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

**Measure Number** (*if previously endorsed*)**:** 0027

**Measure Title**: Medical Assistance with Smoking and Tobacco Use Cessation

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 12/2/2016

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| **Instructions**  *Complete 1a.1 and 1a.12 for all measures.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *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.*   * 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. * 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 Standing 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.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

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

Process: Medical Assistance With Smoking and Tobacco Use Cessation

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.12** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

2016 Update:

Health care provider screens adults for tobacco use >>> Identifies adults who are using tobacco >>> Advises adults who use tobacco to stop using tobacco and discusses cessation medications and strategies >>> Reduction in tobacco use >>> Improved health >>> Improved health outcomes (including mortality)

Prior submission: This measure is based on a US Preventive Services Task Force guideline. The USPSTF recommends screening and counseling for smoking cessation (A Recommendation). The USPSTF evaluates the effect of a screening or counseling intervention’s relationship to health outcomes as part of its analytic framework.

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES- State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process (e.g., intervention, or service).**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

US Preventive Services Task Force Recommendation

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | U.S. Preventive Services Task Force (USPSTF, 2015):  Title: Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement  Author: Albert L. Siu, MD, MSPH for the U.S. Preventive Services Task Force  Date: October 20, 2015  Citation: Siu, A. L. (2015). Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine*, 163(8), 622-635.  URL: Guidelines available from: <http://annals.org/aim/article/2443060/behavioral-pharmacotherapy-interventions-tobacco-smoking-cessation-adults-including-pregnant-women>  U.S. Preventive Services Task Force (USPSTF, 2009):  Title: U.S. Preventive Services Task Force (USPSTF). 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  Author: U.S. Preventive Services Task Force (USPSTF)  Date: April 21, 2009  Citation: U.S. Preventive Services Task Force (USPSTF). 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 Apr 21;150(8):551-5.  URL: http://www.guideline.gov/syntheses/synthesis.aspx?id=16422&search=smoking+cessation    Institute for Clinical Systems Improvement (ICSI, 2004):  Title: Tobacco use prevention and cessation for adults and mature adolescents  Author: Institute for Clinical Systems Improvement (ICSI)  Date: June 24, 2004  Citation: Institute for Clinical Systems Improvement (ICSI). Tobacco use prevention and cessation for adults and mature adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 24. p.  URL: http://www.guideline.gov/syntheses/synthesis.aspx?id=16422&search=smoking+cessation  Veterans’ Affairs/Department of Defense (VA/DoD, 2004):  Title: VA/DoD clinical practice guideline for the management of tobacco use  Author: Veterans Administration/Department of Defense  Date: June, 2004  Citation: Veterans Administration, Department of Defense. VA/DoD clinical practice guideline for the management of tobacco use. Washington (DC): Department of Veteran Affairs; 2004 Jun. 81 p.  URL: http://www.guideline.gov/syntheses/synthesis.aspx?id=16422&search=smoking+cessation  Public Health Service (PHS, 2008):  Title: Treating tobacco use and dependence: 2008 update  Author: Public Health Service  Date: May, 2008  Citation: Public Health Service (PHS). Treating tobacco use and dependence: 2008 update. Rockville (MD): 2008 May. 257 p.  URL: http://www.guideline.gov/syntheses/synthesis.aspx?id=16422&search=smoking+cessation |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | U.S. Preventive Services Task Force (USPSTF, 2015):  The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)–approved pharmacotherapy for cessation to adults who use tobacco. (Grade A recommendation)  The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco. (Grade A recommendation)  The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. (I statement)  The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation in adults, including pregnant women. The USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety (previously stated). (I statement)  United States Preventive Services Task Force (USPSTF, 2009):  The USPSTF guideline strongly recommends that clinicians screen all adult for tobacco use and provide tobacco cessation interventions for those who use tobacco products. The USPSTF found good evidence that brief smoking cessation interventions, including screening, brief behavioral counseling (less than 3 minutes), and pharmacotherapy delivered in primary care settings, are effective in increasing the proportion of smokers who successfully quit smoking and remain abstinent after 1 year (USPSTF, 2003).  Institute for Clinical Systems Improvement (ICSI, 2004):  The ICSI Tobacco Use Prevention and Cessation for Adults and Mature Adolescents cites tobacco use as the single most preventable cause of disease and death in American society. The guideline recommends that clinicians establish tobacco use for all patients and reassess users are every clinic visit. Assessment of interest in quitting and timing of that interest should be done after the main reasons for the visit have been addressed, and should precede any advice about quitting. This allows a 1 to 3 minute tobacco discussion accommodating both the user’s needs and the provider’s time limits (ICSI, 2004).  