December 1, 2015

TO: National Quality Forum

FROM: RAND Health

SUBJECT: Request for Ad Hoc Review of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment)

This memo requests an ad hoc review of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment). NQF 0004 is a two-part measure that consists of the proportion of patients with an initial diagnosis of alcohol or other drug dependence that receive (1) treatment within 14 days of the initial diagnosis, and (2) follow-up treatment within 30 days thereafter. In this memo, we present evidence that the current definition of "treatment" is incomplete, as it only includes psychosocial interventions, but not medication-assisted treatment (MAT). In other words, patients receiving MAT only would be misclassified based on the current definition.

We propose that the measure definition for NQF 0004 be changed so receiving psychosocial treatment only, MAT only, or both psychosocial treatment and MAT would meet the numerator criteria. Based on recent conversations with NQF staff, we understand that there is no plan for a systematic re-evaluation of NQF 0004 in the near future. Therefore, this memo is a request for an ad hoc review of NQF 0004 in order to align the measure definition with current evidence.

This memo provides evidence supporting a "material change" to the measure and therefore, a need for an ad hoc review of NQF 0004, including:

1. Guideline recommendations that support use of MAT for treatment of alcohol or opioid dependence.
2. Evidence from a targeted literature search on the proportion of psychosocial care being provided outside of the formal healthcare system, and therefore, not captured by claims data.

In a subsequent memo to be sent later, we will present empirical results from an analysis of claims data of the effect of changing the measure definitions. This will provide an estimate of the misclassification based on current definitions.

Exhibit 1 in this memo is an excerpt from the *current* Evidence Form for NQF 0004, written by the National Committee for Quality Assurance (NCQA) and submitted to NQF on February 28, 2013. The guideline recommendations cited in this form support the use of psychosocial care for patients with alcohol and other drug dependence, as reflected in the current definition of "treatment". Two of the guidelines that are cited in the current NQF Evidence Form submitted by NCQA, the Department of Veteran Affairs/Department of Defense (VA/DoD) guideline (VA/DoD, 2009) and the American Psychiatric Association (APA) guideline (APA, 2006), support a change in NQF 0004 to include MAT as an appropriate treatment option for patients with alcohol and opioid dependence. The recommendations

on MAT from the VA/DoD and APA guidelines are provided in Exhibits 2 and 3, respectively, for alcohol dependence and in Exhibits 4 and 5, respectively, for opioid dependence.

This memo also includes recommendations from several other clinical practice guidelines, which are not cited in the NQF 0004 Evidence Form, that support the use of MAT for patients with alcohol or opioid dependence. Exhibits 6 through 8 in this memo contain the exact wording of the recommendations for the use of MAT for *alcohol dependence* from three additional guidelines published between 2011 and 2015:

- Substance Abuse and Mental Health Services Administration and National Institute on Alcohol Abuse and Alcoholism, Medication for the Treatment of Alcohol Use Disorder: A Brief Guide. HHS Publication No. (SMA) 15-4907. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015a. Available November 19, 2015, at http://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf
- British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015, at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf
- National Institute for Health and Clinical Excellence (NICE). 2011. Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. National Clinical Practice Guideline 115. National Collaborating Centre for Mental Health commissioned by the National Institute for Health & Clinical Excellence. Available November 19, 2015, at http://www.nice.org.uk/guidance/cg115/evidence

In total, the five guidelines (these three plus those from VA/DoD and APA) recommend that the clinician consider prescribing an FDA-approved medication (i.e., acamprosate calcium, disulfiram, oral naltrexone, or extended-release injectable naltrexone) in treating patients with alcohol dependence. Four of the five guidelines on alcohol dependence recommend that the pharmacological treatment be provided in conjunction with some type of psychosocial treatment. Three of the five organizations issuing these guidelines rated the strength of the recommendation and/or graded the supporting evidence; of these, the 2012 British Association for Psychopharmacology guideline on pharmacological management of substance abuse is the most recent.

Exhibits 9 through 17 in this memo contain the exact wording of the recommendations for the use of MAT for *opioid dependence* from nine additional guidelines, which are not cited in the NQF 0004 Evidence Form, published between 2005 and 2015:

- Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. HHS Publication No. (SMA) 14-4892R. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015b. Available November 19, 2015 at

http://store.samhsa.gov/product/Clinical-Use-of-Extended-Release-Injectable-Naltrexone-in-the-Treatment-of-Opioid-Use-Disorder-A-Brief-Guide/SMA14-4892R

- American Society of Addiction Medicine (ASAM), 2015. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Available November 19, 2015 at http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf
- British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015, at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf
- World Federation of Societies of Biological Psychiatry (WFSBP): Soyka M, Kranzler HR, van den Brink W, Krystal J, Möller H-J, Kasper W. The World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for the Biological Treatment of Substance Use and Related Disorders. Part 2: Opioid dependence. World J Biological Psychiatry 2011; 12:160–187. Available November 19, 2015, at http://www.wfsbp.org/fileadmin/user_upload/Treatment_Guidelines/Guidelines_Addiction_Part_2.pdf
- Centre for Addiction and Mental Health (CAMH): Handford C, Kahan M, Srivastava A, Cirone S, Sanghera S, Palda V. Buprenorphine/naloxone for opioid dependence: clinical practice guideline [Internet].Centre for Addiction and Mental Health; 2011. Available November 19, 2015 at https://knowledgex.camh.net/primary_care/guidelines_materials/Documents/buprenorphine_naloxone_gdlns2011.pdf
- World Health Organization, 2009. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Available November 19, 2015 at http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf
- National Institute for Health and Clinical Excellence (NICE), 2007a. Methadone and buprenorphine for the management of opioid dependence. Technology appraisal guidance. 24 January 2007a. Available November 19, 2015, at http://www.nice.org.uk/guidance/ta114
- National Institute for Health and Clinical Excellence (NICE). 2007b. Naltrexone for the management of opioid dependence. Technology appraisal guidance. 24 January 2007b. Available November 19, 2015, at http://www.nice.org.uk/guidance/ta115
- Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. Available November 19, 2015 at http://store.samhsa.gov/shin/content//SMA12-4214/SMA12-4214.pdf

In total, the eleven guidelines (these nine plus those from VA/DoD and APA) recommend that the clinician consider prescribing one of the FDA-approved medications (i.e., buprenorphine, methadone, oral naltrexone, or extended-release injectable naltrexone) in treating opioid dependence. Seven of the

eleven guidelines on opioid dependence recommend that the pharmacological treatment be provided in conjunction with some type of psychosocial treatment. Six of the eleven organizations issuing these guidelines rated the strength of the recommendation and/or graded the supporting evidence; of these, the 2012 British Association for Psychopharmacology guideline on pharmacological management of substance abuse is the most recent. These recommendations for opioid dependence together with those for alcohol dependence offer strong guideline support for MAT being included in the definition of treatment for alcohol and other drug dependence in the NQF 0004 measure.

As mentioned above, the majority of guidelines in Exhibits 2 through 17 recommend that MAT be provided in conjunction with psychosocial treatment. In other words, patients on MAT should also have psychosocial treatment and therefore, it might be argued that the failure to include MAT in the measure definition might not affect measure results. However, this assumes that psychosocial treatment is captured properly. NQF 0004 relies on claims data to identify psychosocial treatment, which means that treatment received outside of the formal healthcare system, such as self-help groups, and treatment paid by the patient outside of his/her insurance will not be captured.

To estimate the frequency of treatment received outside of the formal healthcare system, this memo includes the results of a targeted literature search to estimate the frequency with which those with alcohol dependence seek psychosocial treatment outside the formal health care system. Two studies identified by our search (Exhibit 18) indicate high levels of participation in 12-Step programs such as Alcoholics Anonymous. According to a study by Dawson et al. (2006), 26 percent of those with alcohol dependence had ever sought help for alcohol problems. Of those who had sought treatment, 12 percent had participated in 12-Step programs only, 22 percent had received formal treatment only, and 67 percent had participated in both a 12-Step program and received formal treatment. Another study (Grant et al., 2015) found only 8 percent with a 12-month alcohol use disorder had sought treatment for their alcohol dependence in the previous 12 months; 59 percent of those who sought treatment reported receiving treatment from a 12-Step program. The same study reported 20 percent of those with a lifetime alcohol use disorder had sought treatment for alcohol dependence, of which 78 percent reported receiving treatment from a 12-Step program. We conclude that a meaningful proportion of patients with MAT will receive psychosocial support outside the formal health care system, and claims data are not able to capture that.

Finally, in the Appendix, we supplement the guideline recommendations with detailed information from five Cochrane reviews cited in the 2012 BAP guidelines to support recommendations regarding MAT.

Exhibit 1. Guideline Recommendations Cited in the Current Evidence Form for NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment)

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
American Psychiatric Association (APA): "Outpatient treatment of substance use disorders is appropriate for patients whose clinical condition or environmental circumstances do not require a more intensive level of care [I]. As in other treatment settings, a comprehensive approach is optimal, using, where indicated, a variety of psychotherapeutic and pharmacological interventions along with behavioral monitoring [I]"

Michigan Quality Improvement Consortium 2009: Schedule appropriate follow-up within 30 days to re-assess and support behavior change.

VA/DoD 2009: Offer referral to specialty SUD care for addiction treatment if the patient:

- May benefit from additional evaluation or motivational interviewing regarding his/her substance use and related problems
- Has tried and been unable to change substance use on his/her own or does not respond to repeated brief intervention
- Has been diagnosed with substance dependence
- Has previously been treated for an alcohol or other substance use disorder

USPSTF 2004: The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings

1c.17 Clinical Practice Guideline Citation:
APA: Work Group on Substance Use Disorders, Kleber HD, Weiss RD, Anton RF, Rounsaville BJ, George TP, Strain EC, Greenfield SF, Ziedonis DM, Kosten TR, Hennessy G, O´Brien CP, Connery HS, American Psychiatric Association Steering Committee on Practice Guidelines, McIntyre JS, Charles SC, Anzia DJ, Nininger JE, Cook IA, Summergrad P, Finnerty MT, Woods SM, Johnson BR, Yager J, Pyles R, Lurie L, Cross CD, Walker RD, Peele R, Barnovitz MA, Gray SH, Shemo JP, Saxena S, Tonnu T, Kunkle R, Albert AB, Fochtmann LJ, Hart C, Regier D. Treatment of patients with substance use disorders, second edition. American Psychiatric Association. Am J Psychiatry 2006 Aug;163(8 Suppl):5-82.

Michigan: Michigan Quality Improvement Consortium. Screening, diagnosis and referral for substance use disorders. Southfield (MI): Michigan Quality Improvement Consortium; 2009

VA/DOD: Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for management of substance use disorders (SUD). Washington (DC): Department of Veteran Affairs, Department of Defense; 2009 Aug. 158 p.

U.S. Preventive Services Task Force. Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse: Recommendation Statement. April 2004.
http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm

1c.18 National Guideline Clearinghouse or other URL:
http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of

representation and any disclosures regarding bias: USPSTF/VA-DOD/MQIC/APA

1c.21 **System Used for Grading the Strength of Guideline Recommendation:** Other

1c.22 **If other, identify and describe the grading scale with definitions:** APA Rating Scheme for the Strength of the Recommendation
Each recommendation is identified as meriting one of three categories of endorsement, based on the level of clinical confidence regarding the recommendation, as indicated by a bracketed Roman numeral after the statement. The three categories are as follows:
[I] Recommended with substantial clinical confidence.
[II] Recommended with moderate clinical confidence.
[III] May be recommended on the basis of individual circumstances.
Method for Rating Strength of Recommendation
Expert Consensus
MQIC Rating Scheme for the Strength of the Recommendation
A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational studies
D. Opinion of expert panel
Method for Rating Strength of Recommendation
External Peer Review
Internal Peer Review

VA/DoD Rating Scheme for the Strength of the Recommendation
A A strong recommendation that the clinicians provide the intervention to eligible patients.
Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.
B A recommendation that clinicians provide (the service) to eligible patients.
At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.
C No recommendation for or against the routine provision of the intervention is made.
At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.
D Recommendation is made against routinely providing the intervention to asymptomatic patients.
At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.
I The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention.
Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined.
Method for Rating Strength of Recommendation
Peer Review

1c.23 **Grade Assigned to the Recommendation:** Grades are included in Section 1c.16

1c.24 **Rationale for Using this Guideline Over Others:** Used multiple guidelines to find areas of consistency in guidelines supporting this measure.

