicable to the measure have been added to the medication list, and agents that have been discontinued for more than three years have been removed. The drug selection criteria have been simplified, and the optional exclusion for individuals monitoring INR at home is now a required exclusion.

**S.4. Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Number of episodes in the denominator with an INR test performed three to seven days after the start date of an anti-infective medication

**S.5. Time Period for Data** (What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)

Numerator Time Window: Three to seven days after the start of an anti-infective medication

Denominator Time Window: The first 358 days of the measurement period

**S.6. 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, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Hospitalizations of more than 48 hours are counted as an INR test.

Table 1. Codes Used to Identify INR Monitoring

Prothrombin Time CPT: 85610

Source: American Medical Association (AMA) (2006). Updated: AMA (2009).

**S.7. Denominator Statement** (Brief, narrative description of the target population being measured)

Number of episodes with a newly started interacting anti-infective medication with an overlapping days' supply of warfarin.

**S.8. Target Population Category** (Check all the populations for which the measure is specified and tested if any):

Populations at Risk, Senior Care

**S.9. Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

Target population meets the following conditions:

1. Continuously enrolled in Part D with no more than a one-month gap in enrollment during the measurement year;
2. Continuously enrolled in Part A and Part B with no more than a one-month gap in Part A enrollment and no more than a one-month gap in Part B enrollment during the measurement year;
3. No more than one month of HMO (Health Maintenance Organization) enrollment during the measurement year; and,
4. Individuals must have at least two claims for warfarin on different dates of service.
  - a. If more than one prescription for warfarin with the same date of service overlaps an interacting anti-infective medication, then keep the prescription with the greatest days' supply.
  - b. If more than one prescription for warfarin with different dates of service overlaps an interacting anti-infective medication, then keep the episode with the greatest number of overlapping days.

Table 2. Anti-Infective Medications

Aminoglycosides

Active ingredients: neomycin, paromomycin

Anticoagulant effect: Increased

Antifungal Agents

Active ingredients: fluconazole, voriconazole, miconazole

Anticoagulant effect: Increased

Active ingredients: griseofulvin

Anticoagulant effect: Decreased

Active ingredients: itraconazole, ketoconazole

Anticoagulant effect: Increased

Active ingredients: terbinafine

Anticoagulant effect: Increased/decreased

Antiviral

Active ingredients: interferon-alfa, interferon-beta

Anticoagulant effect: Increased

Active ingredients: ribavirin

Anticoagulant effect: Decreased

Active ingredients: oseltamivir

Anticoagulant effect: Increased

Active ingredients: atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir

Anticoagulant effect: Increased/decreased

Active ingredients: nevirapine

Anticoagulant effect: Decreased

Cephalosporins



Active ingredients: cefotetan  
Anticoagulant effect: Increased

#### Fluoroquinolones

Active ingredients: ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin,  
Anticoagulant effect: Increased

#### Macrolides

Active ingredients: azithromycin, clarithromycin, erythromycin  
Anticoagulant effect: Increased

#### Penicillin

Active ingredients: nafcillin, dicloxacillin  
Anticoagulant effect: Decreased

Active ingredients: ampicillin, oxacillin, penicillin G, piperacillin, ticarcillin, amoxicillin, amoxicillin/clavulanic acid  
Anticoagulant effect: Increased

#### Tetracycline

Active ingredients: demeclocycline, doxycycline, minocycline, tetracycline, oxytetracycline  
Anticoagulant effect: Increased

#### Others

Active ingredients: rifabutin, rifapentine  
Anticoagulant effect: Decreased

Active ingredients: rifampin  
Anticoagulant effect: Decreased

#### Anti-Infective Agents – Misc

Active ingredients: sulfamethoxazole, chloramphenicol, telithromycin, metronidazole, tinidazole  
Anticoagulant effect: Increased

Active ingredients: sulfisoxazole, isoniazid  
Anticoagulant effect: Increased

Active ingredients: rifaximin  
Anticoagulant effect: Decreased

#### Anti-Malarial

Active ingredients: atovaquone, mefloquine, proguanil  
Anticoagulant effect: Increased

Active ingredients: quinine  
Anticoagulant effect: Increased

Note: Drugs listed were selected based on a severity rating of either “severe or moderate” and a documentation rating of “Probable, Possible, or Suspected” according to Drug Interaction Facts; excludes the following routes of administration: external (EX), inhalation (IN), irrigation (IR), ophthalmic (OP), otic (OT), mouth/throat preparations (MT), and route does not apply (XX) unless otherwise noted. All other formulations and combination products of the active ingredients listed are included unless otherwise noted. Obsolete drug products are excluded from NDCs with an inactive date more than three years prior to the beginning of the measurement period or look-back period, if applicable. Updated: First Databank and Medi-Span, 2013.