Veterans’ Affairs/Department of Defense (VA/DoD, 2004):  The VA/DoD’s Clinical Practice Guideline for the Management of Tobacco Use recommends that any person (age greater than 12 years) who is eligible for care in the Veterans Health Administration (VHA) or the Department of Defense (DoD) health care delivery system should be screened for tobacco use and should be asked about tobacco use at most visits. Tobacco users should be advised to quit and assessed for willingness to quit at every visit. All tobacco users who are willing to quit should be offered an effective tobacco cessation intervention, including: pharmacotherapy, counseling, and follow-up. Tobacco users attempting to quit should be prescribed one or more effective first-line pharmacotherapies for tobacco use cessation. The guideline also cites strong evidence that minimal counseling (lasting less than three minutes) increases overall tobacco abstinence rates.  Public Health Service (PHS, 2008):  The Public Health Service Clinical Practice Guideline recommends that clinicians engage in a number of activities to aid tobacco users in quitting, which includes: • Implement an officewide system that ensures that, for EVERY patient at EVERY clinic visit, tobacco-use status is queried and documented (repeated assessment is not necessary in the case of the adult who has never used tobacco or has not used tobacco for many years, and for whom this information is clearly documented in the medical record). • In a clear, strong, and personalized manner, urge every tobacco user to quit.  • As every tobacco user if he or she is willing to make a quit attempt at this time (e.g., within the next 30 days). • Provide practical counseling (problem solving/training).  • Recommend the use of approved pharmacotherapy, except in special circumstances.  • Provide supplementary materials. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2016 Update: Please see grades for the 2015 USPSTF recommendations.  The measure is based on multiple guidelines graded A and I.  Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  Grade I: 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.  Prior Submission: No grade was provided. |
| Provide all other grades and definitions from the evidence grading system | 2016 Update: N/A.  Prior Submission: N/A. |
| Grade assigned to the **recommendation** with definition of the grade | 2016 Update:  The measure is based on multiple guidelines graded A and I.  Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  Grade I: 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.  Prior Submission:  Grade A for the USPSTF 2009 recommendation. |
| Provide all other grades and definitions from the recommendation grading system | 2016 Update:  Grade 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.  Grade 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.  Grade 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. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 2016 Update:  Please see the USPSTF Final Evidence Review for quantity and quality of studies used in the body of evidence. Located at <https://www.ncbi.nlm.nih.gov/books/NBK321744/>  Below, we provide a high-level summary of the USPSTF’s quantity and quality of studies.  Quantity  USPSTF included a total of 54 systematic reviews that met eligibility criteria in its review for this update. Of the 54 reviews included, 22 served as the basis for USPSTF’s primary findings. The remaining 32 reviews were listed in descriptive tables.  Quality  Of the 54 included reviews, 43 addressed tobacco cessation interventions for the adult population with the majority of study designs being RCTs. Of the 43 reviews, nine reviews addressed the effectiveness and/or adverse events related to pharmacotherapy (nicotine replacement therapy (NRT), bupropion hydrochloride sustained release (bupropion SR), and/or varenicline) among the adult population. One review addressed combined pharmacotherapy and behavioral interventions. Twenty-six reviews addressed behavioral tobacco cessation treatments among the adult population. Seven reviews focused on specific subpoulations within the general adult population and included behavioral and/or pharmacotherapy interventions.  Of the 54 eligible reviews identified, eight were included that evaluated smoking cessation interventions among pregnant women. The majority of study designs included RCTs and quasi-RCTs with few involving cluster-randomized trials, randomized cross-over trials, and prospective cohorts in addition. Of these eight reviews, three reviewed both pharmacotherapy and behavioral interventions, two assessed pharmacotherapy and three assessed only behavioral interventions.  Prior Submission:  Quantity: The measure is based on a USPSTF guideline that is based on a comprehensive meta-analysis (see USPSTF report for full number of studies)  Quality: High |
