



American Society of  
Health-System Pharmacists  
7272 Wisconsin Avenue  
Bethesda, Maryland 20814  
(301) 657-3000  
Fax: (301) 664-8877  
www.ashp.org

May 11, 2009

The National Quality Forum  
601 Thirteenth Street, NW  
Suite 500 North  
Washington, DC 20005

Re: NQF Member Pre-voting Review for *National Voluntary Consensus Standards for Medication Management*

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments on the draft “*National Voluntary Consensus Standards for Medication Management.*” As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP can offer unique and vital feedback on this important health care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams to ensure that medicines are used safely, effectively, and in a cost-conscious manner.

ASHP is pleased to have nominated Jannet M. Carmichael, Pharm.D., FCCP, BCPS, Pharmacy Executive at VA Sierra Pacific Network, to serve as a member of this project’s steering committee. ASHP commends Dr. Carmichael and the other committee members for their diligent work. The Society believes that these measures evaluate several important areas of medication management. While we acknowledge the value of the individual measures, the Society believes there are shortcomings in achieving the goal set by the Centers for Medicare & Medicaid Services (CMS), which was to define both process and outcome measures for medication management. Most notably, there is an absence of outcome measures. The proposed measures focus almost entirely on process, specifically on adherence. While this represents a good first step, CMS also intended to measure additional aspects of medication management, including decision making, appropriate use, monitoring, safety and outcomes of therapy. ASHP acknowledges the challenges of addressing these areas given the limited data sets commonly available as well as the limited extent and type of candidate measures submitted to NQF for consideration. While the Society supports the proposed measures, we recommend that these serve as the foundation for ongoing efforts to develop additional and more robust medication management measures.

[ASHP policy](#) supports the value of pharmacists’ expertise in medication management to ensure the safe and effective use of medications. The Society advocates for the participation of pharmacists in collaborative drug therapy management, which is defined as a multidisciplinary process for selecting appropriate drug therapies, educating patients, monitoring patients, and

**TOGETHER WE MAKE A GREAT TEAM**

continually assessing outcomes of therapy. ASHP believes that the proposed measures fail to address these critical functions performed by pharmacists. NQF's draft document states that medication dispensing can be used to assess the quality of pharmacies. While a comparison of medications prescribed versus medications dispensed can be used to assess the quality and extent of pharmacy interventions and therefore the quality of pharmacy services provided, an assessment of dispensing records alone is more likely to reflect the quality of service provided by the prescriber or the quality of protocols established by the health plan. Thus, current measures do not capture the significant value of pharmacist-provided services which occur during the order review process prior to dispensing and ongoing monitoring.

ASHP encourages NQF to consider the following comments:

### **General Comments**

The Society applauds the work done by the steering committee based on the measures submitted for consideration and appreciates NQF's recognition of the limited spectrum that these measures cover. Measure development should also assess other core elements that correlate with the quality of medication management such as safe practices (e.g., prospective pharmacist order review in hospitals) and technology (e.g., bedside barcoding) that have the potential to improve patient outcomes and overall effectiveness of the medication-use process.

The Society encourages NQF to create a process to pursue an ongoing and broader request of candidate measures for medication management and readdress this area in the near future (it may be useful to establish and release a timeline when issuing these measures). The steering committee and NQF should strive to develop more robust and inclusive measures, especially those that measure outcomes. Measures should ideally measure outcomes (e.g., reduction of adverse drug events, achievement of therapy goals), process measures (e.g., pharmacy interventions per 100 prescriptions/admissions), structural measures (e.g., verification of organizational policies and procedures about the role of pharmacists in the medication management system) and patient-centered measures (e.g., satisfaction with medication management services) as described in NQF's Safe Practices for Better Healthcare, Safe Practice #18: Pharmacist Leadership Structure and Systems. As more robust individual measures are developed, composite measures that are easier to understand should be developed and assessed.

Due to the inherent differences in measures that are developed by various entities, there are many inconsistencies among the measures. As an example, MM-005 assesses patients age 19 years or older while the age range for MM-004 begins at age 18. A more concerning inconsistency is found in the measures relating to the ACE inhibitor class of medications, which is contraindicated for use in pregnancy. Pregnant patients are excluded in one measure (MM-014) but not in the others (MM-001, MM-003, MM-006, and MM-008). Another inherent difference is also manifested in duplication among the measures which has the potential to confuse patients and others who use these measures to select providers or compare the quality of services. There is a considerable extent of overlap between different measures that report the same type of data (i.e. same element of care). For example, MM-001, MM-003, and MM-004 all assess the same element of care: adherence to statin therapy). As the national clearinghouse for quality measures, it is incumbent upon NQF to standardize and streamline endorsed measures, or to justify any such disparities or duplications.