Exhibit 2. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: Department of Veteran Affairs, Department of Defense (VA/DOD), 2009

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Department of Veteran Affairs, Department of Defense (VA/DOD). VA/DoD clinical practice guideline for management of substance use disorders (SUD). Washington (DC): Department of Veteran Affairs, Department of Defense; 2009 Aug. Available November 19, 2015, at http://www.healthquality.va.gov/guidelines/MH/sud/sud_full_601f.pdf

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

Department of Veteran Affairs, Department of Defense (VA/DOD), 2009:

- Routinely consider oral naltrexone, an opioid antagonist, and/or acamprosate for patients with alcohol dependence. [A] (Module P, page 67)
- Medications should be offered in combined with addiction-focused counseling. [A] (Module P, page 67)
- Injectable naltrexone should be considered when medication adherence is a significant concern in treating alcohol dependence and should be combined with addiction-focused counseling. [A] (Module P, page 67)
- If patient does not respond to one of the approved medications, a trial on one of the other approved medications is warranted. (Module P, page 67)
- Because of the risk of significant toxicity and limited evidence of effectiveness, risk and benefits of disulfiram should be considered and disulfiram should only be used when abstinence is the goal and when combined with addiction-focused counseling. [B] The informed consent discussion with the patient should be documented. (Module P, page 67)
- Dosing of these pharmacotherapies should be consistent with medication trials and recommendations in appropriate drug references. (Module P, page 67)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The VA Guideline (2009) assigned strength of recommendation ratings to each recommendation. **[A]** is defined as "A strong recommendation that the clinicians provide the intervention to eligible patients. Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm." **[B]** is defined as "A recommendation that clinicians provide (the service) to eligible patients. At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm." **[C]** is defined as "No recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation." **[D]** is defined as "Recommendation is made against routinely providing the intervention. At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits." **[I]** is defined as "The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined."

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 3. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: American Psychiatric Association (APA), 2006

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

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

American Psychiatric Association (APA) Work Group on Substance Use Disorders, Kleber HD, Weiss RD, Anton RF, Rounsaville BJ, George TP, Strain EC, Greenfield SF, Ziedonis DM, Kosten TR, Hennessy G, O´Brien CP, Connery HS, American Psychiatric Association Steering Committee on Practice Guidelines, McIntyre JS, Charles SC, Anzia DJ, Nininger JE, Cook IA, Summergrad P, Finnerty MT, Woods SM, Johnson BR, Yager J, Pyles R, Lurie L, Cross CD, Walker RD, Peele R, Barnovitz MA, Gray SH, Shemo JP, Saxena S, Tonnu T, Kunkle R, Albert AB, Fochtmann LJ, Hart C, Regier D. Treatment of patients with substance use disorders, second edition. American Psychiatric Association. Am J Psychiatry 2006 Aug;163(8 Suppl):5-82. Available November 19, 2015 at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf

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

American Psychiatric Association (APA), 2006:

- Specific pharmacotherapies for alcohol-dependent patients have well-established efficacy and moderate effectiveness. Naltrexone may attenuate some of the reinforcing effects of alcohol [I], although data on its long-term efficacy are limited. The use of long-acting, injectable naltrexone may promote adherence, but published research is limited and FDA approval is pending. Acamprosate, a γ-aminobutyric acid (GABA) analog that may decrease alcohol craving in abstinent individuals, may also be an effective adjunctive medication in motivated patients who are concomitantly receiving psychosocial treatment [I]. Disulfiram is an effective adjunct to a comprehensive treatment program for reliable, motivated patients whose drinking may be triggered by events that suddenly increase alcohol craving [II]. (page 13)

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

The APA Guideline assigned one of three categories of endorsement to each recommendation, based on the level of clinical confidence. The categories are: [I] Recommended with substantial clinical confidence; [II] Recommended with moderate clinical confidence; and [III] May be recommended on the basis of individual circumstances.

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.*)

See section 1a.4.3 for all grades and associated definitions.

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

See section 1a.4.1 for guideline citation.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 4. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: Department of Veteran Affairs/Department of Defense (VA/DOD), 2009

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Department of Veteran Affairs, Department of Defense (VA/DOD). VA/DoD clinical practice guideline for management of substance use disorders (SUD). Washington (DC): Department of Veteran Affairs, Department of Defense; 2009 Aug. Available November 19, 2015, at http://www.healthquality.va.gov/guidelines/MH/sud/sud_full_601f.pdf

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

Department of Veteran Affairs, Department of Defense (VA/DOD), 2009:

- Provide access to opioid agonist treatment (OAT) for all opioid dependent patients, under appropriate medical supervision and with concurrent addiction-focused psychosocial treatment as indicated. [A] (Module P, page 55)
- Strongly recommend methadone or sublingual buprenorphine/naloxone maintenance as first line treatments due to their documented efficacy in improving retention and reducing illicit opioid use and craving. [A] (Module P, page 55)
- Appropriate psychosocial interventions should be provided as part of the opioid agonist therapy (OAT). [A] (Module P, page 59)
- Consider monitored administration of naltrexone maintenance in highly motivated opioid dependent patients. [C] (Module P, page 64)
- Consider opioid agonist treatment (OAT) or long-term therapeutic community before naltrexone as first line approaches for chronic opioid dependent patients. (Module P, page 64)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The VA Guideline (2009) assigned strength of recommendation ratings to each recommendation. **[A]** is defined as "A strong recommendation that the clinicians provide the intervention to eligible patients. Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm." **[B]** is defined as "A recommendation that clinicians provide (the service) to eligible patients. At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm." **[C]** is defined as "No recommendation for or against the routine provision of the intervention is made. At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation." **[D]** is defined as "Recommendation is made against routinely providing the intervention. At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits." **[I]** is defined as "The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, or poor quality, or conflicting, and the balance of benefits and harms cannot be determined."

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 5. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: American Psychiatric Association (APA), 2006

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
American Psychiatric Association (APA) Work Group on Substance Use Disorders, Kleber HD, Weiss RD, Anton RF, Rounsaville BJ, George TP, Strain EC, Greenfield SF, Ziedonis DM, Kosten TR, Hennessy G, O´Brien CP, Connery HS, American Psychiatric Association Steering Committee on Practice Guidelines, McIntyre JS, Charles SC, Anzia DJ, Nininger JE, Cook IA, Summergrad P, Finnerty MT, Woods SM, Johnson BR, Yager J, Pyles R, Lurie L, Cross CD, Walker RD, Peele R, Barnovitz MA, Gray SH, Shemo JP, Saxena S, Tonnu T, Kunkle R, Albert AB, Fochtmann LJ, Hart C, Regier D. Treatment of patients with substance use disorders, second edition. American Psychiatric Association. Am J Psychiatry 2006 Aug;163(8 Suppl):5-82. Available November 19, 2015 at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
American Psychiatric Association (APA), 2006:

- Maintenance treatment with methadone or buprenorphine is appropriate for patients with a prolonged history (>1 year) of opioid dependence [I]. The goals of treatment are to achieve a stable maintenance dose of opioid agonist and facilitate engagement in a comprehensive program of rehabilitation [I]. Maintenance treatment with naltrexone is an alternative strategy [I], although the utility of this strategy is often limited by lack of patient adherence and low treatment retention. (page 14)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The APA Guideline assigned one of three categories of endorsement to each recommendation, based on the level of clinical confidence. The categories are: [I] Recommended with substantial clinical confidence; [II] Recommended with moderate clinical confidence; and [III] May be recommended on the basis of individual circumstances.

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 6. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: Substance Abuse and Mental Health Services Administration (SAMHSA), 2015a

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Substance Abuse and Mental Health Services Administration and National Institute on Alcohol Abuse and Alcoholism, Medication for the Treatment of Alcohol Use Disorder: A Brief Guide. HHS Publication No. (SMA) 15-4907. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015a. Available November 19, 2015, at http://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
SAMHSA, 2015a:
Clinicians should consider prescribing one of these medications [i.e., acamprosate calcium, disulfiram, oral naltrexone, extended-release injectable naltrexone] when treating a patient who is dependent on alcohol or who has stopped drinking but is experiencing problems including cravings or relapses. Patients with moderate or severe alcohol use disorder, including those who have physiologic dependence or who are experiencing cravings and have not improved in response to psychosocial approaches alone, are particularly strong candidates for medication-assisted treatment. (page 2)

Medications should be prescribed as part of a comprehensive treatment approach that includes counseling and other psychosocial therapies (through referral to a psychiatrist, psychologist, or professional counselor) and social supports (through participation in Alcoholics Anonymous and other mutual-help programs). (page 2)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
SAMHSA, 2015, Medication for the Treatment of Alcohol Use Disorder: A Brief Guide:
The recommendations were not graded.

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.*)
The recommendations were not graded.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**
The recommendations were not graded.

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 7. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012)

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015 at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012):
- Acamprosate can be used to improve abstinence rates (A). It should be continued if the person starts drinking, since there is evidence that acamprosate reduces alcohol consumption (A), at least for a period to assess whether there is overall patient benefit attributable to acamprosate. (page 11)
- Naltrexone can be used to reduce risk of lapse becoming a relapse, but there is less evidence to support its use in maintaining abstinence (A). Naltrexone may therefore be a better choice if someone is 'sampling' alcohol regularly but wishes to be abstinent. (page 11)
- For acamprosate and naltrexone there is no consistent evidence to suggest which types of patient will respond, and relapse prevention medication should be offered to/considered for everyone who is alcohol dependent wanting to be abstinent (A). (page 11)
- Disulfiram is effective if intake is witnessed. Disulfiram can be offered as a treatment option for patients who intend to maintain abstinence, and for whom there are no contraindications (B). (page 11)
- Baclofen should be considered if a patient wants to be abstinent , has high levels of anxiety and has not benefited from or is unable to take acamprosate, naltrexone or disulfiram (C). (page 11)
- SSRIs should be avoided, or used with caution in type 2 alcoholism (B). (page 11)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
Strength of recommendation is defined as **[A]** directly based on category I evidence (from meta-analysis of randomized controlled trials (Ia) or evidence from at least one randomized controlled trial (Ib)); **[B]** directly based on category II evidence (evidence from at least one controlled study without randomization (IIa) or evidence from at least one other type of quasi-experimental study (IIb) or extrapolated recommendation from category I evidence); **[C]** directly based on category III evidence (evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies) or extrapolated recommendation from category I or II evidence; **[D]** directly based on category IV evidence (evidence from expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence; **[S]**: Standard of care (BAP: Lingford-Hughes et al., 2012).

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 8. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: National Institute for Health and Clinical Excellence (NICE), 2011

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

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

National Institute for Health and Clinical Excellence (NICE). 2011. Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. National Clinical Practice Guideline 115. National Collaborating Centre for Mental Health commissioned by the National Institute for Health & Clinical Excellence. Available November 19, 2015, at http://www.nice.org.uk/guidance/cg115/evidence

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

National Institute for Health and Clinical Excellence (NICE), 2011:

- 7.15.1.1 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) focused specifically on alcohol misuse. (page 424)
- 7.16.5.1 For harmful drinkers and people with mild alcohol dependence who have not responded to psychological interventions alone, or who have specifically requested a pharmacological intervention, consider offering acamprosate [6] or oral naltrexone in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) or behavioural couples therapy. (page 429)
- 8.3.6.1 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone in combination with an individual psychological intervention (cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies) focused specifically on alcohol misuse. (page 454)
- 8.3.6.2 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering acamprosate or oral naltrexone in combination with behavioural couples therapy to service users who have a regular partner and whose partner is willing to participate in treatment. (page 454)
- 8.3.6.3 After a successful withdrawal for people with moderate and severe alcohol dependence, consider offering disulfiram in combination with a psychological intervention to service users who:
  - have a goal of abstinence but for whom acamprosate and oral naltrexone are not suitable, or
  - prefer disulfiram and understand the relative risks of taking the drug. (page 455)
- 8.3.7.9 After a careful review of the risks and benefits, specialists may consider offering acamprosate [15] or oral naltrexone in combination with cognitive behavioural therapy to young people aged 16 and 17 years who have not engaged with or benefited from a multicomponent treatment programme. (page 458)

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

The recommendations were not graded.

