Appendix 3-A: Measure Information Form (MIF)

Data Source	Electronic administrative data/claims; Part D enrollment data; beneficiary data For measure calculation, the following Medicare files were required: • Denominator tables • Prescription drug benefit (Part D) coverage tables • Beneficiary file • Institutional claims (Part A) • Non-institutional claims (Part B) —physician carrier/non-DME • Prescription drug benefit (Part D) claims For physician group attribution, the following were required: • Non-institutional claims (Part B) —physician carrier/non-DME • Denominator tables to determine individual enrollment • Beneficiary file or coverage table to determine hospice benefit and Medicare as secondary payor status • CMS physician and physician specialty tables • National Plan & Provider Enumeration System (NPPES) database	**Measure Set ID**	TBD
Version Number and Effective Date	Version 2 01/01/2011 – 12/31/2011	**CMS Approval Date**	TBD
NQF ID	NQF #555	**Date Endorsed**	August 5, 2009
Care Setting	Ambulatory care Office	**Unit of Measurement**	Population: States; Clinicians: Group
Measurement Duration	The measurement period (12 consecutive months)	**Measurement Period**	Year
Measure Type	Process	**Measure Scoring**	Continuous variable
Payer Source	Medicare fee-for-service (FFS) Prescription Drug Plans (PDPs)	**Improvement Notation**	Better quality = lower score
Measure Steward	CMS		
Copyright / Disclaimer	Not applicable		

Measure Description	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. INR Test: Prothrombin time CPT 85610
Rationale	Warfarin has been used for more than 50 years in clinical practice and is the most commonly prescribed anticoagulant in the United States, with more than 31 million prescriptions issued in 2004 (Wysowski, Nourjah, & Swartz, 2007). However, warfarin's narrow range of therapeutic control (Lane & Lip, 2007) necessitates the careful monitoring of patients taking the drug. A study by White et al. (2007) found that patients with poor international normalized ratio (INR) control suffered higher rates of mortality and major bleeding when compared to those with good or moderate INR control. Despite the extensive use of warfarin, it remains one of the primary drugs responsible for adverse drug events (ADEs), particularly among the elderly. In fact, in a recent publication by Budnitz et al. (2006), among patients aged 65 and older, their analysis suggested that only three drugs (insulin, warfarin, and digoxin) were responsible for one out of every three estimated ADEs treated in the emergency departments in the United States. For warfarin, the annual estimate of ADEs treated in the emergency departments in the United States overall was 43,401 (Budnitz et al., 2006). 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 outcome, which was defined as "hospitalization, required intervention, or life threatening or other serious outcome" (Moore, Cohen, & Furberg, 2007). An important consideration for avoiding adverse events is maintaining patients within the therapeutic range through appropriate and timely monitoring. A recent systematic review, which incorporated data from 67 studies, with a goal of describing the effect of study setting on anticoagulation control, found across all patients that the time spent in the therapeutic range was 63.6%, whereas in the community setting, patients spent on average approximately 55% of the time in the therapeutic range (van Walraven, Jennings, Oake, Fergusson, & Forster, 2006; van Walraven, Oake, Wells, & Forster, 2007). Similarly, in an analysis of warfarin safety within the nursing home setting, patients were found to be within the therapeutic range only 49.6% of the time. Further data from the nursing home study identified 720 adverse warfarin related events among 490 patients on warfarin over one year, with 11% of the events deemed serious and 2% life-threatening or fatal. Twenty-nine percent of all of the events were considered preventable, whereas 57% of the serious and life-threatening events were considered preventable (Gurwitz et al., 2007). References: Budnitz, D. S., Pollock, D. A., Weidenbach, K. N., Mendelsohn, A. B., Schroeder, T. J., & Annest, J. L. (2006). National surveillance of emergency department visits for outpatient adverse drug events. *Journal of the American Medical Association, 296*(15), 1858-66. Gurwitz, J. H., Field, T. S., Radford, M. J., Harrold, L. R., Becker, R., Reed, G., et al. (2007). The safety of warfarin therapy in the nursing home setting. *American Journal of Medicine, 120*(6), 539-44. Lane, D. A. & Lip, G. Y. (2007). Maintaining therapeutic anticoagulation: the importance of keeping "within range." *Chest, 131*(5), 1277-1279. 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), 1752-9. 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), 1155-66. 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), 1508-15. White, H. D., M. Gruber, Feyzi, J., Kaatz, S., Tse, H. F., Husted, S., et al. (2007). Comparison of outcomes among patients randomized to warfarin therapy according to anticoagulant control: results from SPORTIF III and V. *Archives of Internal Medicine, 167*(3), 239-245. Wysowski, D. K., Nourjah, P., & Swartz, L. (2007). Bleeding complications with warfarin use: a prevalent adverse effect resulting in regulatory action. *Archives of Internal Medicine, 167*(13), 1414-9.
Clinical Recommendation Statement	The recommendations from clinical practice guidelines related to the frequency of INR monitoring include the following: The 2006 “Guidelines for the Management of Patients With Atrial Fibrillation” issued by the ACC/AHA and the European Society of Cardiology present recommendations regarding the use of anticoagulation therapy in the prevention of thromboembolism. The Guidelines provide the following guidance regarding the frequency of INR monitoring (Fuster et al., 2006): “5. INR should be determined at least weekly during initiation of therapy and monthly when anticoagulation is stable.” (Class I Recommendation, Level of Evidence A).
References	Fuster, V., Ryden, L. E., Cannom, D. S., Crijns, H. J., Curtis, A. B., Ellenbogen, K. A., et al. (2006). ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). *Journal of the American College of Cardiology*, 48, e149-e246. Retrieved September 14, 2007, from http://www.acc.org/qualityandscience/clinical/guidelines/atrial_fib/pdfs/AF_Full_Text.pdf
Release Notes/ Summary of Changes	• Clarified unit of analysis and added optional physician group attribution algorithm. • See Excel Attachment of Code Tables for NDC updates. • Updated National Drug Codes (NDCs) as of October 28, 2011.