ASHP recommends providing guidance to the users of these measures, especially the public, about which measures are most appropriate in different care settings. Lines 100-102 state that the measures can be applied in all settings; however, many of these measures appear to be primarily outpatient chronic care. The Society recommends reassessing the applicable care settings for each of these measures.

We encourage the committee to consider other areas in the recommendations section where research is needed including the development of measures that assess the use of technology. For example, bedside barcoding could significantly reduce the rate of preventable adverse drug events. However, in current practice, the safety capabilities of barcode and CPOE technologies are often disabled or not used appropriately (e.g. bypassed), eliminating the potential to reduce medication errors. Medication management measures that assess the appropriate use of various technologies would give insight into their successful and optimal utilization. In addition, the six national goals set by the National Priorities Partnership should be used to guide future measure development to identify areas of overuse of medications or services (e.g. hospital admissions) that could be avoided through high-quality medication management.

### **Measure-Specific Comments**

#### **MM-001-08: Proportion of Days Covered (PDC): 5 Rates by Therapeutic Category**

ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year. For the subcomponent assessing ACEI and ARB use, these therapies carry a black box warning against use in the second and third trimester, and there is growing evidence about the potential for harm with these therapies in the first trimester. In addition, statins are contraindicated during pregnancy.

#### **MM-003-08: Adherence to Chronic Medications**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

For the subcomponent assessing ACEI and ARB use, ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year. For the subcomponent assessing ACEI and ARB use, these therapies carry a black box warning against use in the second and third trimester, and there is growing evidence about the potential for harm with these therapies in the first trimester. In addition, statins are contraindicated during pregnancy.

#### **MM-004-08: Coronary Artery Disease and Medication Possession Ratio for Statin Therapy**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year as statins are contraindicated during pregnancy.

**MM-006-08: Diabetes Mellitus and Medication Possession Ratio (MPR) for Chronic Medications**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

For the subcomponent assessing ACEI and ARB use, ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year. These therapies carry a black box warning against use in the second and third trimester, and there is growing evidence about the potential for harm with these therapies in the first trimester. In addition, statins are contraindicated during pregnancy.

**MM-008-08: Diabetes Suboptimal Treatment Regimen (SUB)**

For the subcomponent assessing ACEI and ARB use, ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year. These therapies carry a black box warning against use in the second and third trimester, and there is growing evidence about the potential for harm with these therapies in the first trimester.

**MM-010-08: Diabetes and Medication Possession Ratio for Statin Therapy**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

ASHP recommends that this measure include an exclusion for women who become pregnant during the measurement year as statins are also contraindicated during pregnancy.

**MM-014-08: Chronic Kidney Disease, Diabetes Mellitus, Hypertension and Medication Possession Ratio for ACEI/ARB Therapy**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

**MM-022-08: HBIPS-4: Patients Discharged on Multiple Antipsychotic Medications**

The Society suggests that the intent of this measure is unclear. We believe that the perceived intent is that patients should not receive more than one antipsychotic; however, in some instances combination therapy is appropriate. Therefore, MM-023, which requires documentation of the need for dual therapy, should be the preferred measure. ASHP does not recommend endorsement of MM-022.

**MM-023-08: HBIPS-5 Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification**

According to a recent study<sup>1</sup>, “monotherapy should be given at the maximally tolerated dose and at least two antipsychotics of different action/tolerability and clozapine should be given as monotherapy before combination therapy is considered.” Practice guidelines for the treatment of patients with schizophrenia have traditionally recommended that strong documentation be used to support the use of combination therapy. ASHP suggests that “appropriate justification” be defined in the text of this measure to align with clinical guidelines.

**MM-026-08: Care for Older Adults--Medication Review (COA)**

ASHP strongly believes that all pharmacists have the clinical training and expertise to conduct a medication review.

**MM-030-08: Monthly INR Monitoring for Beneficiaries on Warfarin**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

**MM-031-08: INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications**

ASHP suggests reviewing the patient population specified in the numerator. This measure specifies Part D beneficiaries; this text may be a result of the original measure specifications not being edited for more general use. The Society believes that this measure is important to assess for the general population.

