**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**: 2600 (New Measure)**

**Measure Title**: **Tobacco Screening and Follow-up for Individuals with Serious Mental Illness or Alcohol and Other Drug Dependence**

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** **Not applicable.**

**Date of Submission**: **7/25/2014**

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: **Tobacco use screening and follow-up (if identified as a tobacco user) for patients 18 years and older with a serious mental illness or alcohol and other drug dependence**

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**Not applicable**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

**Not applicable**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

**Identify serious mental illness or alcohol and other drug dependence 🡪 Screen for tobacco use (process) 🡪 If patient is a tobacco user🡪 Provide follow-up care (counseling alone or with medication) 🡪 Quit or reduced tobacco use (intermediate outcome) 🡪 Improved health outcomes (outcome).**

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**Not applicable**

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**Not applicable**

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**Not applicable**

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**Not applicable**

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**Not applicable**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**U.S. Preventive Services Task Force. Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women: U.S. Preventive Services Task Force Reaffirmation Recommendation Statement. Ann Intern Med 2009; 150:551-55.**

**URL: http://www.uspreventiveservicestaskforce.org/uspstf09/tobacco/tobaccors2.htm**

**Date: June 9, 2014.**

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.**

**USPSTF recommendation concluded that even brief counseling (<3 minutes) is effective, there is a dose-response relationship between quit rates and the number of sessions or length of counseling sessions; and the combination of counseling and pharmacotherapy is more effective than either component alone.**

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

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| **Grade** | **Definition** | **Suggestions for Practice** |
| **A** | **The USPSTF recommends the service. There is high certainty that the net benefit is substantial.** | **Offer or provide this service.** |

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

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| **Grade** | **Definition** | **Suggestions for Practice** |
| **B** | **The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.** | **Offer or provide this service.** |
| **C** | **The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.** | **Offer or provide this service for selected patients depending on individual circumstances.** |
| **D** | **The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.** | **Discourage the use of this service.** |
| **I Statement** | **The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.** | **Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.** |

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

[**http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm#brec**](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm#brec)

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**Citation:**

**Fiore MC, Jaen CR, Baker TB, et al. (2008) Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline. U.S. Department of Health and Human Services. Public Health Service.**

**URL:**

[**http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html**](http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html)

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

**Not applicable.**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**The evidence review focused on antidepressants for increasing long-term cessation rates in smokers, buproprion for treating smoking in individuals with schizophrenia, counseling and medication for smokers who are receiving chemical dependency treatment, and smoking cessation interventions with concurrent alcohol abstinence.**

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

**All grades assigned to the level of evidence for smoking cessation interventions were evidence Grade C.**

**Definition:**

**Grade C: Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.**

**The Panel evaluated evidence from nonrandomized trials to inform panel members’ understanding of certain topics (e.g., policy issues). If treatment recommendations were based primarily on such evidence, they were of the “C” level and depended on the consistency of findings across different studies.**

**AHRQ Guidelines for Treating Tobacco Use and Dependence: 2008 Update**

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| **AHRQ Guidelines for Treating Tobacco Use and Dependence:2008 Update** | **Evidence Grade** |
| **Page 244, “Smokers with comorbid psychiatric conditions should be provided smoking cessation treatments identified as effective in this Guideline.”** | **C** |
| **Page 244, “Bupropion SR and nortriptyline, efficacious treatments for smoking cessation in the general population, also are effective in treating depression. Therefore, bupropion SR and nortriptyline especially should be considered for the treatment of tobacco dependence in smokers with current or past history of depression.”** | **C** |
| **Page 244, “Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore, smokers receiving treatment for chemical dependency should be provided smoking cessation treatments shown to be effective in this Guideline, including both counseling and medications.”** | **C** |

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**Grade A: Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.**

**Grade B: Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.**

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**:

**AHRQ: 1975 – 2007**

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

**The AHRQ guideline (page 146) included a total of 25 studies for the applicable recommendations which included the following:**

**Meta-analyses: 5**

**RCTs: 11**

**Literature reviews: 5**

**Other (i.e., case-control, cohort, and survey studies): 5**

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**Overall, the quality of the evidence was high as it included systematic reviews (e.g., meta-analyses) and randomized controlled trials. The following provides an overview of the studies that were included in the evidence review.**

**The guideline identified one meta-analysis which found that antidepressant medications (bupropion SR and notriptyline) increase long-term cessation rates in smokers with past depression. The other four studies (randomized placebo-controlled trials) included intensive psychosocial treatments in conjunction with medication use.**

**Five studies (1 systematic review, 2 narrative reviews, one crossover study, and one follow-up after a randomized controlled trial) suggested that smokers with psychiatric disorders benefit from tobacco dependence treatment.**

**Three randomized controlled trials, one follow-up study (after randomized controlled trial) and one longitudinal study suggested that bupropion and nicotine replacement therapy may be effective for tobacco cessation rates in people with schizophrenia.**

**One randomized controlled trial and one survey study found insufficient evidence to determine if smokers with psychiatric illness would benefit from tobacco cessation treatments tailored to their specific psychiatric condition than from standard tobacco cessation treatment.**

**One systematic, one non-systematic review and two randomized controlled trials suggested that counseling and medication are effective for smokers who are in treatment for chemical dependency.**

**Four randomized controlled trials, one narrative review and one meta-analysis found little evidence that tobacco cessation treatments would interfere with recovery from abuse of other substances. However, one randomized controlled trial suggested that smoking cessation treatment with alcohol dependence treatments may negatively affect alcohol abstinence.**

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

**The AHRQ guideline found that the combination of pharmacology and cessation counseling significantly increases the likelihood of success in smoking cessation among people with past depression. Specifically, smokers with recurrent depression were found more likely to stop smoking with the introduction of pharmacotherapy into their cessation treatment.**

**The evidence supporting this measure can be broken down into two categories: (1) pharmacology and (2) cessation counseling. In general, despite an increased risk for relapse, smokers with psychiatric disorders (e.g., schizophrenia or depression) or chemical dependency may increase long-term cessation rates through pharmacology interventions (e.g., antidepressants) combined with intensive psychosocial interventions.**

**The evidence was insufficient to determine whether smoking cessation programs tailored for psychiatric disorders/symptoms improve outcomes for smokers compared to standard treatments.**

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

**The AHRQ guideline explored the potential harms of the smoking cessation treatment interventions. Certain medications (i.e., varenicline) used in smoking cessation programs are associated with depressed mood, agitation, suicidal ideation, and suicide. There was considerable evidence suggesting that tobacco dependence treatment does not interfere with patients’ recovery from the abuse of other substances. The AHRQ guideline recommended smoking cessation treatments for smokers with comorbid mental health and substance abuse problems. This suggests that there is a preponderance of benefit over harms for tobacco cessation treatment in people with mental health or substance abuse conditions.**

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

**Not applicable.**

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**Not applicable.**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

**Not applicable.**