Technical Specifications	
Target Population	At least 18 years of age as of the end of the measurement period.
Denominator	
Denominator Statement	Individuals with warfarin claims for at least 40 days.
Denominator Details	During the measurement period, the individual may not have more than a one-month gap in Part D coverage. Active ingredients by class to identify warfarin: Anticoagulants: warfarin Note: The active ingredient is limited to oral formulations only.
Denominator Exceptions and Exclusions	**Optional Exclusion Criteria** Individuals that are monitoring INR at home identified by HCPCS (G0248-G0250).
Denominator Exceptions and Exclusions Details	Not applicable
Numerator	
Numerator Statement	Sum of the percentage of monthly intervals **without** an INR test for each individual in the denominator.
Numerator Details	For each individual in the denominator, the percentage of monthly intervals without an INR test is calculated as the number of monthly intervals without an INR test divided by the number of monthly intervals with warfarin. The INR tests for each individual will be compared to the 40-day intervals in the denominator. Each 40-day interval without an INR test is counted in the numerator. An interval with a hospitalization of more than 48 hours is considered an interval with an INR test. "Warfarin usage" or "warfarin therapy" is determined by the start date of the first prescription for warfarin up through the start date of the last prescription for warfarin plus the days' supply from the last claim. Interval: 40 days The first day of the the first 40-day interval is the start date of the first warfarin prescription, and the last day of the first 40-day interval is the start date of the first warfarin prescription + 39. The subsequent 40-day interval starts on the day after the first 40-day interval and ends 40 days following the first 40-day interval, as long as this end date occurs within the warfarin therapy time frame. This process continues until a calculated 40-day interval end date does not occur within the warfarin therapy time frame. If there are fewer than 40 days of warfarin therapy remaining, those remaining days are not counted in any interval in determining the numerator. Only full 40-day intervals are used for calculating the numerator. ***For individuals who died during the measurement year, set warfarin therapy end date to be the death date of the individual.***

Stratification or Risk Adjustment

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

- State
- Physician Group*
- Gender
- Age – Divide age group 18-64 into 3 categories: 18-24, 25-44, 45-64
- Race/ethnicity
- Dual Eligibility

*See algorithm section below for physician group attribution methodology used for this measure.

No risk adjustment necessary

Sampling

Not applicable

Calculation Algorithm

Denominator: Individuals at least18 years of age as of the end of the measurement period with warfarin therapy for at least 40 days.

Create Denominator:

1. Pull individuals who are 18 or older as of December 31 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 1 month of HMO enrollment during the current measurement year (FFS individuals only).