#### Citations

Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc.; December 2013. Accessed December 13, 2013.

**S.10. Denominator Exclusions** (Brief narrative description of exclusions from the target population)

We excluded the following individuals from the denominator:

- Individuals with a diagnosis of cancer
- Individuals who are monitoring INR at home

**S.11. Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

Exclusion One

Table 3. Codes Used to Identify Cancer

ICD-9-CM: 210.0-228.1, 273.3, 288.3, V10.00-V10.89, V10.90, V10.91, V87.41

ICD-10-CM: C88.0, D10.0, D10.1, D10.2, D10.30, D10.39, D10.4, D10.5, D10.6, D10.7, D10.9, D11.0, D11.7, D11.9, D12.0, D12.1, D12.2, D12.3, D12.4, D12.5, D12.6, D12.7, D12.8, D12.9, D13.0, D13.1, D13.2, D13.30, D13.39, D13.4, D13.5, D13.6, D13.7, D13.9, D14.0, D14.1, D14.2, D14.30, D14.31, D14.32, D14.4, D15.0, D15.1, D15.2, D15.7, D15.9, D16.00, D16.01, D16.02, D16.10, D16.11, D16.12, D16.20, D16.21, D16.22, D16.30, D16.31, D16.32, D16.4, D16.5, D16.6, D16.7, D16.8, D16.9, D17.0, D17.1, D17.20, D17.21, D17.22, D17.23, D17.24, D17.30, D17.39, D17.4, D17.5, D17.6, D17.7, D17.9, D18.00, D18.01, D18.02, D18.03, D18.09, D18.1, D19.0, D19.1, D20.0, D20.1, D21.0, D21.10, D21.11, D21.12, D21.20, D21.21, D21.22, D21.3, D21.4, D21.5, D21.6, D21.9, D22.0, D22.10, D22.11, D22.12, D22.20, D22.21, D22.22, D22.30, D22.39, D22.4, D22.5, D22.60, D22.61, D22.62, D22.70, D22.71, D22.72, D22.9, D23.0, D23.10, D23.11, D23.12, D23.20, D23.21, D23.22, D23.30, D23.39, D23.4, D23.5, D23.60, D23.61, D23.62, D23.70, D23.71, D23.72, D23.9, D24.1, D24.2, D24.9, D25.0, D25.1, D25.2, D25.9, D26.0, D26.1, D26.7, D26.9, D27.0, D27.1, D27.9, D28.0, D28.1, D28.2, D28.7, D28.9, D29.0, D29.1, D29.20, D29.21, D29.22, D29.30, D29.31, D29.32, D29.4, D29.8, D29.9, D30.00, D30.01, D30.02, D30.10, D30.11, D30.12, D30.20, D30.21, D30.22, D30.3, D30.4, D30.8, D30.9, D31.00, D31.01, D31.02, D31.10, D31.11, D31.12, D31.20, D31.21, D31.22, D31.30, D31.31, D31.32, D31.40, D31.41, D31.42, D31.50, D31.51, D31.52, D31.60, D31.61, D31.62, D31.90, D31.91, D31.92, D32.0, D32.1, D32.9, D33.0, D33.1, D33.2, D33.3, D33.4, D33.7, D33.9, D34, D35.00, D35.01, D35.02, D35.1, D35.2, D35.3, D35.4, D35.5, D35.6, D35.7, D35.9, D36.10, D36.11, D36.12, D36.13, D36.14, D36.15, D36.16, D36.17, D72.1, K31.7, K63.5, Z85.00, Z85.01, Z85.020, Z85.028, Z85.030, Z85.038, Z85.040, Z85.048, Z85.05, Z85.060, Z85.068, Z85.07, Z85.09, Z85.110, Z85.118, Z85.12, Z85.20, Z85.21, Z85.22, Z85.230, Z85.238, Z85.29, Z85.3, Z85.40, Z85.41, Z85.42, Z85.43, Z85.44, Z85.45, Z85.46, Z85.47, Z85.48, Z85.49, Z85.50, Z85.51, Z85.520, Z85.528, Z85.53, Z85.59, Z85.6, Z85.71, Z85.72, Z85.79, Z85.810, Z85.818, Z85.819, Z85.820, Z85.821, Z85.828, Z85.830, Z85.831, Z85.840, Z85.841, Z85.848, Z85.850, Z85.858, Z85.89, Z85.9, Z92.21