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.*)

The recommendations were not graded.

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

The recommendations were not graded.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 9. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: Substance Abuse and Mental Health Services Administration (SAMHSA), 2015b

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. HHS Publication No. (SMA) 14-4892R. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015b. Available October 29, 2015 at http://store.samhsa.gov/product/Clinical-Use-of-Extended-Release-Injectable-Naltrexone-in-the-Treatment-of-Opioid-Use-Disorder-A-Brief-Guide/SMA14-4892R

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

Substance Abuse and Mental Health Services Administration (SAMHSA), 2015b:

- All medications for the treatment of the opioid use disorder should be prescribed as part of a comprehensive treatment approach that includes counseling and other psychosocial therapies delivered by a psychiatrist, psychologist, or professional counselor, as well as social support through participation in Narcotics Anonymous (NA) and other mutual-help programs. Health care providers who choose to offer medication-assisted treatment in their office practices need to understand the nature of the underlying disorder, the specific actions of each available medication (and the associated contraindications or cautions), and the importance of careful patient selection and monitoring. (page 3)
- Clinical Recommendations. Although no definitive research supports which patients benefit most from extended-release injectable naltrexone, patients in the following categories may be good candidates for such treatment.
  - Patients who have not had treatment success with methadone or buprenorphine: Depending on the reasons for treatment failure, individuals with an opioid use disorder who have not been successfully treated with methadone or buprenorphine may benefit from medically supervised withdrawal followed by a trial of extended-release injectable naltrexone. (page 8)
  - Patients who have a high degree of motivation for abstinence: Individuals who are highly motivated to achieve and maintain abstinence from opioids may be good candidates for treatment with extended-release injectable naltrexone. This category includes people who are required to demonstrate abstinence on urine drug screens, such as individuals in programs for impaired health care professionals, parolees, probationers, and airline pilots. (page 8)
- Some patients respond to psychosocial interventions or medication therapy alone, but most patients need both. The different approaches (medication-assisted treatment, professional counseling, and mutual-help groups) are complementary. They support the same goals while addressing different aspects of opioid use disorder: neurobiological, psychological, and social. (page 9)
- Offering the full range of effective treatments maximizes patient choice and outcomes, because no single approach is universally successful. Many studies show that the combination of pharmacologic and nonpharmacologic interventions may be more effective than either approach used alone. (page 9)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The recommendations were not graded.

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.*)
The recommendations were not graded.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**
The recommendations were not graded.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 10. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: American Society of Addiction Medicine (ASAM), 2015

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

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

American Society of Addiction Medicine (ASAM). 2015. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Available November 19, 2015 at http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf

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

American Society of Addiction Medicine (ASAM), 2015:

- Methadone is a treatment option recommended for patients who are physiologically dependent on opioids, able to give informed consent, and who have no specific contraindications for agonist treatment when it is prescribed in the context of an appropriate plan that includes psychosocial intervention. (page 17)
- Psychosocial treatment, though sometimes minimally needed, should be implemented in conjunction with the use of methadone in the treatment of opioid use disorder. (page 17)
- Buprenorphine is recommended for the treatment of opioid use disorder. Buprenorphine relieves drug cravings without producing the euphoria or dangerous side effects of other opioids. In addition to its pharmacological properties, an important feature of buprenorphine is its ability to be prescribed in office-based treatment settings. (page 84)
- Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder. (page 92)
- Naltrexone is a recommended treatment in preventing relapse in opioid use disorder. Oral formula naltrexone may be considered for patients where adherence can be supervised or enforced. Extended-release injectable naltrexone may be more suitable for patients who have issues with adherence. (page 98)
- Psychosocial treatment is recommended in conjunction with treatment with naltrexone. The efficacy of naltrexone use in conjunction with psychosocial treatment has been established, whereas the efficacy of extended-release injectable naltrexone without psychosocial intervention has not been established. (page 99)

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

The recommendations were not graded.

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.*)

The recommendations were not graded.

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

The recommendations were not graded.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 11. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012)

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015, at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf

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

British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012):

- MMT is an appropriate treatment option for opioid-dependent patients. It is effective in reducing heroin use, injecting, and sharing of injecting equipment (A). (page 14)
- BMT is an appropriate treatment option for opioid-dependent patients. It is effective in reducing heroin use (A). (page 14)
- Both methadone and buprenorphine are effective treatments. Opioid-dependent patients should be offered either medication, guided by patient choice and safety considerations. (A). (page 14)
- MMT or BMT should be provided in conjunction with psychosocial interventions such as regular counselling (B). (page 14)
- Oral naltrexone treatment should be considered for formerly opioid-dependent people who are highly motivated to remain abstinent (D). (page 16)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
Strength of recommendation is defined as **[A]** directly based on category I evidence (from meta-analysis of randomized controlled trials (Ia) or evidence from at least one randomized controlled trial (Ib)); **[B]** directly based on category II evidence (evidence from at least one controlled study without randomization (IIa) or evidence from at least one other type of quasi-experimental study (IIb) or extrapolated recommendation from category I evidence); **[C]** directly based on category III evidence (evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies) or extrapolated recommendation from category I or II evidence; **[D]** directly based on category IV evidence (evidence from expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence; **[S]**: Standard of care (BAP: Lingford-Hughes et al., 2012).

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 12. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: World Federation of Societies of Biological Psychiatry (WFSBP), 2011

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
World Federation of Societies of Biological Psychiatry (WFSBP): Soyka M, Kranzler HR, van den Brink W, Krystal J, Möller H-J, Kasper W. The World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for the Biological Treatment of Substance Use and Related Disorders. Part 2: Opioid dependence. World J Biological Psychiatry 2011; 12:160–187. Available November 19, 2015, at http://www.wfsbp.org/fileadmin/user_upload/Treatment_Guidelines/Guidelines_Addiction_Part_2.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
World Federation of Societies of Biological Psychiatry (WFSBP) (2011):

- Methadone is the standard medication for the treatment of opioid dependence [RG1]. Its efficacy can be enhanced when combined with contingency management [RG1]. (page 168)
- Buprenorphine and buprenorphine/naloxone are standard medications for the treatment of opioid dependence. [RG1] Whether the combination of buprenorphine and naloxone has advantages over buprenorphine alone requires empirical validation. There are no indications that adding contingency management to buprenorphine maintenance treatment enhances its effectiveness [RG1]. (page 171)
- Oral naltrexone is not a first line treatment for opioid dependence [RG1]. However, oral naltrexone might be effective in a small subgroup of highly motivated and well-integrated patients [RG3]. Retention in naltrexone treatment is usually poor. (page 172)
- Although depot naltrexone is now approved and available in the United States for the treatment of opioid dependence, additional studies are needed to define more clearly its clinical efficacy over the long term. Naltrexone implants cannot yet be recommended for clinical use because although there are promising efficacy data for them, safety concerns remain and require further evaluation. (page 173)
-

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The recommendation grades are defined as follows: RG1=Category A evidence (Full Evidence From Controlled Studies) and good risk-benefit ratio; RG2=Category A evidence (Full Evidence From Controlled Studies) and moderate risk-benefit ratio; RG3=Category B evidence (Limited Positive Evidence From Controlled Studies); RG4=Category C evidence (Evidence from Uncontrolled Studies or Case Reports/Expert Opinion); RG5=Category D evidence (Inconsistent results).

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 13. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: Centre for Addiction and Mental Health (CAMH), 2011

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Centre for Addiction and Mental Health (CAMH): Handford C, Kahan M, Srivastava A, Cirone S, Sanghera S, Palda V. Buprenorphine/naloxone for opioid dependence: clinical practice guideline [Internet].Centre for Addiction and Mental Health; 2011. Available November 19, 2015 at https://knowledgex.camh.net/primary_care/guidelines_materials/Documents/buprenorphine_naloxone_gdlns2011.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
Centre for Addiction and Mental Health (CAMH), 2011:

- Once a patient is diagnosed with opioid dependence and is deemed appropriate for opioid agonist treatment, prescribers are encouraged to consider prescribing either buprenorphine/naloxone or methadone in order to increase retention in treatment and decrease opioid misuse. (Level I, Grade A) (page 22)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
Levels of evidence are defined as follows: I=Evidence from randomized, controlled trial(s); II-1=Evidence from controlled trial(s) without randomization; II-2=Evidence from cohort or case-control analytic studies, preferably from more than one centre or research group; II-3 Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here; III=Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees.
Grades of recommendation are defined as follows: A=There is good evidence to recommend the action; B=There is fair evidence to recommend the action; C=The existing evidence is conflicting and does not allow making a recommendation for or against the use of the action; however, other factors may influence decisionmaking; D=There is fair evidence to recommend against the action; E=There is good evidence to recommend against the action; I=There is insufficient evidence (in quantity and/or quality) to make a recommendation; however, other factors may influence decision-making.

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 14. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: World Health Organization (WHO), 2009

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
World Health Organization. 2009. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Available November 19, 2015 at http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf

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

World Health Organization (WHO), 2009:

- For the pharmacological treatment of opioid dependence, clinicians should offer opioid withdrawal, opioid agonist maintenance and opioid antagonist (naltrexone) treatment, but most patients should be advised to use opioid agonist maintenance treatment. (Strength of recommendation=strong; Quality of evidence=low to moderate) (page 29)
- For opioid-dependent patients not commencing opioid agonist maintenance treatment, consider antagonist pharmacotherapy using naltrexone following the completion of opioid withdrawal. (Strength of recommendation = standard; Quality of evidence = low) (page 29)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
As recommended in the GRADE system, recommendations were divided into two strengths, here termed as "strong" or "standard" recommendations. Strong recommendations are those for which: most individuals should receive the intervention, assuming that they have been informed about and understand its benefits, harms and burdens; most individuals would want the recommended course of action and only a small proportion would not; the recommendation could unequivocally be used for policy making. Standard recommendations are those for which: most individuals would want the suggested course of action, but an appreciable proportion would not; values and preferences vary widely; policy making will require extensive debates and involvement of many stakeholders.

In the GRADE system, evidence is classified as "high", "moderate", "low" or "very low". Definitions are as follows: High=Further research is very unlikely to change confidence in the estimate of effect; Moderate=Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate; Low=Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate; Very low=Any estimate of effect is very uncertain.

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 15. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: National Institute for Health and Clinical Excellence (NICE), 2007a

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
National Institute for Health and Clinical Excellence (NICE). 2007a. Methadone and buprenorphine for the management of opioid dependence. Technology appraisal guidance. 24 January 2007a. Available November 19, 2015, at nice.org.uk/guidance/ta114

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

National Institute for Health and Clinical Excellence (NICE), 2007a:

- 1.1 Methadone and buprenorphine (oral formulations), using flexible dosing regimens, are recommended as options for maintenance therapy in the management of opioid dependence. (page 3)
- 1.2 The decision about which drug to use should be made on a case by case basis, taking into account a number of factors, including the person's history of opioid dependence, their commitment to a particular long-term management strategy, and an estimate of the risks and benefits of each treatment made by the responsible clinician in consultation with the person. If both drugs are equally suitable, methadone should be prescribed as the first choice. (page 3)
- 1.3 Methadone and buprenorphine should be administered daily, under supervision, for at least the first 3 months. Supervision should be relaxed only when the patient's compliance is assured. Both drugs should be given as part of a programme of supportive care. (page 3)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The recommendations were not graded.