4. Of the individuals identified in Step 3, include those who had warfarin claims during the measurement period.

5. Of the individuals identified in Step 4, calculate the start date and end date of warfarin therapy for each individual and count the days between the start date and the end date inclusive. *For individuals who die during the measurement period and prior to the calculated end date of warfarin therapy, reset the end date of warfarin therapy to be the death date.*

6. Keep individuals that have at least 40 days of warfarin therapy during the measurement period and calculate the number of 40-day intervals for each individual.

7. Calculate optional denominator exclusion:
   Identify and delete from the denominator individuals with mechanical heart valves who are monitoring their INR at home during the current measurement period.

Numerator: Sum of the percentage of monthly intervals **without** an INR test for each individual in the denominator

Create Numerator:

1. Pull all INR test claims from Part A and Part B claims data for the current measurement period.

2. From the claims identified in Step 1, keep only those INR test claims for the individuals that are included in the denominator.

3. From Part A claims data, identify and pull all inpatients stays of more than 48 hours during the measurement period (calculate and keep stays of at least 3 days). **Note: To identify inpatient stays in the Part A claims data, confirm the third character in the hsp_id field is a "0" and the nch_clm_type_cd field is either "60" or "61."**

4. From the claims identified in Step 3, keep those that are also included in the denominator.

5. Combine the INR test claims dataset from Step 2 and the hospitalizations of more than 48 hours dataset from Step 4.

6. Using the start date of warfarin therapy identified in the denominator, determine the subsequent start dates for each of the calculated 40-day interval(s) of warfarin therapy and determine the number of warfarin 40-day intervals designated in the denominator for each individual.

7. From the dataset created in Step 5, create a dataset containing INR test done/48-hour hospitalizations by unique individual and date of service (hse_clm_from_dt in the Part A claims hospitalizations).

8. Calculate which 40-day intervals **did not** have an INR test completed and **did not** have a 48-hour inpatient stay by comparing each date of service from Step 7 to each individual 40-day interval for each individual designated in Step 6.

9. From the dataset created in Step 8, calculate the individual's rate **without** an INR test as the sum of the numbers of 40-day intervals **without** an INR test, divided by the total number of intervals.

10. From the dataset created in Step 9, calculate the final rate numerator as the sum of the individual's rates.

Physician Group Attribution:
Physician group attribution was adapted from *Generating Medicare Physician Quality Performance Measurement Results (GEM) Project: Physician and Other Provider Grouping and Patient Attribution Methodologies* (http://www.cms.gov/GEM). The following is intended as guidance and reflects only one of many methodologies for assigning individuals to a medical group. Please note that the physician group attribution methodology excludes patients that died even though the overall measure does not.

I. Identify Physician and Medical Groups

1. Identify all Tax Identification Numbers (TINs)/National Provider Identification (NPI)/UPIN combinations from all Part B claims in the measurement year and the prior year. The NPI for the performing provider is used.

   If no NPI is available on the claim, check other data sources such as CMS provider tables or the National Plan and Provider Enumeration System (NPPES) for a current NPI based on the physician UPIN. Keep records with valid NPI. Valid NPIs have 10 numeric characters (no alpha characters).

   Note: Due to NPI implementation, UPINs are not necessary for attribution using Part B data from 2008 and later.

2. For valid NPIs, pull credentials and specialty code(s). Credentials and specialty codes are pulled in the following order:
   a. From the CMS provider tables.
   b. If not found in A, then pull from NPPES.

3. Create 1 record per NPI with all credentials and all specialties. A provider may have more than 1 specialty.

4. Attach TIN to NPI, keeping only those records with credentials indicating a physician (MD or DO), physician assistant (PA), or nurse practitioner (NP).

5. Identify medical group TINs: Medical group TINs are defined as TINs that had physician, physician assistant, or nurse practitioner provider specialty codes on at least 50% of Part B carrier claim line items billed by the TIN during the measurement year or prior year. (The provider specialty codes are listed after Patient Attribution.)
    a. Pull Part B records billed by TINS identified in #4 during the measurement year and prior year.
    b. Identify claims that had the performing NPI (npi_prfrmg) in the list of eligible physicians/TINs, keeping those that match by TIN, performing NPI, and provider state code.
    c. Calculate the percent of Part B claims that match by TIN, npi_prfrmg, and provider state code for each TIN, keeping those TINs with percent greater or equal to 50%.
    d. Delete invalid TINs. Examples of invalid TINs are defined as having the same value for all 9 digits or values of 012345678, 012345678, 123456789, 987654321, or 87654321.