Exclusion Two

Table 4. INR Monitoring at Home: HCPCS Codes

G0248 - DEMONSTRATE USE HOME INR MON

G0249 - PROVIDE TEST MATS & EQUIP HOME INR

G0250 - MD INR TEST REVIEW INTER MGMT

**S.12. Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)

Depending on the operational use of the measure, measure results may be stratified by:

- State
- Plan
- Accountable Care Organizations (ACOs)
- Age- Divided into six categories: 18-24, 25-44, 45-64, 65-74, 75-84, and 85+ years
- Race/Ethnicity
- Dual Eligibility Status

**S.13. Risk Adjustment Type** (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)

No risk adjustment or risk stratification

If other:

**S.14. Identify the statistical risk model method and variables** (Name the statistical method - e.g., logistic regression and list all the

*risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)*

Not applicable

**S.15. Detailed risk model specifications** (must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)

*Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.*

**S.15a. Detailed risk model specifications** (if not provided in excel or csv file at S.2b)

Not applicable

**S.16. Type of score:**

Rate/proportion

If other:

**S.17. Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Higher score

**S.18. 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.)

Create Denominator

1. Pull individuals who are 18 years of age or older as of January 1 of the measurement period.
2. Include individuals who were continuously enrolled in Part D coverage during the measurement year, with no more than a one-month gap in enrollment during the measurement year.
3. Include individuals who had no more than a one-month gap in Part A enrollment, no more than a one-month gap in Part B enrollment, and no more than one month of HMO enrollment during the current measurement year (FFS individuals only).
4. Identify and delete individuals with cancer, based on Part A and B claims.
5. Identify and delete individuals who are monitoring INR at home, based on Part A and B claims.
6. Pull all warfarin claims from the Part D claims data for the individuals still eligible in Step 4.
7. From the dataset created in Step 5, include those individuals with at least two claims for warfarin on different dates of service.
8. Using the dataset from Step 6, calculate the warfarin start date and warfarin end date.
9. Pull all anti-infective claims from the Part D claims data.
10. From the dataset in Step 8, keep the anti-infective prescription with the highest days' supply for each unique date for each individual.
11. From the dataset in Step 9, keep only the "newly-started" anti-infectives (no other anti-infective in the prior 30 days).
12. Using the dataset from Step 10, calculate the anti-infective start date and anti-infective end date.
13. Merge the warfarin claims dataset from Step 7 and the anti-infective dataset from Step 11, keeping only the individuals' episodes where there are overlapping days' supply of warfarin therapy and anti-infective therapy. If there is more than one anti-infective started on the same date, keep the overlap episode with the largest overlapping period.

Create Numerator

1. Pull all individuals who had an INR test performed, identified using a CPT code, or who had a hospitalization of more than 48 hours during the measurement period from the Part A and Part B claims data.
2. Of the individuals identified in Step 1, keep those who are also included in the denominator.
3. Compare start date of anti-infective medication with the INR/hospitalization date.
4. Keep only the claims where the INR/hospitalization date occurred at least three days after the start of the anti-infective therapy.
5. Keep unique episodes of anti-infective date and first occurring INR test/hospitalization.
6. Keep the episodes in which the first INR/hospitalization occurred within three to seven days after the start of the anti-infective.