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.*)
The recommendations were not graded.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**
The recommendations were not graded.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 16. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: National Institute for Health and Clinical Excellence (NICE). 2007b

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
National Institute for Health and Clinical Excellence (NICE). 2007b. Naltrexone for the management of opioid dependence. Technology appraisal guidance. 24 January 2007b. Available November 19, 2015, at nice.org.uk/guidance/ta115

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
National Institute for Health and Clinical Excellence (NICE), 2007b:

- 1.1 Naltrexone is recommended as a treatment option in detoxified formerly opioid dependent people who are highly motivated to remain in an abstinence programme. (page 3)
- 1.2 Naltrexone should only be administered under adequate supervision to people who have been fully informed of the potential adverse effects of treatment. It should be given as part of a programme of supportive care. (page 3)
- 1.3 The effectiveness of naltrexone in preventing opioid misuse in people being treated should be reviewed regularly. Discontinuation of naltrexone treatment should be considered if there is evidence of such misuse. (page 3)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The recommendations were not graded.

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.*)
The recommendations were not graded.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**
The recommendations were not graded.

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***
☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 17. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: Substance Abuse and Mental Health Services Administration (SAMHSA), 2005

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. Available November 19, 2015 at http://store.samhsa.gov/shin/content//SMA12-4214/SMA12-4214.pdf

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

Substance Abuse and Mental Health Services Administration (SAMHSA), 2005:

- OTPs [opioid treatment programs] can provide several treatment options:
- Maintenance treatment combines pharmacotherapy with a full program of assessment, psychosocial intervention, and support services; it is the approach with the greatest likelihood of long-term success for many patients. (page 5)
- Medical maintenance treatment is provided to stabilize patients and may include long-term provision of methadone, buprenorphine, LAAM, or naltrexone, with a reduction in clinic attendance and other services. A patient can receive medical maintenance at an OTP, after he or she is stabilized fully. The patient usually must complete a comprehensive treatment program first. The decision about whether to provide medical maintenance must be made by a licensed practitioner. A designated medication unit (e.g., physician's office, pharmacy, long-term care facility) affiliated with an OTP can provide some medical maintenance services. To reduce clinic attendance—a key feature of medical maintenance—patients must qualify, subject to variations in State regulations (which may be more stringent than Federal regulations), to receive 7- to 14-day supplies of methadone for take-home dosing after 1 year of continuous treatment and 15- to 30-day supplies after 2 years of continuous treatment in an OTP (if additional criteria are satisfied [see chapter 5]) (42 CFR, Part 8 § 12(h); Federal Register 66:4079). (page 5-6)
- Maintenance treatment with methadone or buprenorphine is appropriate for patients with a prolonged history (>1 year) of opioid dependence [I]. The goals of treatment are to achieve a stable maintenance dose of opioid agonist and facilitate engagement in a comprehensive program of rehabilitation [I]. Maintenance treatment with naltrexone is an alternative strategy [I], although the utility of this strategy is often limited by lack of patient adherence and low treatment retention. (page 14)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
The recommendations were not graded.

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.*)
The recommendations were not graded.

1a.4.5. Citation and URL for methodology for grading recommendations (*if different from 1a.4.1*)**:**
The recommendations were not graded.

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit 18. Results of Targeted Literature Review on Psychosocial Treatment for Alcohol and Other Drug Dependence Outside the Formal Health Care System

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?

Targeted literature search

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

The so-called "12-Step programs" for treating substance abuse, such as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA), have become an important component of substance abuse treatment in the United States and worldwide. AA's worldwide membership grew from 2 members in 1935 to over 2 million in 1990. In recent years, its worldwide membership has fluctuated around 2 million (Alcoholics Anonymous, 2015a). In 2015, AA reported almost 1.3 million members and 60,000 groups in the US (Alcoholics Anonymous, 2015b). No comparable data for NA could be identified, although NA reports more than 63,000 weekly meetings worldwide (Narcotics Anonymous, 2014).

Two studies reported data on the frequency of psychosocial treatment outside the formal health care system, which would not be identifiable through claims data:

Dawson et al. (2006): This study presents the results of the first wave of the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), conducted in 2001-2002. Of the 4,422 individuals with DSM-IV alcohol dependence in the past year that made up the sample, only 25.6% of them had ever sought help for alcohol problems. Of the entire sample, 3.0% had participated in 12-Step programs only (11.7% of those seeking treatment), 5.6% had received formal treatment only (21.9% of those seeking treatment), and 17.1% had both participated in a 12-Step program and received formal treatment (66.8% of those seeking treatment). This study was funded by the Intramural Research Program of the National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism.

Grant et al. (2015): This study presents the results of the third wave of the NESARC, conducted in 2012-2013. Investigators interviewed a representative sample of 36,309 US adults on their alcohol drinking habits. In this sample, 13.9% and 29.1% of respondents had alcohol use disorders (AUDs) in the past 12 months and their lifetime, respectively, (DSM-5 definition of AUD). Of those with 12-month DSM-5 AUDs, only 7.7% had sought treatment in the previous 12 months, of which 59.0% reported receiving treatment from a 12-Step program. Of those with lifetime DSM-5 AUDs, 19.8% had sought treatment, of which 77.7% reported receiving treatment from a 12-Step program. This study was supported by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse, the National Institutes of Health, and by the Intramural Research Program of the NIAAA.

In conclusion, the high percentage of those seeking treatment who attend 12-step program meetings (78.5% [Dawson et al., 2006] and 59.0-77.7% [Grant et al., 2015]) indicates that a meaningful proportion of patients with MAT will receive psychosocial support outside the formal health care system, and claims data are not able to capture that.

References

Alcoholics Anonymous. (2015a, May 2015). Estimated Worldwide AA Individual and Group Membership. Retrieved November 12, 2015, from http://www.aa.org/assets/en_US/smf-132_en.pdf

Alcoholics Anonymous. (2015b, May 2015). Estimates of AA Groups and Members as of January 1, 2015. Retrieved November 12, 2015, from http://www.aa.org/assets/en_US/smf-53_en.pdf

Dawson, Deborah A, Grant, Bridget F, Stinson, Frederick S, & Chou, Patricia S. (2006). Estimating the effect of help-seeking on achieving recovery from alcohol dependence. *Addiction, 101*(6), 824-834.

Grant, Bridget F, Goldstein, Risë B, Saha, Tulshi D, Chou, S Patricia, Jung, Jeesun, Zhang, Haitao, . . . Huang, Boji.

(2015). Epidemiology of DSM-5 alcohol use disorder: results from the national epidemiologic survey on alcohol and related conditions III. *JAMA psychiatry, 72*(8), 757-766.
Narcotics Anonymous. (2014). Information about NA. Retrieved November 12, 2015, from https://www.na.org/admin/include/spaw2/uploads/pdf/PR/Information_about_NA.pdf

Appendix A

Exhibit A.1. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Alcohol Dependence: British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012)

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015 at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012) (page 11):

- Acamprosate can be used to improve abstinence rates (A). It should be continued if the person starts drinking, since there is evidence that acamprosate reduces alcohol consumption (A), at least for a period to assess whether there is overall patient benefit attributable to acamprosate.
- Naltrexone can be used to reduce risk of lapse becoming a relapse, but there is less evidence to support its use in maintaining abstinence (A). Naltrexone may therefore be a better choice if someone is 'sampling' alcohol regularly but wishes to be abstinent.
- For acamprosate and naltrexone there is no consistent evidence to suggest which types of patient will respond, and relapse prevention medication should be offered to/considered for everyone who is alcohol dependent wanting to be abstinent (A).
- Disulfiram is effective if intake is witnessed. Disulfiram can be offered as a treatment option for patients who intend to maintain abstinence, and for whom there are no contraindications (B).
- Baclofen should be considered if a patient wants to be abstinent, has high levels of anxiety and has not benefited from or is unable to take acamprosate, naltrexone or disulfiram (C).
- SSRIs should be avoided, or used with caution in type 2 alcoholism (B).

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
Strength of recommendation is defined as **[A]** directly based on category I evidence (from meta-analysis of randomized controlled trials (Ia) or evidence from at least one randomized controlled trial (Ib)); **[B]** directly based on category II evidence (evidence from at least one controlled study without randomization (IIa) or evidence from at least one other type of quasi-experimental study (IIb) or extrapolated recommendation from category I evidence); **[C]** directly based on category III evidence (evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies) or extrapolated recommendation from category I or II evidence; **[D]** directly based on category IV evidence (evidence from expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence; **[S]**: Standard of care (BAP: Lingford-Hughes et al., 2012).

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit A.2. Systematic Reviews Cited by the British Association for Psychopharmacology (BAP) Guideline on Pharmacological Management of Substance Abuse: Acamprosate for alcohol dependence (Rosner et al., 2010a)

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.
Systematic review on:
Rösner S, Hackl-Herrwerth A, Leucht S, et al. (2010a) Acamprosate for alcohol dependence. Cochrane Database Syst Rev 9: CD004332.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review? Treatment of alcohol dependence with acamprosate was the focus of the review.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade: The systematic review did not grade the evidence.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system. The systematic review did not grade the evidence.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1990 - 2006

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*) Twenty-four RCTs were included in the review. Eighteen of the 24 RCTs employed a multicenter design, and 6 trials, a single-center design.

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*) "Within the acamprosate trials included in the review, various features of the study design have been adequately implemented to ensure a high level of validity: Patients were randomly assigned to treatment groups to prevent selection bias. Active medication and placebo with identical appearance were used to mask treatment allocation and to reduce the general susceptibility of outcomes to bias effects; objective measures of drinking were considered…either to validate patient-reported outcomes or as a discrete outcome criteria [sic] in the majority of studies." "Nevertheless, some uncertainties still persist. …The poor reporting of the study design mainly concerns the methods used for generating random sequences, the specification of person groups included in the blinding process and the methods applied for allocation concealment."

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 results are based on 6915 patients in 24 RCTs. "Compared to placebo, acamprosate was shown to significantly reduce the risk of any drinking RR 0.86 (95% CI 0.81 to 0.91); NNT 9.09 (95% CI 6.66 to 14.28) and to significantly increase the cumulative abstinence

duration MD 10.94 (95% CI 5.08 to 16.81), while secondary outcomes (gammaglutamyltransferase, heavy drinking) did not reach statistical significance."
RR= risk ratio, CI=confidence interval, NNT=number needed to treat, MD=mean difference

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?
"Diarrhea was the only side effect that was more frequently reported under acamprosate than placebo RD 0.11 (95% 0.09 to 0.13); NNTB 9.09 (95% CI 7.69 to 11.11)." Other side effects that did not differ were abdominal pain, constipation, nausea, vomiting, gastrointestinal symptoms, headache, pruritus, vertigo, and several others."

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 <u>each</u> new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

Exhibit A.3. Systematic Reviews Cited by the British Association for Psychopharmacology (BAP) Guideline on Pharmacological Management of Substance Abuse: Opioid antagonists for alcohol dependence (Rosner et al., 2010b)

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.
Systematic review:
Rösner S, Hackl-Herrwerth A, Leucht S, et al. (2010b) Opioid antagonists for alcohol dependence. Cochrane Database Syst Rev 12: CD001867.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review? Treatment of alcohol dependence with opioid antagonists was the focus of the review.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade: The systematic review did not grade the evidence.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system. The systematic review did not grade the evidence.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1992-2009

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*) Fifty randomized controlled trials were included in the review. Fourteen of the 50 were multicenter trials and 36 were single center.

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*) "Various features of the study design, which have been implemented in the naltrexone and nalmefene trials included in the review, ensure a high methodological quality of the primary database: To prevent selection bias, patients were randomly assigned to treatment groups, to mask treatment allocation, active medication and placebo with identical appearance were used and to reduce the general susceptibility of outcomes to bias effects, objective measures of drinking were considered … either to validate patient-reported outcomes or as a discrete outcome criteria [sic] in the majority of studies." "Nevertheless, some uncertainties persist. As specific features of the study designs were omitted from trial reports, it remains unclear whether these have not been implemented or whether they were implemented, but not reported … poor reporting concerned the methods used for generating random sequences, the exact specification of person groups included in the blinding process and the methods applied for allocation concealment. Particularly the latter, unclear concealment, has repeatedly been shown to be associated with bias effects in various fields of clinical research."