**MM-034-08: HBIPS-6 Post Discharge Continuing Care Plan Created; MM-035-08: HBIPS-7 Post Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge**

The Society suggests clarifying the intended level of measurement (individual clinician, hospital, pharmacy) for these and all the measures being proposed for endorsement.

**Editorial Comments**

Line 5: The Society questions rather the term “frequent” is necessary and correct. Use of that term here is misleading because frequency of medication use has not been shown to cause patient harm, rather harm is associated with inappropriate use and monitoring. Suggest rewording sentence to “...there is growing evidence that medication use, especially use of multiple medications in the chronically ill, can lead to safety and quality concerns if those therapies are not managed appropriately.”

Lines 6 to 8: Suggest that NQF consult reference 1 and clarify this statement. Does the 7% of patients taking five or more medications represent prescription use only, or combined prescription and nonprescription and supplement use? It would also be useful to clarify that the 81% of adults taking at least one medication represents both prescription and nonprescription drug use, assuming that is factual based on the source document. See also same data presented on lines 53 to 54.

Line 8: Here and for the context of the section that follows, it would be beneficial to define “inappropriate medications” such as wrong drug, wrong dose, wrong indication, duplicative or omitted therapy. See also same data presented on line 57.

Line 10: Should refer to “adverse patient safety outcomes” not simply “patient safety outcomes.” See also same statement presented on lines 58 to 59.

Line 22: The Society questions whether the medications listed here should be described as high-impact; rather it is the conditions they are used to treat that are high impact. In addition, NQF may wish to point out that while those conditions (e.g., asthma, diabetes, and coronary artery disease) do not define the universe of high-impact conditions from a morbidity, mortality and cost perspective, they are the initial measures that were submitted for consideration at this time. While this is described on lines 157 to 159, it would be beneficial to include a similar statement in the executive summary.

Lines 53 to 54, see above comment for lines 6 through 8.

Line 57, see above comment for line 8.

Line 58 to 59, see above comment for line 10.

Line 77, text is missing that is intended to describe “Driving toward high performance.”

Line 213 here and elsewhere for other measures, NQF uses the terminology “intermediate outcome measure” but the rationale for this classification is unclear. Is the use here consistent with NQF’s classification of intermediate outcome measures for other projects? If so, it would be useful to describe this early in the document.

Lines 223 to 229 acknowledge important limitations in using fill rates to measure adherence, including the lack of records for out-of-pocket payment, prescriptions for Medicare patients in the donut hole, etc. It would also be useful to note that data limitations based on the use of multiple pharmacies by ambulatory care patients as well as hospital admissions with subsequent discharge prescriptions filled by the outpatient or discharge pharmacy. These records would also be in disparate systems. It should also be noted that out-of-pocket payments will become increasingly common with the emergence of \$4 generic prescription programs offered by many retailers. NQF might also consider placing this information in the introductory section of the document because these factors will be pertinent to a number of the proposed measures.

Lines 232 to 233, The rationale for excluding beta blockers and calcium channel blockers is presumably because they are used for many indications, which can not be discerned without diagnosis data. While this may be inferred from information presented on lines 227 to 232, NQF may wish to clarify the connection between these to statements. Lines 244 to 245 provide a more succinct explanation that may beneficial to include here as well.

Line 239, see comment on line 213 regarding definition of intermediate outcome measure.

Thank you for the opportunity to provide feedback on the proposed National Voluntary Consensus Standards for Medication Management. If you have any questions concerning the Society's comments, please contact me by phone at (301) 664-8815 or via e-mail at [mandrawis@ashp.org](mailto:mandrawis@ashp.org).

Regards,

A handwritten signature in black ink, appearing to read 'Mary Andrawis', with a long horizontal flourish extending to the right.

Mary Andrawis, Pharm.D., M.P.H.  
Medication-Use Quality Improvement Associate  
American Society of Health-System Pharmacists

---

#### **References**

1. Goodwin G, Fleischhacker W, Arango C, Baumann P, Davidson M, de Hert M et al. Advantages and disadvantages of combination treatment with antipsychotics ECNP Consensus Meeting, March 2008, Nice. *Eur Neuropsychopharmacol*. 2009 May 1.