<p><b>S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment</b> (You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1) Available in attached appendix at A.1</p>
<p><b>S.20. Sampling</b> (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.) IF a PRO-PM, identify whether (and how) proxy responses are allowed. This measure does not use a sample or survey.</p> <p><b>S.21. Survey/Patient-reported data</b> (If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.) IF a PRO-PM, specify calculation of response rates to be reported with performance measure results. Not applicable</p> <p><b>S.22. Missing data</b> (specify how missing data are handled, e.g., imputation, delete case.) Required for Composites and PRO-PMs. To reduce the potential for measure result bias, patients who have warfarin claims or anti-infective claims with missing days' supply are excluded from the analysis.</p>
<p><b>S.23. Data Source</b> (Check ONLY the sources for which the measure is SPECIFIED AND TESTED). If other, please describe in S.24. Administrative claims, Electronic Clinical Data : Pharmacy</p> <p><b>S.24. Data Source or Collection Instrument</b> (Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.) IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration. For measure calculation, the following Medicare files were required:</p> <ul style="list-style-type: none"> <li>• Denominator tables</li> <li>• Prescription drug benefit (Part D) coverage tables</li> <li>• Beneficiary file</li> <li>• Institutional claims (Part A)</li> <li>• Non-institutional claims (Part B) —physician carrier/non-DME</li> <li>• Prescription drug benefit (Part D) claims</li> </ul> <p>For ACO attribution, the following were required:</p> <ul style="list-style-type: none"> <li>• Denominator tables for Parts A and B enrollment</li> <li>• Prescription drug benefit (Part D) coverage tables</li> <li>• Beneficiary file</li> <li>• Institutional claims (Part A)</li> <li>• Non-institutional claims (Part B)—physician carrier/non-DME</li> <li>• Prescription drug benefit (Part D) claims</li> </ul> <p><b>S.25. Data Source or Collection Instrument</b> (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1) No data collection instrument provided</p> <p><b>S.26. Level of Analysis</b> (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED) Health Plan, Integrated Delivery System, Population : State</p> <p><b>S.27. Care Setting</b> (Check ONLY the settings for which the measure is SPECIFIED AND TESTED) Ambulatory Care : Clinician Office/Clinic If other:</p>
<p><b>S.28. COMPOSITE Performance Measure</b> - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.) Not applicable</p>

**2a. Reliability – See attached Measure Testing Submission Form**

**2b. Validity – See attached Measure Testing Submission Form**

[NQF\\_0556\\_Measure\\_Testing\\_Form.docx](#)

### 3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

#### 3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

##### 3a.1. Data Elements Generated as Byproduct of Care Processes.

[Coded by someone other than person obtaining original information \(e.g., DRG, ICD-9 codes on claims\)](#)

If other:

#### 3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

**3b.1. To what extent are the specified data elements available electronically in defined fields?** (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*)

[ALL data elements are in defined fields in electronic claims](#)

**3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.**

**3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.**

[No feasibility assessment](#) Attachment:

#### 3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

**3c.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.**

**IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.**

[Testing demonstrated that the measure was feasible to specify and calculate using CMS administrative claims data. Data sources needed to implement the measure are readily available, accessible, and timely. No threats to the validity of this measure were identified using a limited analysis designed to address missing data.](#)

**3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified** (*e.g., value/code set, risk model, programming code, algorithm*).

[The administrative data \(collected by CMS primarily for billing purposes\) are used as the data source for this measure. Therefore, the cost of data collection is negligible.](#)

### 4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance

results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

#### 4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

##### 4.1. Current and Planned Use

*NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.*

Planned	Current Use (for current use provide URL)
Not in use	

##### 4a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

Not Applicable

##### 4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

The measure was previously reported in the Quality and Resource Use Report (QRUR) program but was not reliable at the physician level due to sample size limitations.

##### 4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

The measure has been submitted to the Measures under Consideration list for the Medicare Shared Savings Program. Results from testing suggest that the measure is reliable at the ACO level.