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 results are based on 7793 patients in 50 RCTs. "[N]altrexone reduced the risk of heavy drinking to 83% of the risk in the placebo group RR 0.83 (95% CI 0.76 to 0.90) and decreased drinking days by about 4%, MD -3.89 (95% CI -5.75 to -2.04). Significant effects were also demonstrated for the secondary outcomes of the review including heavy drinking days, MD - 3.25 (95% CI -5.51 to -0.99), consumed amount of alcohol, MD - 10.83 (95% CI -19.69 to -1.97) and gamma-glutamyltransferase, MD -10.37 (95% CI -18.99 to -1.75), while effects on return to any drinking, RR 0.96 (95 CI 0.92 to 1.00) missed statistical significance." MD=mean difference

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)? "Side effects of naltrexone were mainly gastrointestinal problems (e.g. nausea: RD 0.10; 95% CI 0.07 to 0.13) and sedative effects (e.g. daytime sleepiness: RD 0.09; 95% CI 0.05 to 0.14)." RD=risk difference

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.

Exhibit A.4. Guideline Recommendations Not in Current Evidence Form for NQF 0004 That Support Medication-Assisted Treatment of Opioid Dependence: British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012)

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (*including date*) and **URL for guideline** (*if available online*):
British Association for Psychopharmacology (BAP): Lingford-Hughes AR, Welch S, Peters L, Nutt DJ. BAP updated guidelines: evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and co-morbidity: recommendations from BAP. J Psychopharmacol 2012; 26: 899–952. Available November 19, 2015 at http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf

1a.4.2. Identify guideline recommendation number and/or page number and **quote verbatim, the specific guideline recommendation**.
British Association for Psychopharmacology (BAP) (Lingford-Hughes, 2012):

- MMT is an appropriate treatment option for opioid dependent patients. It is effective in reducing heroin use, injecting, and sharing of injecting equipment (A).
- MMT is more effective at doses in the range 60–120 mg than at lower doses. Following safe induction of methadone treatment (see Department of Health Guidelines), consideration should be given to higher maintenance doses (A).
- BMT is an appropriate treatment option for opioid-dependent patients. It is effective in reducing heroin use (A).
- Buprenorphine should be prescribed at doses of 8 mg or higher when used for maintenance treatment (B), and preferably at doses over 12 mg (D).
- Where concerns over diversion are paramount, buprenorphine/ naloxone combinations may be preferred (B).
- Both methadone and buprenorphine are effective treatments. Opioid-dependent patients should be offered either medication, guided by patient choice and safety considerations. (A).
- MMT or BMT should be provided in conjunction with psychosocial interventions such as regular counselling (B).
- Oral naltrexone treatment should be considered for formerly opioid-dependent people who are highly motivated to remain abstinent (D).
-

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:
Strength of recommendation is defined as **[A]** directly based on category I evidence (from meta-analysis of randomized controlled trials (Ia) or evidence from at least one randomized controlled trial (Ib)); **[B]** directly based on category II evidence (evidence from at least one controlled study without randomization (IIa) or evidence from at least one other type of quasi-experimental study (IIb) or extrapolated recommendation from category I evidence); **[C]** directly based on category III evidence (evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies) or extrapolated recommendation from category I or II evidence; **[D]** directly based on category IV evidence (evidence from expert committee reports or opinions and/or clinical experience of respected authorities) or extrapolated recommendation from category I, II or III evidence; **[S]**: Standard of care (BAP: Lingford-Hughes et al., 2012).

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.*)
See section 1a.4.3 for all grades and associated definitions.

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

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***

☐ No → ***report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***

Exhibit A.5. Systematic Reviews Cited by the British Association for Psychopharmacology (BAP) Guideline on Pharmacological Management of Substance Abuse: Methadone maintenance therapy for opioid dependence (Mattick et al., 2009)

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.
Systematic review on methadone:
Mattick RP, Breen C, Kimber J, et al. (2009) Methadone maintenance therapy versus no opioid replacement for opioid dependence. Cochrane Database Syst Rev 3: CD002209.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review? Treatment of opioid dependence with methadone maintenance treatment was the focus of the review.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:
The systematic review graded the evidence for five outcomes:
Retention in treatment – Old studies (before 2000): high
Retention in treatment – New studies (2000 and after): high
Morphine positive urine or hair analysis: high
Criminal activity: moderate
Mortality: moderate

High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1969-2008

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*) Eleven randomized clinical trials were included in the review.

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*)
Five of the studies were deemed to have adequate sequence generation for randomization. One study was determined to have in adequate sequence generation for randomization. One of the five adequate studies also had

adequate concealment of allocation, as did two additional studies.
"Of the eleven studies included in this review, two were placebo-controlled trials. Both of these studies were double-blind but [one] did not provide sufficient data to be confident about the concealment of allocation. The remaining studies were not blinded. All studies addressed the issue of incomplete outcome data adequately and were independently deemed by reviewers to be free of other major bias."

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) <u>across studies</u> 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 results are based on 1969 patients in 11 randomized clinical trials. "Methadone appeared statistically significantly more effective than non-pharmacological approaches in retaining patients in treatment and in the suppression of heroin use as measured by self report and urine/hair analysis (6 RCTs, RR = 0.66 95%CI 0.56-0.78), but not statistically different in criminal activity (3 RCTs, RR=0.39; 95%CI: 0.12-1.25) or mortality (4 RCTs, RR=0.48; 95%CI: 0.10-2.39)." RR=risk ratio

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?
No harms were discussed in the systematic review.

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 <u>each</u> new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

Exhibit A.6. Systematic Review Cited by the British Association for Psychopharmacology (BAP) Guideline on Pharmacological Management of Substance Abuse: Oral naltrexone maintenance treatment for opioid dependence (Minozzi et al., 2011)

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.
Systematic review on methadone:
Minozzi S, Amato L, Vecchi S, et al. (2011) Oral naltrexone maintenance treatment for opioid dependence. Cochrane Database Syst Rev 4: CD001333.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review? Prevention of relapse in opioid addicts following detoxification using naltrexone maintenance treatment.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade: The systematic review did not grade the evidence.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system. The systematic review did not grade the evidence.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1976-2008

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*) Thirteen randomised controlled trials were included in this review.

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*)
"The majority of the studies where [sic] not of high quality. Only two studies reported information about sequence generation and only three about allocation concealment. Eight out of thirteen studies were double blind, the other were open trial. Nevertheless we think that this did not introduce bias in the main outcomes addressed in this review, because the retention in treatment is an objective measure and abstinence is assessed by urine analysis in all trials. Incomplete outcome data was addressed correctly in the majority of the studies and in any case it does not introduce bias for the outcome retention and retention and abstinence which are the main outcomes on which the review is focused."

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 results are based on 13 studies of 1158 patients. "Comparing naltrexone versus placebo or no pharmacological treatments, no statistically significant difference were [sic] noted for all the primary outcomes considered. The only outcome statistically significant in favour of naltrexone is reincarceration, RR 0.47 (95% CI 0.26-0.84), but results come only from two studies. Considering only studies were [sic] patients were forced to adherence a statistical significant difference in favour of naltrexone was found for retention and abstinence, RR 2.93 (95%CI 1.66-5.18)." RR=risk ratio

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

Four of the 13 studies reported side effects (varied by study but included abdominal discomfort, sleep disturbances, loss of appetite, diarrhea, and nausea), but there was no statistically significant difference between treatment and control groups.

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 <u>each</u> new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

Exhibit A.7. Systematic Review Cited by the British Association for Psychopharmacology (BAP) Guideline on Pharmacological Management of Substance Abuse: Buprenorphine maintenance therapy for opioid dependence (Mattick et al., 2014)

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.
Systematic review on methadone:
Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2014, Issue 2. Art. No.: CD002207. DOI: 10.1002/14651858.CD002207.pub4. (Note that this is an update of the systematic review cited by the BAP guideline.)

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review? Treatment of opioid dependence using buprenorphine maintenance and methadone maintenance.

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade: The systematic review graded the evidence for five outcomes:
Retention in treatment: high
Morphine-positive urines: moderate
Self-reported heroin use: moderate
Cocaine-positive urines: moderate
Benzodiazepine-positive urines: moderate

High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1992-2010

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*) Thirty-one randomized controlled trials were included in this review.

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*)

"The clinical trials represented in this review are of reasonable quality, and whilst many of them did not fully explain how randomization was concealed, they appear to have used doses which are clinicallyrelevant and to have treated participants for significant periods of time. Moreover, despite the tendency of randomised studies to include selected populations, characteristics of drug users enrolled in the studies included in this review appear to be heterogeneous enough to allow generalisability of the results across different clinical and cultural settings. Based on the nature of the trials, it would appear the external validity or generalisability of the results is quite good, particularly from those trials which have used large sample sizes and adequate doses."

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 results are based on 5430 patients in 31 RCTs. "There is high quality of evidence that buprenorphine was superior to placebo medication in retention of participants in treatment at all doses examined. Specifically, buprenorphine retained participants better than placebo: at low doses (2 - 6 mg), 5 studies, 1131 participants, risk ratio (RR) 1.50; 95% confidence interval (CI) 1.19 to 1.88; at medium doses (7 - 15 mg), 4 studies, 887 participants, RR 1.74; 95% CI 1.06 to 2.87; and at high doses (≥ 16 mg), 5 studies, 1001 participants, RR 1.82; 95% CI 1.15 to 2.90. However, there is moderate quality of evidence that only high-dose buprenorphine (≥ 16 mg) was more effective than placebo in suppressing illicit opioid use measured by urinanalysis in the trials, 3 studies, 729 participants, standardised mean difference (SMD) -1.17; 95% CI -1.85 to -0.49, notably, low-dose, (2 studies, 487 participants, SMD 0.10; 95% CI -0.80 to 1.01), and medium-dose, (2 studies, 463 participants, SMD -0.08; 95% CI -0.78 to 0.62) buprenorphine did not suppress illicit opioid use measured by urinanalysis better than placebo."

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

"Few studies reported adverse events; two studies compared adverse events statistically, finding no difference between methadone and buprenorphine, except for a single result indicating more sedation among those using methadone." Adverse events reported by the two studies included but were not limited to: sedation, insomnia, headache, depression, sweating, and dyspepsia.

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.

December 22, 2015

TO: National Quality Forum

FROM: RAND Health

SUBJECT: Request for Ad Hoc Review of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment) **Part 2 of 2**

Overview

This memo requests an ad hoc review of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment). NQF 0004 is a two-part measure that consists of the proportion of patients with an initial diagnosis of alcohol or other drug dependence that receive (1) treatment within 14 days of the initial diagnosis, and (2) follow-up treatment within 30 days thereafter. In this memo, we present evidence that the current definition of "treatment" is incomplete, as it only includes psychosocial interventions, but not medication-assisted treatment (MAT). In other words, patients who receive MAT only, and health plans that provide coverage for them, would be meaningfully misclassified based on the current definition.

We propose that the measure definition for NQF 0004 be changed so receiving psychosocial treatment only, MAT only, or both psychosocial treatment and MAT would meet the numerator criteria. Based on recent conversations with NQF staff, we understand that there is no plan for a systematic re-evaluation of NQF 0004 in the near future. Therefore, this memo is a request for an ad hoc review of NQF 0004 in order to align the measure definition with current evidence. In a previous memo sent to NQF on December 1, 2015, we presented guideline recommendations that support the use of MAT for treatment of alcohol or opioid dependence, as well as evidence from a targeted literature search on the proportion of psychosocial care being provided outside of the formal healthcare system.

The current memo (Part 2 of 2) presents an analysis of commercial claims data of the effect of changing the measure definitions. In this memo, we define two versions of the measure: the original version and the revised version. We describe how we estimated the differences between the two versions, including the data source, the methods used to identify the index episode, and the qualifying events that define the numerators and denominators of the measure. We present a comparison of the original version of the measure and our proposed revision, and the estimated misclassification based on current specifications.

Data Source

Data for the analysis were derived from the MarketScan® Commercial Database (including data from Standard Quarterly Updates) for calendar years 2013 and 2014. These databases contain fully adjudicated, patient-level claims and include files on enrollment (summary and detail), drug claims, facility headers, inpatient admissions, outpatient claims, population counts, and inpatient services. All records in these files were used as input to identify individuals that met the measure's eligibility criteria.