| Estimates of benefit and consistency across studies | 2016 Update:  Please see the USPSTF Final Evidence Review for estimates of benefit and consistency across studies. Located at <https://www.ncbi.nlm.nih.gov/books/NBK321744/>  Below, we provide a high-level summary of the USPSTF’s benefit and consistency across studies.  Benefit  Of the included pharmacotherapy intervention reviews, there were no existing systematic reviews that assessed pharmacotherapy interventions among adults that reported the effects of interventions on mortality, morbidity, or other health outcomes. Reviews concluded that any for of NRT was beneficial to increasing the rate of smoking cessation, effect of bupropion SR were similar regardless of treatment or recruitment setting, and varenicline reviews provided statistically significant benefits of 1.35 mg daily dose and 0.5 mg twice daily doses, compared with placebo  Of the review that assessed the effect of combining pharmacotherapy and behavioral support for smoking cessation among adults, there was a statistically significant benefit of combined pharmacotherapy and behavioral interventions versus control on smoking cessation at 6 months followup or longer.  Of the reviews that evaluated the effects of behavioral tobacco cessation among the general adult population, there was considerable overlap in the included studies within groupings (i.e., within the reviews on behavioral support and counseling) and between intervention categories (i.e., behavioral support and counseling and telephone counseling).  Of the included reviews that assessed specific subpopulations, the review concluded that more intensive interventions and interventions with combined approaches (pharmacotherapy and followup counseling) achieve the best outcomes.  Of the included reviews that assessed pregnant women, the reviews concluded that the impacts on infant health outcomes with NRT were sparse, somewhat mixed, but generally favoring no harm or slight benefit and that there was evidence of statistically significant infant health benefits from behavioral interventions. The reviews found there was no evidence of adverse events related to behavioral interventions among pregnant women.  Consistency  The 32 reviews listed in the descriptive tables were consistent in terms of significance and magnitude of effects in relation to primary reviews.  Of the reviews that assessed the effect of pharmacotherapy support for smoking cessation among adults, the USPSTF determined there was a positive net benefit of using NRTs, that bupropion SR reviews were consistent whether group-based or individual-based behavioral therapy, and varenicline reviews were consistent with the time frame tested.  There was a single review that assessed the effect of combining pharmacotherapy and behavioral support for smoking cessation among adults. It was consistent with other studies in that interventions were overall positive when compared to placebo.  Of the reviews that evaluated the effects of behavioral tobacco cessation among the general adult population, the reviews were widely varied as they were subcatagorized into nine subgroupings.  Of the included reviews that assessed specific subpopulations, the reviews were widely varied and included multiple review catwegories; one review concentrated on smokeless tobacco users, four reviews focused on cessation interventions for racial and ethnic minority groups, one only included results for young adults and one focused on interventions among older adult smokers. None of these reviews were considered part of the primary review.  Of the included reviews that assessed pregnant women, there was considerably more evidence available on the effects of behavioral interventions during pregnancy than for pharmacotherapies.  Prior Submission: Consistent. The USPSTF determined there was a positive net benefit. |
| What harms were identified? | 2016 Update:  For a complete summary of the identified harms, please see the USPSTF Final Evidence Review. Located at <https://www.ncbi.nlm.nih.gov/books/NBK321744/>  Below, we provide a high-level summary of the USPSTF’s review of the evidence about harms.  General Adult Population  NRT users were found to experience minimal harm related to cardiovascular (CV) adverse events, typically low-risk events like tachycardia.  Post-marketing research of bupropion sustained release (SR) and varenicline as smoking cessation aids raised concerns regarding patient safety related to neuropsychiatric outcomes (including suicidal ideation and attempts) for bupropion SR as well as serious CV events for varenicline. FDA boxed warnings have been placed on bupropion SR used for smoking cessation for possible serious neuropsychiatric adverse events and on varenicline for neuropsychiatric adverse events. The FDA issued a warning for varenicline and its risk of CV adverse events. Continuing research is being conducted for these medications to assess safety.  USPSTF found limited evidence of harms related to behavioral interventions used for smoking cessation.  Pregnant Women  USPSTF found no studies evaluating bupropion SR and varenicline pharmacotherapy harms for pregnant women.  Most studies with pregnant women using NRT reported no harm or slight benefit on infant health outcomes. However, in one trial the potential of cesarean section was higher among pregnant women assigned to NRT when compared to placebo group. USPSTF acknowledges that there are few NRT trials for pregnant women and most inconsistently reported adverse events.  Electronic nicotine delivery systems (ENDS) have not been approved as a cessation intervention by the FDA and multiple studies are ongoing to effectively assess the harms of ENDS.  Prior Submission: N/A. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | 2016 Update:  We have not identified any new studies conducted since the systematic review.  Prior Submission: N/A. |

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**1a.4 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.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

N/A

**1a.4.2 What process was used to identify the evidence?**

N/A

**1a.4.3.** **Provide the citation(s) for the evidence.**

N/A