#### 4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

##### 4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

Not applicable

##### 4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Not applicable

#### 4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

**4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.**

Not applicable

## 5. Comparison to Related or 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.

### 5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

#### 5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0555 : INR Monitoring for Individuals on Warfarin

0586 : Warfarin\_PT/ INR Test

#### 5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

None identified

### 5a. Harmonization

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

#### 5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications completely harmonized?

No

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

The measure under review (NQF 0556) is related to two NQF-endorsed measures:

- NQF 0555: Lack of Monthly INR Monitoring for Individuals on Warfarin (Centers for Medicare & Medicaid Services): Average percentage of monthly intervals in which individuals with claims for warfarin do not receive an International Normalized Ratio (INR) test during the measurement period; and,
- NQF 0586: Warfarin PT/INR Test (Resolution Health, Inc.): This measure identifies the percentage of patients taking warfarin during the measurement year who had at least one PT/INR test within 30 days after the first warfarin prescription in the measurement year. These two related measures address the same measure focus (i.e., INR monitoring) as NQF 0556. However, the measures use a different denominator (i.e., individuals on warfarin) than NQF 0556 (i.e., individuals taking warfarin and interacting anti-infective medications). Below we describe the differences between NQF 0556 and the two related measures and the implications of those differences. Time Period for INR Test - Difference: NQF 0556 requires that the INR test be performed within three to seven days of the interacting anti-infective prescription. NQF 0555 requires monthly INR tests and NQF 0586 requires one INR test within 30 days of the first warfarin prescription of the measurement year. Rationale: Patients on warfarin who start an interacting anti-infective medication are at higher risk of a warfarin-related adverse event. The INR test must be performed shortly after the interacting anti-infective prescription is started to assess the effect on the INR value and to adjust the warfarin dose if necessary. Impact on interpretability: The narrow time window for the INR test is a logical way to track the impact of the interacting anti-infective medication. Data collection burden: Because NQF 0556 and the two related measures are based on administrative claims data, identifying the INR test should require approximately the same resources. Definition of Denominator - Difference: The denominator of NQF 0556 includes patients on warfarin who start an interacting anti-infective medication. The denominators of the two related measure include all patients on warfarin. Rationale: The denominator definition used in NQF 0556 adds value because it restricts the measure to patients at higher risk of an adverse event due to warfarin to capture an acute event. Impact on interpretability: Because the rationale for restricting the denominator is clearly stated, NQF 0556 should be easy to interpret. Data collection burden: Because NQF 0556 and the two related measures are based on administrative claims data, identifying individuals



for the denominator should require about the same time and resources, regardless of the definition.

#### 5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

**OR**

Multiple measures are justified.

**5b.1. If this measure conceptually addresses 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.)**

There are no NQF-endorsed measures that compete (i.e., conceptually addresses both the same measure focus and the same target population) with NQF 0556.

## Appendix

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

[Attachment](#) **Attachment:** [NQF\\_0556\\_Algorithm.pdf](#)

## Contact Information

**Co.1 Measure Steward (Intellectual Property Owner):** [Centers for Medicare & Medicaid Services](#)

**Co.2 Point of Contact:** [Corette, Byrd](#), [MMSSupport@Battelle.org](mailto:MMSSupport@Battelle.org), 202-786-1158-

**Co.3 Measure Developer if different from Measure Steward:** [Centers for Medicare & Medicaid Services](#)

**Co.4 Point of Contact:** [Elizabeth, Ricksecker](#), [Elizabeth.Ricksecker@cms.hhs.gov](mailto:Elizabeth.Ricksecker@cms.hhs.gov), 410-786-6723-

## Additional Information

**Ad.1 Workgroup/Expert Panel involved in measure development**

**Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**

[Original Technical Expert Panel \(TEP\) Members](#)

[Douglas Bell, MD, PhD, Associate Professor in Residence, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research](#)

[Jill S. Borchert, PharmD, BCPS, FCCP, Professor, Pharmacy Practice & PGY1 Residency Program Director, Midwestern University, Chicago College of Pharmacy](#)

[Anne Burns, RPh, Vice President, Professional Affairs, American Pharmacists Association](#)

[Jannet Carmichael, PharmD, BCPS, FCCP, FAPHA, VISN 21 Pharmacy Executive, VA Sierra Pacific Network](#)

[Marshall H. Chin, MD, MPH, Professor of Medicine, University of Chicago](#)