Methods Used To Calculate Measure Rates

We followed the technical specifications in the NQF submission form for NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment) to calculate the original measure rates. These specifications for the measure include for each of the two rates (Initiation and Engagement): definitions of and time periods for the numerator and denominator (first column of Table 1), detailed instructions for creating the numerator and denominator, and numerator and denominator exclusions. We calculated a "Revised Version" that counted MAT as treatment in the definition of initiation and engagement (specifications in second column of Table 1). The following list highlights key aspects of the methods used for the two versions of the measure:

- We used HCPCS codes, CPT codes, UBREV codes, and ICD-9-CM diagnosis and procedure codes obtained from NQF.
- We used National Drug Codes (NDCs) identified by RAND for FDA-approved medications for medication-assisted treatment for alcohol and opioid dependence, as well as J codes for injectable drugs.
- Rates were calculated for index episodes occurring between January 1, 2014, and November 15, 2014, inclusive.
- For patients with more than one AOD episode, the first index episode in the time period was included; subsequent episodes were excluded.
- For index episodes that are inpatient admissions, the admit date was used to scan for a prior clean period but the discharge date was used as the date of the event.
- Patient must have been continuously enrolled from 60 days before the index episode through 44 days after.
- We excluded index episodes that were missing any enrollment records for the member, with enrollment records indicating the individual was not a member at the time of the event, or with enrollment records indicating the member was less than 13 years of age or 65 years of age or over at the time of the event.
- Episodes with detoxification codes were counted in the denominator, but were not counted in the numerator of the initiation or engagement rates.
- All inpatient admissions were counted as self-initiating except those with a detoxification code present.
- An index episode based on an emergency department visit resulting in inpatient admission was treated as an inpatient admission.
- Multiple events on the same day were counted as separate if they were from distinct provider IDs, or the provider ID was missing and the events were from separate claims files.

- A 60-day clean period was required for the episode to be counted in the denominator. For the calculation including filled prescriptions for MAT, the clean period excluded those with a filled prescription for MAT in the prior 60 days.
- A single filled prescription for MAT after initiation was sufficient for the case to be counted as engaged.

In addition, we compared the original and revised rates for initiation and engagement based on index episodes for alcohol dependence only, opioid dependence only, and both alcohol and opioid dependence at the population level.

Lastly, we attempted to estimate the effect of the changes in definitions in relative rankings of health plans. Estimation was necessary because the data do not contain a health plan identifier. We formed pairs of U.S. Census codes for industry and Metropolitan Statistical Areas (MSA) under the assumption that benefits will be similar for the same industry in a given market. We then drew one random sample of 50 and of 100 eligible patients from each of those pairs to represent a hypothetical health plan operating in this market. We calculated the average absolute difference, relative percentage difference, difference in rank, for the initiation and engagement rates separately.

Table 1. Definitions of Original and Revised Versions of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment)

Component	Original Version	Revised Version
Measure statement (Measure 1-Initiation)	The percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who received the following. - Initiation of AOD Treatment. The percentage of patients who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis.	The percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who received the following. - Initiation of AOD Treatment. The percentage of patients who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, or ***a filled prescription or injection for medication-assisted treatment*** within 14 days of the diagnosis.
Measure statement (Measure 2-Engagement)	The percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who received the following. - Engagement of AOD Treatment. The percentage of patients who initiated treatment and who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit.	The percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who received the following. - Engagement of AOD Treatment. The percentage of patients who initiated treatment and who had two or more additional services with a diagnosis of AOD, ***or at least one additional filled prescription for medication-assisted treatment or injection*** within 30 days of the initiation visit.
Numerator of Measure 1: Initiation of AOD Dependence Treatment	Initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of diagnosis.	Initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization, ***or filled prescription or injection for medication-assisted treatment*** within 14 days of diagnosis.

Component	Original Version	Revised Version
Numerator of Measure 2: Engagement of AOD Treatment	Initiation of AOD treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis within 30 days after the date of the Initiation encounter (inclusive).	Initiation of AOD treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis ***or filled prescription for medication-assisted treatment or injection*** within 30 days after the date of the Initiation encounter (inclusive).
Denominator of Measures 1 and 2	Patients 13-64 years of age who were diagnosed with a new episode of alcohol or other drug dependency (AOD) during the first 10 and ½ months of the measurement year (e.g., January 1-November 15).	
Time Period for Initiation Numerator	14 days after diagnosis	
Time Period for Engagement Numerator	30 days after the date of initiation encounter	
Time Period for Denominator	The first 10 and ½ months of the measurement year (e.g., January 1 to November 15)	

Results

Population Level

Table 2 displays the initiation and engagement rates for the original and revised versions of the measure at the population level. The results for the original version of NQF 0004 indicate that 38.9% of eligible patients had an inpatient or outpatient visit within 14 days of the index episode (i.e., met the initiation criterion), and 12.9% had two or more inpatient or outpatient visits within 30 days of the initiation visit (i.e., met the engagement criterion).

Including MAT in the numerator increases both the initiation and engagement rates. The initiation rate increased from 38.9% to 40.1%, representing a 3.1% relative increase. The engagement rate increased from 12.9% to 14.5%, representing a 12.2% relative increase.

Importantly, changing the definition meant that fewer index episodes were eligible for the denominator, because patients with ongoing MAT in the 60 days preceding the index episode were excluded. The number of eligible episodes in the denominator decreased from 296,750 in the original version to 281,672 in the revised version of the measure. In other words, about 15,000 episodes (or about 5% of the episodes) in patients under ongoing treatment were incorrectly included in the measure.

Table 2. Measure Rates for Original and Revised Versions of NQF 0004 (Initiation and Engagement of Alcohol and Other Drug Dependence Treatment)

Version	Total Index Episodes	Number Initiated	Initiation Rate	Number Initiated and Engaged	Engagement Rate
Original (MAT Not Included)	296,750	115,347	38.9%	38,289	12.9%
Revised (MAT Included)	281,672	112,900	40.1%	40,787	14.5%

Opioid versus Alcohol Use

We analyzed the effect of adding MAT on the measure rate for diagnosis-specific subgroups related to drug dependence (Table 3). In the alcohol dependence subgroup, the initiation and engagement rates increased from 39.6% to 40.0%, and from 12.1% to 13.0%, respectively, after MAT was included; these represent 1.0% and 7.4% relative increases for the initiation and engagement rates, respectively. The subgroup with opioid dependence exhibited a larger increase in the initiation and engagement rates. When MAT was included in the measure numerator, the initiation rate rose from 36.8% to 41.7% (a 13.3% relative increase) and the engagement rate rose from 16.7% to 22.9% (a 37.1% relative increase).

Table 3. Measure Rates for Original and Revised Versions of NQF 0004 for Alcohol and Opioid Subgroups

Version and Subgroup	Total Index Episodes	Number Initiated	Percent Initiated	Number Initiated and Engaged	Percent Initiated and Engaged
Original Version (MAT Not Included)					
Alcohol Only	156,402	61,935	39.6%	18,925	12.1%
Opioid Only	56,505	20,794	36.8%	9,436	16.7%
Alcohol and Opioid	4,210	2,922	69.4%	1,406	33.4%
Revised Version (MAT Included)					
Alcohol Only	153,888	61,555	40.0%	20,005	13.0%
Opioid Only	46,410	19,353	41.7%	10,628	22.9%
Alcohol and Opioid	3,854	2,748	71.3%	1,438	37.3%

Approximation of Health Plan-Level Results

As described above, we estimated the effect of the change in definitions on the relative ranking of health plans, by drawing a random sample of 50 patients from industry-MSA pairs with 50 or more index episodes (N=566) and of 100 patients from those with 100 or more index episodes (N=328).

For rates based on 50 index episodes, including MAT increased the measure rate by two percentage points on average for both initiation and engagement, with a maximum difference of 14 percentage

points for initiation and 11 for engagement (Table 4). For rates based on 100 index episodes, including MAT increased the measure rate by two percentage points on average for both initiation and engagement as well, with a maximum difference of nine percentage points for both initiation and engagement. These absolute differences represent substantially larger relative increases for engagement (21.2% and 19.1% for 50 and 100 patients, respectively) than initiation (5.2% and 4.4% for 50 and 100 patients, respectively).

The rate differences also influence relative ranking of health plans, with the rank changing by an average of 32 and 51 places for the initiation and engagement rates, respectively, for 50 patient samples, and 17 and 27 places for 100 patient samples. We calculated the proportion of our "health plans" for which the relative rankings changed by at least one quintile when MAT was included in the numerator definition. For the 50 patient samples, about **21% changed by at least one quintile for the initiation and 39% for the engagement measure.** The corresponding rates were **27% and 36%** for the 100 patient samples.

Table 4. Effect of Including Medication-Assisted Treatment in the Definition of Treatment on Initiation and Engagement Rates for Alcohol and Other Drug Dependence on "Health Plan" Performance

	Based on 50 Index Episodes (N=566)				Based on 100 Index Episodes (N=328)			
	Average	Std Dev	Min	Max	Average	Std Dev	Min	Max
Absolute Difference								
Initiation Rate	0.02	0.02	0.00	0.14	0.02	0.01	0.00	0.09
Engagement Rate	0.02	0.02	0.00	0.11	0.02	0.02	0.00	0.09
Relative Difference								
Initiation Rate	5.2%	4.9%	0.0%	36.1%	4.4%	3.7%	0.0%	22.3%
Engagement Rate	21.2%	30.5%	0.0%	334.8%	19.1%	21.8%	0.0%	226.1%
Difference in Rank								
Initiation Rate	32	29	0	168	17	17	0	112
Engagement Rate	51	42	0	209	27	23	0	156

Std Dev=standard deviation, Min=minimum, Max=maximum

Summary and conclusion

Based on our testing of an alternate measure definition using commercial claims data, we conclude that including MAT in the numerator definition of NQF 0004 changes the measure results and health plan rankings based on those results in a meaningful way. Together with the information included in our previous memo that MAT is a guideline-supported treatment option for patients with substance abuse disorders, we would argue that sufficient reason exists to augment the measure definition by including MAT in the numerator.

We acknowledge the limitation that we can only approximate the implications for the relative ranking of health plans, but suggest that the presented evidence is strong enough to justify the proposed minor change to the measure definition on an ad hoc basis, as the current definition may lead to a biased assessment of the performance of health plans.

TO: National Quality Forum

FROM: National Committee for Quality Assurance

SUBJECT: Behavioral Health Off-Cycle Discussion: #0004: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET)

DATE: October 5, 2016

This memo provides an overview of NCQA's current re-evaluation of the IET measure for HEDIS® reporting. We are requesting that the Behavioral Health Standing Committee wait for completion of our re-evaluation (June 2017) before formally reviewing #0004 endorsement status.

Situation

NCQA is currently re-evaluating the HEDIS Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (NQF #0004) measure. The NQF off-cycle discussion of the IET measure requested by RAND will be better informed following NCQA's comprehensive re-evaluation of the measure.

Background

NCQA routinely re-evaluates HEDIS measures necessitated by new research evidence, the release of clinical practice guidelines, and feedback from the field. NCQA's current re-evaluation of the IET measure was scheduled for our 2016-2017 work plan in early 2016 and addresses, among other areas, medication-assisted treatment (MAT) raised by RAND. If approved by NCQA's Committee on Performance Measurement (CPM) and our Board of Directors, the IET measure updates will be effective for HEDIS 2018, published in July 2017.

Assessment

The NCQA team is evaluating if and how MAT should be counted in the measure. This requires close examination of the strength and quality of evidence on MAT for substance abuse, discussion with NCQA's Behavioral Health Measurement Advisory Panel (BHMAP), development of a revised draft specification, release in NCQA's HEDIS 2018 Public Comment period (February, 2017), and review and approval by the Committee on Performance Measurement (CPM) of changes to the specification. Figure 1 shows the development and governance process and timeline for our IET measure re-evaluation.