6. Identify TINs that are not solo practices.
    a. Pull Part B records billed by physicians identified in #4 for the measurement year and/or prior year. If the performing NPI is not on the claim, match to obtain NPI from the list created in #4 by UPIN.
    b. Count unique NPIs per TIN.
    c. Keep only those TINs having 2 or more providers.
    d. Delete invalid TINs. Examples of invalid TINs are defined as having the same value for all 9 digits or values of 012345678, 012345678, 123456789, 987654321, or 87654321.

7. Create final group of TINs from #5 and #6 (TINs that are medical groups and are not solo practices).

8. Create file of TINs and NPIs associated with those TINs. These are now referred to as the medical group TINs.

II. Identify Individual Sample and Claims

9. Create individual sample.
    a. Pull individuals with 11+ months of Parts A, B, & D during the measurement year.
    b. Verify the individual did not have any months with Medicare as secondary payor. Remove individuals with BENE_PRMRY_PYR_CD not equal to one of the following:
        i. A = working-age individual/spouse with EGHP
        ii. B = ESRD in the 18-month coordination period with an employer group health plan
        iii. G = working disabled for any month of the year.
    c. Verify the individual resides in the U.S., Puerto Rico, Virgin Islands or Washington D.C.
    d. Exclude individuals that enter the Medicare hospice at any point during the measurement year.
    e. Exclude individuals that died during the measurement year.

10. For individuals identified in #9, pull office visit claims that occur during the measurement year and in the 6 months prior to the measurement year.
    a. Office visit claims have CPT codes of 99201-99205, 99211-99215 and 99241-99245.
    b. Exclude claims with no physician_upin and no npi_prfrmg.

11. Attach medical group TIN to claims by NPI or UPIN if no performing NPI is available.

III. Patient Attribution.

12. Pull all Part B office claims from #11 with designated specialties indicating primary care, cardiology, oncology, cardiac surgery, or orthopedic surgery (see list of provider specialties and specialty codes). Attribute each individual to at most 1 medical group TIN for each measure.
    a. Evaluate specialty on claim (HSE_B_HCFA_PRVDR_SPCLTY_CD) first. If specialty on claim does not match any of the measure-specific specialties, then check additional specialty fields.
    b. If the provider specialty indicates nurse practitioners or physician assistants ('50' or '97'), then check additional specialty codes

13. For each individual, count claims per medical group TIN. Keep only individuals with 2 or more E&M claims.

14. Attribute individual to the medical group TIN with the most claims. If a tie occurs between medical group TINs, attribute the TIN with most recent claim.

15. Attach the medical group TIN to the denominator and numerator files by individual.

Provider Specialties and Specialty Codes
Provider specialties and specialty codes include only physician, physician assistants, and nurse practitioners for physician grouping, TIN selection, and patient attribution. The provider specialty codes and the associated provider specialty are shown below:
01—General practice*
02—General surgery
03—Allergy/immunology
04—Otolaryngology
05—Anesthesiology
06—Cardiology*
07—Dermatology
08—Family practice*
09—Interventional pain management
10—Gastroenterology
11—Internal medicine*
12—Osteopathic manipulative therapy
13—Neurology
14—Neurosurgery
16—Obstetrics/gynecology*
18—Ophthalmology
20—Orthopedic surgery*
22—Pathology
24—Plastic and reconstructive surgery
25—Physical medicine and rehabilitation
26—Psychiatry
28—Colorectal surgery
29—Pulmonary disease
30—Diagnostic radiology
33—Thoracic surgery
34—Urology
36—Nuclear medicine
37—Pediatric medicine
38—Geriatric medicine*
39—Nephrology
40—Hand surgery
44—Infectious disease
46—Endocrinology

50—Nurse practitioner*
66—Rheumatology
70—Multi-specialty clinic or group practice*
72—Pain management
76—Peripheral vascular disease
77—Vascular surgery
78—Cardiac surgery*
79—Addiction medicine
81—Critical care (intensivists)
82—Hematology
83—Hematology/oncology
84—Preventive medicine*
85—Maxillofacial surgery
86—Neuropsychiatry
90—Medical oncology*
91—Surgical oncology*
92—Radiation oncology*
93—Emergency medicine
94—Interventional radiology
97—Physician assistant*
98—Gynecologist/oncologist
99—Unknown Physician Specialty
Other—NA

*Provider specialty codes specific to this measure.