[Edward Eisenberg, MD, Vice President and Chief Medical Officer, Medicare, Medco Health Solutions](#)

[Jay A. Gold, MD, JD, MPH, Senior Vice President and Medicare Chief Medical Officer, MetaStar, Inc.](#)

[David Nau, PhD, MS, Senior Director of Research & Performance Measurement, PQA, Inc.](#)

[N. Lee Rucker, PhD, MS, Senior Strategic Policy Advisor, AARP - Public Policy Institute](#)

[Marissa Schlaifer, RPh, MS, Director of Pharmacy Affairs Academy of Managed Care Pharmacy](#)

[Brad Tice, PharmD, Chief Clinical Officer, PharmMD Solutions, LLC](#)

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[Darren Triller, PharmD, Director, Pharmacy Services, IPRO](#)

[Neil Wenger, MD, MPH, Professor of Medicine, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research](#)

The TEP evaluated proposed medication measures drafted by FMQAI in regard to the four primary measure evaluation criteria used in the NQF consensus endorsement process (importance, scientific acceptability, feasibility, and usability). The TEP discussed the

strengths and weaknesses of the proposed measures and made recommendations regarding measure specifications, inclusion and exclusion criteria, and appropriate risk adjustment as applicable.

#### Current TEP Members

Dale W. Bratzler, DO, MPH, TEP Chair, Professor and Associate Dean, College of Public Health, University of Oklahoma Health Sciences Center

Mary Brennan-Taylor, Adjunct Research Instructor of Family Medicine, School of Medicine and Biomedical Sciences, University of Buffalo

Frank E. Briggs III, PharmD, MPH, Vice President, Quality and Patient Safety, West Virginia University Healthcare

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Joan Ching, RN, MN, CPHQ, Administrative Director, Hospital Quality & Safety, Virginia Mason Medical Center

Edward S. Eisenberg, MD, FACP, Senior Vice President, Performance Measurement and Strategic Alliances, Pharmacy Quality Alliance

Floyd Eisenberg, MD, MPH, FACP, President, iParsimony, LLC

Marybeth Farquhar, PhD, MSN, RN, Vice President of Research & Measurement, URAC

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The current TEP reviewed the measure specifications through a work group process. Members of the work group included the following:

#### TEP Work Group Members

1. Daniel Castillo, MD, MBA, Medical Director, Healthcare Quality Evaluation, The Joint Commission

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<p>6. Janet Maurer, MD, MBA, FCCP, Operations Medical Director, National Imaging Associates, Health Dialog</p> <p>7. N. Lee Rucker, MSPH, Senior Advisor, National Council on Patient Information and Education</p> <p>8. Darren M. Triller, PharmD, TEP Co-Chair, Senior Director, Quality Improvement, IPRO QIO</p> <p>Federal Guests</p> <p>9. Mary Andrawis, PharmD, MPH, Contract Officer Representative &amp; Medication Safety Co-Lead, Centers for Medicare &amp; Medicaid Services, Center for Medicare &amp; Medicaid Innovation</p> <p>10. Nadine Shehab, PharmD, MPH, Senior Service Fellow, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention</p>
<p><b>Measure Developer/Steward Updates and Ongoing Maintenance</b></p> <p><b>Ad.2 Year the measure was first released:</b> 2009</p> <p><b>Ad.3 Month and Year of most recent revision:</b> 01, 2013</p> <p><b>Ad.4 What is your frequency for review/update of this measure?</b> Annually</p> <p><b>Ad.5 When is the next scheduled review/update for this measure?</b> 12, 2014</p>
<p><b>Ad.6 Copyright statement:</b> Limited proprietary coding is contained in the measure specifications for user convenience. Use of these codes may require permission from the code owner or agreement to a license.</p> <p>ICD-10 codes are copyright © World Health Organization (WHO), Fourth Edition, 2010. CPT © 2010 American Medical Association. CPT is a registered trademark of the American Medical Association. All rights reserved</p> <p><b>Ad.7 Disclaimers:</b> This performance measure does not establish a standard of medical care and has not been tested for all potential applications.</p>
<p><b>Ad.8 Additional Information/Comments:</b> Not applicable</p>