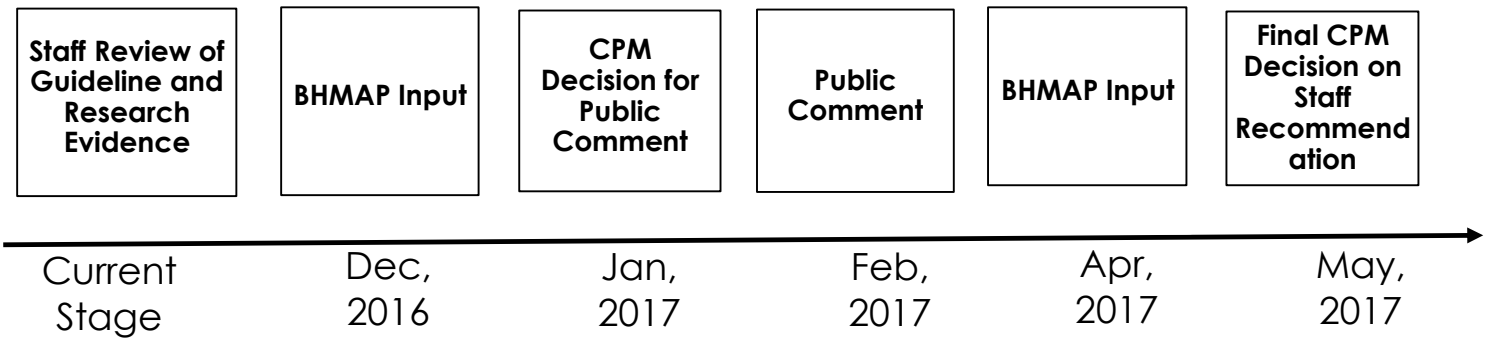
The majority of guidelines referenced by RAND in the memo to NQF state that MAT should be used in conjunction with psychosocial therapy. RAND's testing allowed MAT to be used exclusive of psychosocial care. We will be exploring whether this approach is consistent with the majority of guidelines. We note that RAND's results with MAT included showed rates improving by 1-2 percentage points, on average, for alcohol and opioid dependence.

The NCQA team will review i) alternative specifications for allowing MAT in combination with psychosocial care with BHMAP; ii) medications for MAT with the NCQA's Pharmacy Panel. As part of our HEDIS re-evaluation process, we will seek broader stakeholder feedback through public comment and welcome RAND's feedback on the draft specification. Final CPM vote on staff recommendations for measure specification changes will be made in May 2017 and voted by our Board in June.

Recommendation

NCQA appreciates NQF, the Behavioral Health Standing Committee, and RAND's interest in discussing the IET measure. We share with you the common goal of improving the measure which requires our evaluation of the strength of evidence and an assessment of options for combining psychosocial care with MAT, if warranted. The NCQA team requests reviewing the IET measure for endorsement after we have completed our current re-evaluation process. This will better enable the NQF committee to use results from NCQA's work to inform your review for continued endorsement.

Figure 1. NCQA IET Measure Re-evaluation Process and Timeline



NATIONAL QUALITY FORUM

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 #: 0004
Corresponding Measures:
De.2. **Measure Title:** Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET)
Co.1.1. **Measure Steward:** National Committee for Quality Assurance
De.3. **Brief Description of Measure:** The percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who received the following.

- Initiation of AOD Treatment. The percentage of patients who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis.

- Engagement of AOD Treatment. The percentage of patients who initiated treatment and who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit.

1b.1. **Developer Rationale:** This measure assesses the degree to which the organization initiates and engages members identified with a need for alcohol and other drug (AOD). By providing data on access to AOD dependence treatment across care settings, this measure provides insight on how providers and plans may need to target education efforts and assists patient in accessing care.

S.4. **Numerator Statement:** Initiation of AOD Dependence Treatment:
Initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date.

Engagement of AOD Treatment:
Initiation of AOD treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis within 30 days after the date of the Initiation encounter (inclusive).

S.7. **Denominator Statement:** Patients age 13 years of age and older who were diagnosed with a new episode of alcohol or other drug dependency (AOD) during the first 10 and ½ months of the measurement year (e.g., January 1-November 15).

S.10. **Denominator Exclusions:** Exclude patients who had a claim/encounter with a diagnosis of AOD during the 60 days (2 months) before the Index Episode Start Date. (See corresponding Excel document for the AOD Dependence Value Set)

Exclude from the denominator for both indicators (Initiation of AOD Treatment and Engagement of AOD Treatment) patients whose initiation of treatment event is an inpatient stay with a discharge date after December 1 of the measurement year.

De.1. **Measure Type:** Process
S.23. **Data Source:** Administrative claims, Electronic Clinical Data
S.26. **Level of Analysis:** Health Plan, Integrated Delivery System

IF Endorsement Maintenance – Original Endorsement Date: Aug 10, 2009 **Most Recent Endorsement Date:** Nov 02, 2012

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. **IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** N/A

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

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. ***Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
0004_Evidence_MSF5.0_Data.doc

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., the benefits or improvements in quality envisioned by use of this measure)*
This measure assesses the degree to which the organization initiates and engages members identified with a need for alcohol and other drug (AOD). By providing data on access to AOD dependence treatment across care settings, this measure provides insight on how providers and plans may need to target education efforts and assists patient in accessing care.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(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). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

Initiation:

Medicaid

Measurement Year: 2009; 2010; 2011

AVE:	44.52	44.35	42.93
N:	61 68	79	
Min:	17.74	22.72	23.86
Max:	69.09	76.71	78.88
SD:	10.01	10.31	10.96
P10:	32.74	31.78	30
P25	37.21	38.42	35.68
P50	43.79	43.92	40.81
P75	51.26	48.79	48.84
P90	57.33	57.31	60.72

Medicare

Measurement Year: 2009; 2010; 2011

AVE:	46.55	48.89	48.02
N:	268	306	368
Min:	5.19	12.12	7.32
Max:	84.85	98.23	98.24
SD:	13.94	15.72	17.07
P10:	29.25	27.41	27.31
P25:	38.48	38.88	36.17
P50:	46.83	49.17	46.08
P75:	54.7	56.9	57.62
P90:	64.29	70.27	74.11

Commercial

Measurement Year: 2009; 2010; 2011

AVE:	42.46	42.28	41.89
N:	415	402	392

Min:	14.71	12.9	16.67
Max:	70.18	72.65	69.77
SD:	7.4	7.32	7.51
P10:	33.47	34.03	33.01
P25:	38.6	38.2	37.42
P50:	42.2	41.79	41.81
P75:	46.67	46.27	45.71
P90:	51.33	50.6	50.27

Engagement
Medicaid
Measurement Year: 2009; 2010; 2011

AVE:	12.43	12.31	14.19
N:	61	68	79
Min:	0	0.99	0.5
Max:	55.57	54.26	41.44
SD:	11.45	10.73	9.79
P10:	1.69	2.34	2.02
P25:	3.46	4.15	5.72
P50:	10.06	10.18	14.53
P75:	16.79	17.6	20.52
P90:	21.7	21.42	25.89

Medicare
Measurement Year: 2009; 2010; 2011

AVE:	5.36	4.51	4.02
N:	268	311	366
Min:	0	0	0
Max:	41.79	35.64	26.25
SD:	6.23	4.17	3.46
P10:	0.7	0.8	0.56
P25:	1.97	2.08	1.71
P50:	3.13	3.52	3.19
P75:	6.32	5.78	5.61
P90:	11.63	8.53	7.95

Commercial
Measurement Year: 2009; 2010; 2011

AVE:	16.2	15.93	15.78
N:	415	402	392
Min:	0	1.61	0.85
Max:	53.4	46.99	46.45
SD:	5.7	5.88	5.6
P10:	9.74	8.51	9.54
P25:	12.43	12.19	12.01
P50:	15.85	15.61	15.56
P75:	19.82	19.19	18.68
P90:	22.46	22.19	22.09

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.
Section 1b.2 references data from the most recent three years of measurement for this measure. The data in section 1b.2 includes N = number of health plans, percentiles, mean, min, max and standard deviations.

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 measure is not stratified to detect disparities. NCQA has participated with IOM and others in attempting to include information on disparities in measure data collection. However, at the present time, this data, at all levels (claims data, paper chart review, and electronic records), is not coded in a standard manner, and is incompletely captured. There are no consistent standards for what entity (physician, group, plan, employer) should capture and report this data. While "requiring" reporting of the data could push the field forward, it has been our position that doing so would create substantial burden with inability to use the data because of its inconsistency. At the present time, we agree with the IOM report that disparities are best considered by the use of zip code analysis which has limited applicability in most reporting situations. At the health plan level, for HEDIS health plan data collection, NCQA does have extensive data related to our use of stratification by insurance status (Medicare, Medicaid and private-commercial) and would strongly recommend this process where the data base supporting the measurement includes this information. However, we believe that the measure specifications should NOT require this since the measure is still useful where the data needed to determine disparities cannot be ascertained from the data available.

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.**
N/A

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**
A leading cause of morbidity/mortality, Severity of illness
1c.2. **If Other:**

1c.3. **Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare. List citations in 1c.4.**
The health burden of substance use includes harmful effects of acute intoxication, substance use associated injury and violence, and the consequences of numerous medical and psychiatric disorders associated with chronic alcohol and other drug use (NIDA, 2010). Treatment is essential and cost effective to stem the economic and human costs associated with the use of alcohol and other drugs when it has progressed to the stage of dependence or addiction (Frederic, 2010 and SAMHSA, 2006). Treatment frequency and intensity of engagement is important for successful outcomes.

Health Importance

Alcohol and other drug dependence (AOD) is prevalent across age groups and is one of the most preventable health conditions. This measure helps to address access to care for AOD patients.

In 2010, an estimated 22.1 million persons (8.7 percent of the population aged 12 or older) were classified with substance dependence or abuse. Of these, 68 percent were dependent on or abused alcohol, but not illicit drugs, 13 percent abused or were dependent on both alcohol and illicit drugs, while 19 percent were dependent on or abused illicit drugs, but not alcohol (SAMHSA, 2011).

Of the 20.5 million persons aged 12 or older in 2010 who were classified as needing substance use treatment but did not receive treatment at a specialty facility in the past year, 1.0 million persons (5.0 percent) reported that they felt they needed treatment for their illicit drug or alcohol use problem. Of these 1.0 million persons who felt they needed treatment, only 341,000 (33.3 percent) reported that they made an effort to get treatment, while 683,000 (66.7 percent) reported making no effort to get treatment (SAMHSA, 2011).

The number of people receiving specialty treatment in the past year in 2010 (2.6 million) was similar to the number in 2002 (2.3 million). However, the number receiving specialty treatment for a problem with nonmedical pain reliever use more than doubled during this period, from 199,000 to 406,000 (SAMHSA, 2011).

There are more deaths, illnesses and disabilities from substance abuse than from any other preventable health condition. Treatment of medical problems caused by substance use and abuse places a huge burden on the health care system (Schneider Institute, 2001). Nevertheless, there are treatment interventions that can help diminish the social and economic impact. Many of the traditional forms of substance abuse treatment (e.g. methadone maintenance, therapeutic communities, outpatient drug-free treatment) have been evaluated multiple times and have been shown to be effective. The benefits of these treatments typically extend beyond the reduction of substance abuse to areas that are important to society, such as reduced crime, reduced risk of infectious diseases, and improved function. In addition, the costs associated with the provision of substance abuse treatment provide three- to sevenfold returns to employers, health insurers and society within 3 years following treatment (McLellan, 1997).

Research also supports the need for individuals with alcohol and other drug dependence to not only stabilize, or cease using the substance(s), but engage in ongoing treatment to prevent relapse. Individuals who complete treatment or receive more days of treatment typically show more improvements than those who leave care prematurely. It is also important to note that the acute stage of treatment is associated with lasting improvements only when there is continued rehabilitative treatment (IOM, 1990).
One of the substances most commonly abused by older adults besides alcohol is psychoactive drugs. The primary goals of drug abuse or addiction treatment are abstinence, relapse prevention and rehabilitation. Less than 20 percent of diagnosed people with substance abuse and less than 40 percent of those with substance addiction problems seek out treatment (Frederic, 2010). One in four deaths in the U.S. is attributed to alcohol, tobacco and/or illicit drugs (NIDA, 2010).

Financial Importance

Total overall costs of substance abuse in the U.S., including productivity, health and crime-related costs, exceed $600 billion annually. Every American adult pays nearly $1,000 per year for the damages of addiction (NIDA, 2010 and Keyes, 2010).

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

Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011.
Frederic, C.B., Bartels, S.J., Brockmann, L.M., Van Citters, A.D. 2010. Evidence-Based Practices for Preventing Substance Abuse and Mental Health Problems in Older Adults Excerpt: Prevention of Substance Misuse Problems: Alcohol Misuse. www.public-health.uiowa.edu/icmha/.../Evidence-basedCareForAlcohol.DOC (June 10, 2011).
National Institute on Drug Abuse. 2010. Monitoring the Future: National results on adolescent drug use. http://monitoringthefuture.org/pubs/monographs/mtf-overview2010.pdf
Keyes, K.M., Hatzenbuehler, M.L., McLaughlin, K.A., Link, B., Olfson, M., Grant, B.F. 2010. Stigma and Treatment for Alcohol Disorders in the United States. American Journal of Epidemiology 172 (12): 1364-1372.
National Institute on Drug Abuse. 2010. Comorbidity: Addiction and Other Mental Illnesses. http://www.drugabuse.gov/PDF/RRComorbidity.pdf (June 10, 2010).
Substance Abuse and Mental Health Services Administration (SAMHSA). 2006. Report to Congress: Addictions Treatment Workforce Development. http://www.pfr.samhsa.gov/docs/Report_to_Congress.pdf (June 10, 2010).
Institute of Medicine (IOM). 1990. Broadening the Base of Treatment for Alcohol Problems. Washington, DC: National Academy Press.
McLellan AT, Can the Outcomes Research Literature Inform the Search for Quality Indicators in Substance Abuse Treatment? Appendix B: Managing Managed Care: Improvement in Behavioral Health. 1997, IOM Publication accessed via Web http://www.nap.edu
Schneider Institute for Health Policy, Brandeis University, Substance Abuse: The Nation's Number One Health Problem, for The Robert Wood Johnson Foundation, Princeton, New Jersey (2001).

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.)*

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):*
Behavioral Health, Behavioral Health : Alcohol, Substance Use/Abuse

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

S.2a. **If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped 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)
This is not an eMeasure **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:** 0004_IET_Value_Sets-635860535088567062.xlsx

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

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.
Initiation of AOD Dependence Treatment:
Initiation of AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date.

Engagement of AOD Treatment:
Initiation of AOD treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis within 30 days after the date of the Initiation encounter (inclusive).

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.)*
Initiation Numerator: 14 days after diagnosis.
Engagement Numerator: 30 days after the date of initiation encounter

Denominator: The first 10 and ½ months of the measurement year (e.g., January 1 to November 15)

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.

Index Episode Start Date: The earliest date of service for an inpatient, intensive outpatient, partial hospitalization, outpatient, detoxification or ED encounter during the first 10 and ½ months of the measurement year (e.g., January 1 to November 15) with a diagnosis of AOD.

- For an outpatient, intensive outpatient, partial hospitalization, detoxification or ED visit (not resulting in an inpatient stay), the Index Episode Start Date is the date of service.
- For an inpatient (acute or nonacute) event, the Index Episode Start Date is the date of discharge.
- For an ED visit that results in an inpatient event, the Index Episode Start Date is the date of the inpatient discharge.
- For direct transfers, the Index Episode Start Date is the discharge date from the second admission

INITIATION OF AOD TREATMENT

If the Index Episode was an inpatient discharge, the inpatient stay is considered initiation of treatment and the patient is compliant

If the Index Episode was an outpatient, intensive outpatient, partial hospitalization, detoxification or ED visit, the patient must have an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization, with an AOD diagnosis, on the Index Episode Start Date or in the 13 days after the Index Episode Start Date (14 total days). If the Index Episode Start Date and the initiation visit occur on the same day, they must be with different providers in order to count. Any of the following code combinations meet criteria:

- An acute or nonacute inpatient admission with a diagnosis of AOD (AOD Dependence Value Set). To identify acute and nonacute inpatient admissions: 1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set). 2. Identify the admission date for the stay.
- IET Stand Alone Visits Value Set WITH AOD Dependence Value Set
- IET Visits Group 1 Value Set WITH IET POS Group 1 Value Set AND AOD Dependence Value Set
- IET Visits Group 2 Value Set WITH IET POS Group 2 Value Set AND AOD Dependence Value Set.

(See corresponding Excel document for appropriate value sets)

Do not count Index Episodes that include detoxification codes (including inpatient detoxification) as being initiation of treatment
- See corresponding Excel document for the Detoxification Value Set.

ENGAGEMENT OF AOD TREATMENT

Identify all patients who meet the following criteria:

1) Numerator compliant for the Initiation of AOD Treatment numerator and

2) Two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis, beginning on the day after the initiation encounter through 29 days after the initiation event (29 total days). Multiple engagement visits may occur on the same day, but they must be with different providers in order to count. Any of the following code combinations meet criteria:

– An acute or nonacute inpatient admission with a diagnosis of AOD (AOD Dependence Value Set). To identify acute or nonacute inpatient admissions: First Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set), Then Identify the admission date for the stay.
– IET Stand Alone Visits Value Set with AOD Dependence Value Set.
– IET Visits Group 1 Value Set with IET POS Group 1 Value Set and AOD Dependence Value Set.
– IET Visits Group 2 Value Set with IET POS Group 2 Value Set and AOD Dependence Value Set.

For patients who initiated treatment via an inpatient admission, the 29-day period for the two engagement visits begins the day after discharge.

Do not count events that include inpatient detoxification or detoxification codes (Detoxification Value Set) when identifying engagement of AOD treatment.

The time frame for engagement, which includes the initiation event, is 30 total days.

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

Patients age 13 years of age and older who were diagnosed with a new episode of alcohol or other drug dependency (AOD) during the first 10 and ½ months of the measurement year (e.g., January 1-November 15).

S.8. **Target Population Category** *(Check all the populations for which the measure is specified and tested if any):*
Children's Health, 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)*
Identify the Index Episode. Identify all patients in the specified age range who during the first 10 and ½ months of the measurement year (e.g., January 1 to November 15) had one of the following:
• An outpatient visit, intensive outpatient encounter or partial hospitalization with a diagnosis of AOD. Any of the following code combinations meet criteria:
– IET Stand Alone Visits Value Set WITH AOD Dependence Value Set.
– IET Visits Group 1 Value Set WITH IET POS Group 1 Value Set AND AOD Dependence Value Set.
– IET Visits Group 2 Value Set WITH IET POS Group 2 Value Set AND AOD Dependence Value Set.
(See corresponding Excel document for the appropriate value sets)

• A detoxification visit (See corresponding Excel document for the Detoxification Value Set)
• An ED visit with a diagnosis of AOD (See corresponding Excel document for the ED Value Set and the AOD Dependence Value Set).
• An acute or nonacute inpatient discharge with either a diagnosis of AOD (AOD Dependence Value Set) or an AOD procedure code (AOD Procedures Value Set). To identify acute and nonacute inpatient discharges: First, identify all acute and nonacute inpatient stays (Inpatient Stay Value Set), Second, identify the discharge date for the stay.

For patients with more than one episode of AOD, use the first episode.

For patients whose first episode was an ED visit that resulted in an inpatient event, use the inpatient discharge.

Select the Index Episode Start Date.

S.10. **Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*
Exclude patients who had a claim/encounter with a diagnosis of AOD during the 60 days (2 months) before the Index Episode Start Date. (See corresponding Excel document for the AOD Dependence Value Set)

Exclude from the denominator for both indicators (Initiation of AOD Treatment and Engagement of AOD Treatment) patients whose initiation of treatment event is an inpatient stay with a discharge date after December 1 of the measurement year.

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)*
Exclude patients who had a claim/encounter with a diagnosis of AOD during the 60 days (2 months) before the Index Episode Start Date. (See corresponding Excel document for the AOD Dependence Value Set)
- For an inpatient Index Episode Start Date, use the admission date to determine if the patient had a period of 60 days prior to the Index Episode Start Date with no claims with a diagnosis of AOD dependence.
- For an ED visit that results in an inpatient event, use the ED date of service to determine if the patient had a period of 60 days prior to the Index Episode Start Date with no claims with a diagnosis of AOD dependence.
- For direct transfers, use the first admission to determine if the patient had a period of 60 days prior to the Index Episode Start Date with no claims with a diagnosis of AOD dependence.

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)*
The total population is stratified by age: 13-17 and 18+ years of age.

Report two age stratifications and a total rate.

The total is the sum of the age stratifications.

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)*
N/A

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*)

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.)*
Step 1. Determine the eligible population. The eligible population is all patients who satisfy all specified denominator criteria (S9-S11).

Step 2. Search administrative systems to identify numerator events for all patients in the eligible population (S6).

Step 3. Calculate the rate of numerator events in the eligible population.

S.19. **Calculation Algorithm/Measure Logic Diagram URL or Attachment** *(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)*

S.20. **Sampling** *(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.
N/A

S.21. **Survey/Patient-reported data** *(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.

S.22. **Missing data** (specify how missing data are handled, e.g., imputation, delete case.)
Required for Composites and PRO-PMs.

S.23. **Data Source** *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
If other, please describe in S.24.
Administrative claims, Electronic Clinical Data

S.24. **Data Source or Collection Instrument** *(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.
NCQA collects HEDIS data directly from Health Management Organizations and Preferred Provider Organizations via a data submission portal - the Interactive Data Submission System (IDSS).

S.25. **Data Source or Collection Instrument** *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*
URL

S.26. **Level of Analysis** *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*
Health Plan, Integrated Delivery System

S.27. **Care Setting** *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
Ambulatory Care : Clinician Office/Clinic, Ambulatory Care : Urgent Care, Behavioral Health/Psychiatric : Inpatient, Behavioral Health/Psychiatric : Outpatient, Emergency Medical Services/Ambulance, Hospital/Acute Care Facility
If other:

S.28. **COMPOSITE Performance Measure** - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

2a. Reliability – See attached Measure Testing Submission Form
2b. Validity – See attached Measure Testing Submission Form
0004_MeasureTesting_MSF5.0_Data.doc

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 a combination of electronic sources

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.
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.
NCQA´s multi-stakeholder advisory panels examined an analysis of the measure after its first year of reporting. The measure was deemed appropriate for public reporting. NCQA has processes to ensure coding and specifications are clear and updated when needed.

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)*.

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)
Public Reporting Quality Improvement with Benchmarking (external benchmarking to multiple organizations) Quality Improvement (Internal to the specific organization)	

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

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?*)

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.*)

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**

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.**

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.**

NCQA recognizes that, despite the clear specifications defined for HEDIS measures, data collection and calculation methods may vary, and other errors may taint the results, diminishing the usefulness of HEDIS data for managed care organization (MCO) comparison. In order for HEDIS to reach its full potential, NCQA conducts an independent audit of all HEDIS collection and reporting processes, as well as an audit of the data which are manipulated by those processes, in order to verify that HEDIS specifications are met. NCQA has developed a precise, standardized methodology for verifying the integrity of HEDIS collection and calculation processes through a two-part program consisting of an overall information systems capabilities assessment followed by an evaluation of the MCO´s ability to comply with HEDIS specifications (. NCQA-certified auditors using standard audit methodologies will help enable purchasers to make more reliable "apples-to-apples" comparisons between health plans.

The HEDIS Compliance Audit addresses the following functions:

1) information practices and control procedures
2) sampling methods and procedures
3) data integrity
4) compliance with HEDIS specifications
5) analytic file production
6) reporting and documentation

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.

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

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

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?

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

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.)
N/A

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:

Contact Information

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Co.3 **Measure Developer if different from Measure Steward:** National Committee for Quality Assurance
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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.
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Kevin Weiss, MD, FACP, American Board of Medical Specialties

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 **Year the measure was first released:** 2004

Ad.3 **Month and Year of most recent revision:** 01, 2012

Ad.4 **What is your frequency for review/update of this measure?** Approximately every 3 years, sooner if the clinical guidelines have changed significantly.

Ad.5 **When is the next scheduled review/update for this measure?**

Ad.7 **Disclaimers:** These performance Measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications.

THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.

Ad.8 **Additional Information/Comments:**